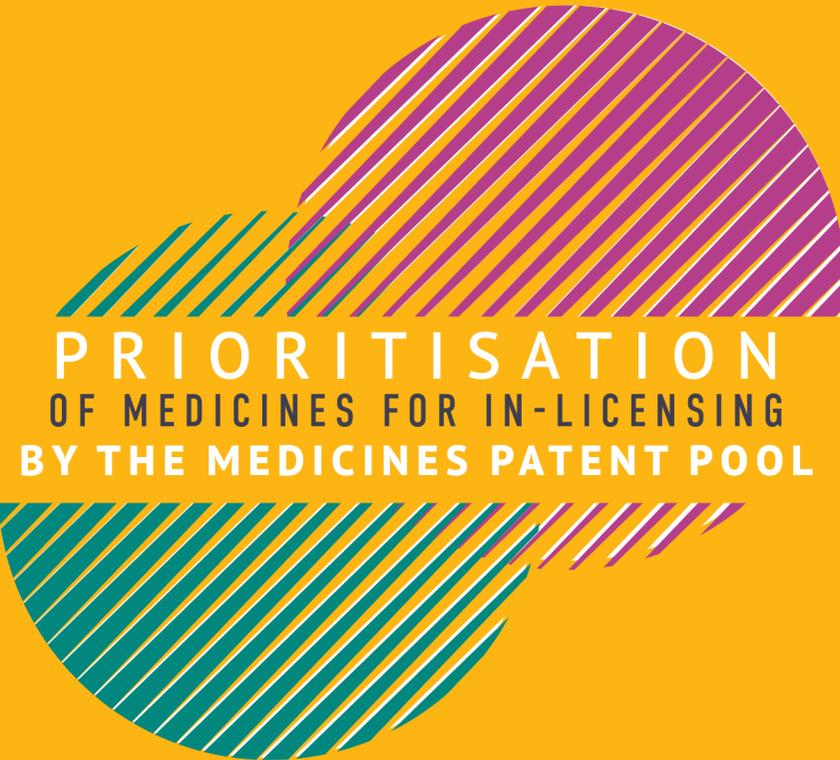


medicines
patent
pool



PRIORITISATION
OF MEDICINES FOR IN-LICENSING
BY THE MEDICINES PATENT POOL

ANNUAL REPORT
2024

Medicines Patent Pool
March 2024

Suggested citation

Prioritisation of medicines for in-licensing by the Medicines Patent Pool, Annual Report 2024. Medicines Patent Pool, May 2024.

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Introduction

The mission of the Medicines Patent Pool (MPP) is to facilitate the development of and increase access to, life-saving medicines and health technologies for low- and middle-income countries (LMICs) through public-health oriented voluntary licensing and technology transfer.

To do so, the first step for MPP is to identify suitable candidates for in-licensing using a prioritisation framework that is applied to assess products of potential interest in all health areas and all stages of clinical development. In line with MPP's current mandate, products assessed include biotherapeutics and novel medical technologies.

This prioritisation process contributes to ensuring MPP focuses its efforts on medicines for which licensing could have the greatest public health impact.

Scope

MPP's initial work began with infectious diseases including human immunodeficiency virus (HIV), viral hepatitis and tuberculosis (TB), and obtained licences that resulted in high public health impact.

In 2018, MPP's mandate expanded to target patented medicines included in the World Health Organisation (WHO) Model List of Essential Medicines (EML) or with potential for future inclusion, which encompass a whole range of disease areas, including cancers, diabetes and cardiovascular diseases, and is exploring other areas of intervention, as relevant.

Additionally, MPP has been working on COVID-19 interventions since 2020. MPP's new strategy for the 2023-2025 period embraces a disease agnostic approach, by which patented medicines for which an MPP intervention would potentially make a difference in public health, might be considered for prioritisation, regardless of the health area.

MPP's work started with small molecules, and after conducting a feasibility study on expanding access to biotherapeutics in 2022, expanded its mandate on biologics. Moreover, given their ground-breaking potential impact, long-acting technologies and formulations designed to achieve longer exposure to medicines are considered for prioritisation since 2021, together with any relevant novel medical technologies for which an MPP intervention might generate positive impact for public health.

In line with MPP new strategy, candidate products in earlier stages of development are increasingly being considered for prioritisation. Therefore, MPP might consider for prioritisation candidates at any stage of development, from pre-clinical to marketed.

MPP prioritisation

MPP's prioritisation process generates two lists of patented medicines for which expanded access in LMICs could provide significant health benefits over standards of care, and where a voluntary agreement, including licensing, through MPP could lead to substantial public health impact. These list guide MPP in-licensing efforts.

Two lists are generated:

PRIORITY LIST

MPP priority list of medicines includes patented medicines for which expanded access could provide significant health benefits over standards of care, and where voluntary licensing through MPP would lead to substantial public health impact.

WATCHLIST

Products in MPP watchlist are patented medicines for which expanded access could provide significant health benefits but for which supporting data are lacking and/or key challenges need to be addressed for expanded access through MPP licensing to provide significant benefits and lead to substantial public health impact.

Additionally, we include medicines in the watchlist when a potential added benefit might be obtained through an MPP licence, but where a full assessment is still ongoing.

Note: In the previous iteration of the prioritisation, we had two categories within the priority medicines list: list A and list B. List A included products approved by Stringent Regulatory Authorities (SRAs) and List B investigational products. We have simplified this classification into a single category : "priority list".

Prioritisation framework

The products classification into priority and watchlist medicines is evidence-based and guided by MPP's prioritisation framework. Both lists are reassessed periodically based on new clinical evidence, changes to WHO recommendations and other recognised public health guidelines, changes in intellectual property landscape, evolution in access programmes, changes in prices or market forecasts, or any other

relevant event. In order to guide products' assessment, the framework addresses the following considerations, as guiding principles:

1. Does the product address a public health need?

This question is assessed through the first pillar of the framework: the public health pillar, where the burden of the health condition is assessed, as well as the advantages of the candidate product over existing alternatives of care for this condition.

2. Are there any access hurdles (anticipated or existing) for the product in low-and-middle-income countries?

This question is assessed through the second pillar: the access pillar. It includes access considerations on which MPP directly intervenes (e.g. intellectual property), as well as additional access considerations which may be important in the treatment cascade (e.g. access to diagnostics).

3. What would be the effect of MPP intervention on access?

This question elaborates on both public health and access pillars, and it ensures that candidate products are prioritised where an MPP intervention could yield the greatest impact.

By addressing these questions, MPP collects insights about public health and access dimensions of the products assessed, as well as insights to assess the potential impact of an MPP intervention.

The framework is structured into seven pillars as shown in the next page. These are the clinical relevance of the candidate, the burden of disease that is targeted, the product's intellectual property landscape, the service delivery enablers to be considered for the product implementation, regulatory aspects, manufacturing requirements and market prospects.

Within each pillar, several criteria are considered. These are further broken down into subcriteria. For reading ease, the graphic only comprises the pillars and criteria. The detailed sub-criteria are presented [in the annex at the end of this report](#).



MPP prioritised and watchlist products 2024



HIV

lenacapavir *Gilead*

cabotegravir & rilpivirine *ViiV & Janssen*

doravirine *MSD*

islatravir *Merck*

broadly neutralising antibodies for HIV post-natal prophylaxis

Multiple patent holders



TUBERCULOSIS

quabodepistat

Otsuka

BTZ-043

Univ. of Munich & DZIF

delpazolid

LegoChem BioSciences

ganfeborole

GSK

macozinone

EPFL

sudapyridine

Shanghai Jiatan Biotech



VIRAL HEPATITIS

bulevirtide *Gilead*



OTHER INFECTIOUS DISEASES

gepotidacin *GSK*



PANDEMIC & EPIDEMIC THREATS

baloxavir marboxil *Roche*



DIABETES, CARDIOVASCULAR & METABOLIC DISORDERS

Incretin-based therapies

Multiple patent holders

cardiovascular fixed-dose combination therapies

Multiple patent holders



CHILDHOOD ONSET DISEASES

RESPIRATORY SYNCYTIAL VIRUS

nirsevimab *Astrazeneca/Sanofi*

clesrovimab *MSD*

SICKLE CELL DISEASE

voxelotor *Pfizer*

CYSTIC FIBROSIS

elexacaftor/tezacaftor/ivacaftor *Vertex*



ONCOLOGY

LUNG CANCER

aumolertinib *Revolution Medicines*

osimertinib *Astrazeneca*

adagrasib *Mirati*

lazertinib *Janssen*

sotorasib *Amgen*

BREAST CANCER

abemaciclib *Eli Lilly*

ribociclib *Novartis*

trastuzumab SQ *Roche*

CHRONIC LYMPHOCYTIC LEUKAEMIA

ibrutinib *Janssen*

zanubrutinib *Beigene*

PROSTATE CANCER

apalutamide *Janssen*

darolutamide *Bayer*

MULTIPLE CANCER INDICATIONS

immune checkpoint inhibitors

Multiple patent holders

including pembrolizumab

MSD

oral paclitaxel / encequidar

Athenex

PRIORITY LIST

WATCHLIST

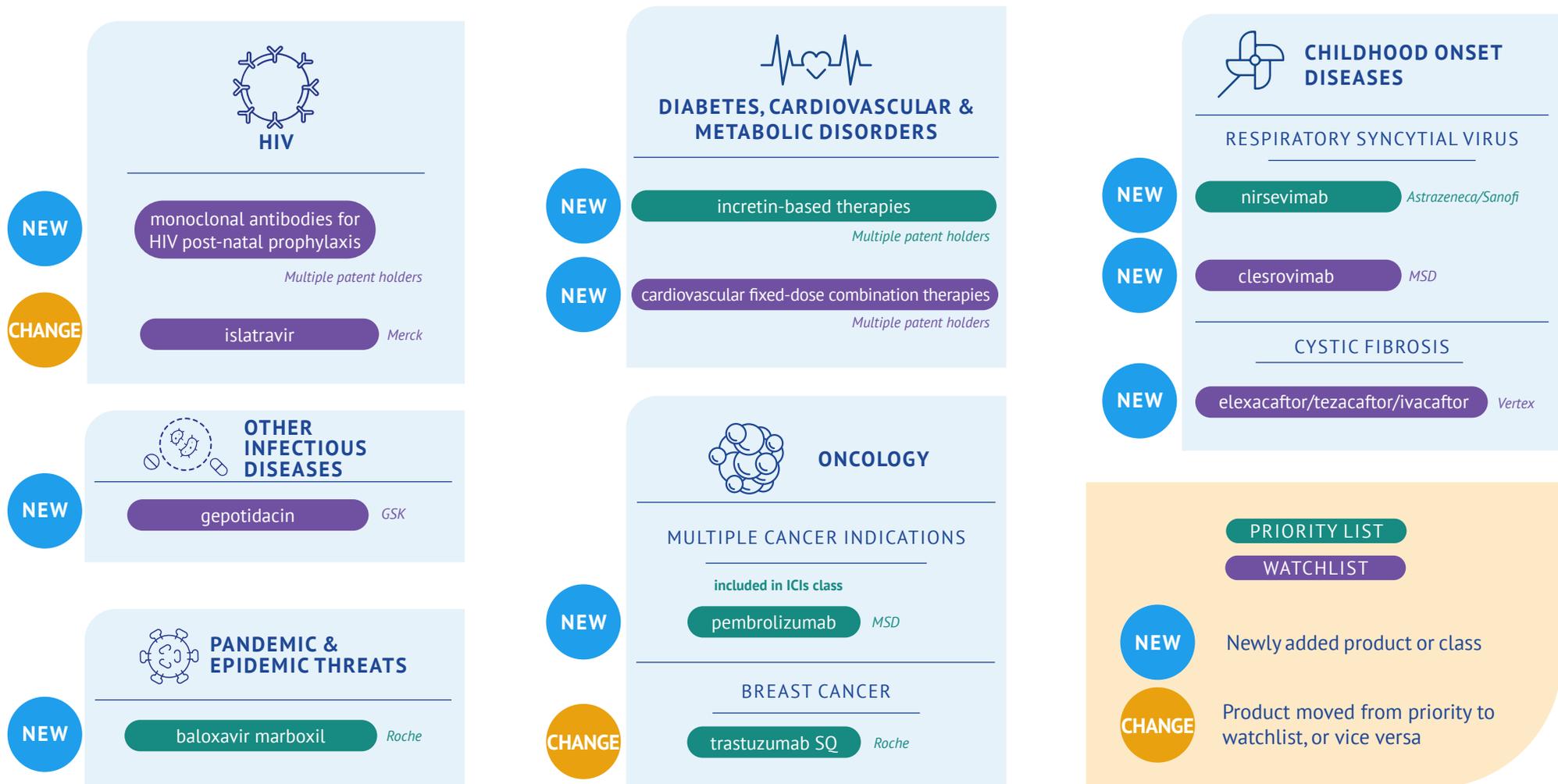
MARCH 2024

What is new in 2024 list?

The following graph and table summarise the main changes in the list compared to 2023 prioritisation. There were additions, changes in classification, and products that have been de-prioritised and removed from the list.

It should be also noted that MPP does not include in its prioritisation medicines for which it has already obtained licences*.

Additions and changes



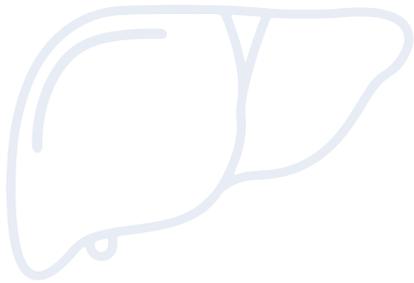
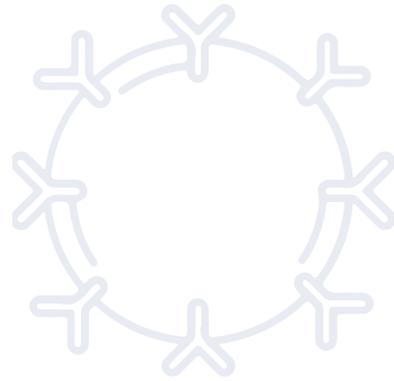
*MPP licences



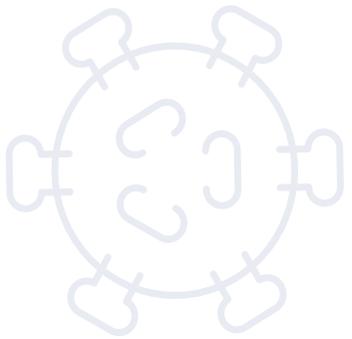
Access the searchable
repository of MPP priorities
and watchlist candidates

Removals

Health Area	Indication	Product/class	Originator	Rationale for removal
HIV		ultra-long acting injectable formulation of antiretrovirals (ARVs)	University of North Carolina at Chapel Hill	Patent coverage
		GSK3640254	ViiV Healthcare	Development seems halted
		three-monthly dual vaginal ring for HIV PrEP and prevention of unintended pregnancy	Population Council	Development seems paused
TUBERCULOSIS		bedaquiline	Janssen	Licensed out
		telacebec	Qurient Therapeutics	Licensed out
		fobrepodacin	Spero Therapeutics	Indication too narrow
MATERNAL HEALTH	PREVENTION OF POST-PARTUM HAEMORRHAGE	heat-stable carbetocin	Ferring Pharmaceuticals	MPP agreement
ONCOLOGY	LUNG CANCER	furmonertinib	Allist Pharmaceuticals	Impending patent expiry
	PROSTATE CANCER	enzalutamide	Pfizer/Astellas	Patent coverage
	MULTIPLE CANCER INDICATIONS	oral docetaxel	Athenex	Development seems halted
DIABETES, CARDIOVASCULAR AND METABOLIC DISORDERS		empagliflozin	Boehringer Ingelheim	Class effect of SGLT2i
		canagliflozin	Janssen	Class effect of SGLT2i



Overview of products by health area





There are 39 million people living with human immunodeficiency viruses (HIV) worldwide, but only 29.8 million currently receive antiretroviral therapy (ART). HIV paediatric care is improving, but still only one in two children living with the virus has access to treatment.

HIV prevention is also key to tackle the transmission of the disease. Although Pre-Exposure Prophylaxis (PrEP) has proven efficient in preventing HIV infection, its uptake is still slow. Affordable, effective HIV medicines are imperative, especially for people living with HIV (PLHIV) in low- and middle-income countries (LMICs) where HIV is most prevalent.

Medicines must also be available in the right formulations. Fixed-dose combinations and long-acting formulations increase adherence. Specially formulated treatments for children, appropriate for different ages and weights, improve care.

Since 2010, we have worked with leading HIV drug manufacturers, governments, international organisations, civil society, and affected communities to improve access to World Health Organization prioritised and recommended medicines for people living with HIV in LMICs. We have also worked to increase access to HIV prevention tools and support the diversification of prevention options. In 2022, MPP signed a voluntary licensing agreement with ViiV Healthcare for cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP). This is an important step in accelerating affordable and equitable access to long-acting PrEP in over 90 countries.

Given the current landscape in the HIV space, MPP has identified one medicine as priority and has included two medicines, one regimen and class in the watchlist.

Relevant changes in the 2023 MPP prioritisation report compared to the previous year are:

- addition of monoclonal antibodies for HIV post-natal prophylaxis in the watchlist,
- removal of ultra-long-acting injectable formulations for ARVs from the priority list, because of lack of patent coverage,
- removal of the three monthly dual vaginal ring for HIV PrEP and prevention of unintended pregnancy, because of lack of progress in development,
- removal of GSK3640254 from the watchlist because its development was stopped.

lenacapavir *Gilead*

Lenacapavir was first included as a priority for MPP in 2022 and it continues to be a priority because it has a new mechanism of action and its half-life allows for a 6 months dosing interval. Lenacapavir will likely be an important product in HIV prevention and/or treatment (in combination with other medicines). The clinical programs continue to show an overall favourable efficacy and safety profile. It is being investigated as a standalone injectable for HIV PrEP (6 monthly) and for treatment in combination with islatravir as weekly treatment regimen. Furthermore, lenacapavir has been prioritised by the Conference on Antiretroviral Drug Optimization (CADO) and is present in the Paediatric Antiretroviral Drug Optimization (PADO) watchlist.

cabotegravir & rilpivirine *ViiV & Janssen*

Cabotegravir (CAB) is the only approved integrase strand transfer inhibitor (INSTI) in combination with the non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine (RPV) constituting a fully long-acting treatment for HIV.

This combination regimen is indicated in virologically suppressed adults with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

Injectable cabotegravir and rilpivirine regimen for HIV treatment is not currently listed in WHO guidelines for the treatment of HIV.

This regimen could support treatment adherence and sustain virological suppression in comparison with daily oral treatments. Recent data presented at the 2024 Conference on Retroviruses and Opportunistic Infections (CROI2024) indicated that people living with HIV with adherence challenges and receiving long-acting injectable cabotegravir and rilpivirine (CAB/RPV) had further reductions in their viral loads than with oral antiretroviral treatment (ART).

Additionally, recent data from the CARES study showed that in sub-Saharan Africa, switching to LA CAB/RPV vs. continuing oral ART yielded high rates of HIV-1 RNA suppression at week 48 (LA CAB/RPV was non-inferior to oral ART). This study represents an initial success of such combination in LMIC settings.

There might be still some challenges that could prevent this 2-drugs regimen from being widely implemented in LMICs. Eventual rilpivirine resistance could challenge future use of the NNRTI class drugs. Additionally, rilpivirine (not cabotegravir) requires a cold chain and presents some safety issues including hepatic adverse effect.

For people living with hepatitis B, switching from a tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF)-containing regimen (such as oral tenofovir/lamivudine/dolutegravir (TLD)) to CAB/RPV would deprive these individuals from the HBV suppressive action of TDF or TAF. Finally there are some drug-drug interactions with tuberculosis treatment regimens including rifampicin and rifabutin.

doravirine *MSD*

Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It is being investigated for HIV treatment in combination with islatravir as once daily oral treatment and it has the potential to be an alternative treatment, including PLHIV experiencing weight-gain.

Additionally, some of its development program is focused on infants and children. However, the evidence of clinical benefits over the standard of care is unclear.

islatravir *Merck*

Islatravir is the first drug of a new class called nucleoside reverse transcriptase translocation inhibitors (NRTTIs). Its new mechanism of action and its long-acting properties have the potential to make it an important product in HIV treatment. After a period of pause in clinical development involving islatravir due to safety concerns, Merck has resumed some islatravir's development programs while monitoring closely its safety.

Furthermore, islatravir is one of the most promising drugs studied in combination with lenacapavir for oral weekly treatment.

monoclonal antibodies for HIV post-natal prophylaxis *Multiple patent holders*

These laboratory-made proteins emulate the immune system's ability to counteract harmful pathogens, including HIV.

Although still in the early stages of development, broadly-neutralising antibodies demonstrate significant potential for use in post-natal prophylaxis (PNP) against HIV, due to their favourable safety profile and the convenience they may offer through a single administration via intramuscular injection. Despite the potential benefits, crucial clinical data on the efficacy of monoclonal antibodies for PNP remain lacking. Specifically, there is a notable gap in understanding whether a single monoclonal antibody could suffice for prevention. If multiple mAbs are necessary, the cost could become a challenge, especially when compared to cheaper small molecules.

PRIORITY LIST

WATCHLIST



TUBERCULOSIS

An estimated global total of 10.6 million people fell ill with tuberculosis (TB) in 2021, most in low- and middle-income countries. TB is the leading cause of death for people with HIV and a major contributor to antimicrobial resistance. In 2021, 1.6 million people died from TB, including 187 000 people with HIV.

Globally, there were an estimated 450 000 incident cases of multidrug-resistant or rifampicin-resistant tuberculosis (MDR/RR-TB) in 2021. The World Health Organization's post-2015 Global TB Strategy sets ambitious targets at reducing TB deaths by 95% between 2015 and 2035, and to end TB. To meet these targets, better therapies to treat TB are urgently needed, particularly for MDR-TB.

Since 2020, PAN-TB, Project to Accelerate New Treatments for Tuberculosis (both drug sensitive (DS-TB) and multidrug-resistant TB) aims at developing new drug regimens to transform the care of patients with tuberculosis. We work to improve access to new treatments for MDR-TB and DS-TB.

We also facilitate the development of new regimens by licensing TB drugs that are still under development. In early 2017, MPP signed its first agreement with the Johns Hopkins University. This agreement was signed to facilitate the clinical development of sutezolid, a promising investigational treatment for tuberculosis. It was followed by a second agreement with Pfizer in October 2019 to access Pfizer's preclinical, phase I and phase IIa clinical study data and results on sutezolid. The agreement's aim was to further study, develop and make available this potential important component of new TB regimens.

Given the current situation in the TB space, MPP has identified one medicine as a priority and has included five in the watchlist. Relevant change in the 2023 MPP prioritisation report compared to the previous year are the removal of fobrepodacin and telacebec from the watchlist. This removal is justified by the fact that fobrepodacin has been studied mainly for non-tuberculous mycobacterial disease and telacebec has been licensed to TB alliance, a public health organisation already committed to LMICs access.



quabodepistat

Otsuka

Quabodepistat (OPC-167832) is a molecule with a new mechanism of action that has potent antituberculosis activity and a favourable safety profile. It is now studied as part of a new, promising, TB regimen under the Project to Accelerate New Treatments for Tuberculosis (PAN-TB) program, in combination with delamanid, bedaquiline, and sutezolid (DBOS) or in combination with pretomanid, bedaquiline and sutezolid (PBOS).

BTZ-043

University of Munich & DZIF

BTZ-043 is an investigational agent, active against all tested *Mycobacterium tuberculosis* strains, including multidrug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB) clinical isolates. The clinical data on BTZ-043 are still immature and therefore the drug candidate remains on the watchlist.

delpazolid

LegoChem BioSciences

Delpazolid is an investigational antitubercular agent. It is being studied in combination with delamanid and bedaquiline. As the clinical data are still immature, the drug candidate remains in the watchlist.

ganfeborole

GSK

Ganfeborole (GSK3036656) is an investigational agent, demonstrating early bactericidal activity with a low, once-daily oral dose after 14 days of treatment in participants with drug-susceptible pulmonary tuberculosis. The clinical data on GSK3036656 is still immature and therefore the drug candidate remains in the watchlist.

macozinone

EPFL

Macozinone (PBTZ-169) is a tuberculosis drug candidate that has demonstrated high potency against drug-susceptible and drug resistant *Mycobacterium tuberculosis* in pre-clinical studies. Macozinone has additive effects with many tuberculosis therapeutic agents, both marketed and in development, and has synergic effects with bedaquiline and clofazimine in preclinical models. Clinical data on macozinone are still immature.

sudapyridine

Shanghai Jiatan Biotech

Sudapyridine (WX-081) is a bedaquiline analogue, displaying antimycobacterial activity and low toxicity. Clinical data on sudapyridine are still immature.

PRIORITY LIST

WATCHLIST



VIRAL HEPATITIS

Of the five types of hepatitis infections, hepatitis B and C (HBV and HCV) cause most of the disease and deaths. 354 million people globally live with a hepatitis B or C infection. Hepatitis causes liver damage and cancer. Globally, viral hepatitis causes approximately 1.34 million deaths annually, with 66% of the deaths attributed to HBV infection. HCV can be cured; however, only 21% of people living with hepatitis C infection are diagnosed and only 13% have received curative treatment.

MPP works with a wide range of partners including originator and generic companies, governments, WHO, civil society and communities, procurement agencies, and others to expand and accelerate the development and distribution of these new treatments that can eliminate the virus through a short course of oral therapy in LMICs with a high HCV burden.

Among the other types of hepatitis infections, it is estimated that hepatitis D virus (HDV) affects nearly 5% of people globally who have a chronic infection with HBV, and that HDV co-infection could explain about one in five cases of liver disease and liver cancer in people with HBV infection. Patients with HDV-induced cirrhosis are at an increased risk of hepatocellular carcinoma (HCC). It is still unknown which fraction of the HBV-associated mortality involves disease complicated by HDV infection, and quantitative data on the contribution of HDV infection on the outcome of HBV infection are largely lacking.

Given the current pipeline in the viral hepatitis space, MPP has not identified a priority product and has included one medicine in the watchlist for Hepatitis D.

bulevirtide

吉利德

Bulevirtide was recently conditionally approved by the European Medicines Agency (EMA) and is today the only specific treatment for hepatitis delta. The treatment's duration and the necessity of a daily subcutaneous injection may present some challenges in LMICs. Additionally, its safety and efficacy are still under evaluation and therefore bulevirtide has been included in the watchlist.

PRIORITY LIST

WATCHLIST



OTHER INFECTIOUS DISEASES

MPP started its work by focusing on infectious diseases, notably HIV, aiming to expand access to life-saving medications. Supported by its successes in HIV, MPP expanded its scope to include TB and hepatitis, recognizing the significant burden these diseases impose on global health and particularly in LMICs due to their high prevalence. Other infectious diseases, while not commanding the level of attention to HIV, TB, or hepatitis, still represent significant public health burden in LMICs.

An example of one such pressing issue is antimicrobial resistance and in particular, antibiotic resistance, where the development of innovative antibiotics is crucial to mitigate the rising threat posed by resistant pathogens. MPP's commitment to identify promising new medicines for infectious diseases caused by pathogens which have developed resistance against available therapies, is balanced with stewardship efforts to avoid development of resistance to new antimicrobials. This is an area in which MPP has already undertaken work in the context of its TB activities, and it will continue to support ongoing efforts to combat antimicrobial resistance.

In this context, MPP has included one medicine in the watchlist for Uncomplicated Urinary Tract Infections (UUTI) and of Uncomplicated Urogenital Gonorrhoea (UUG).

gepotidacin

GSK

Gepotidacin is an investigational first-in-class oral antibiotic for treatment of uncomplicated urinary tract infections and of Uncomplicated Urogenital Gonorrhoea (UUG). Gepotidacin is active against most strains of target uropathogens, such as *E.coli* and *Staphylococcus saprophyticus*, including isolates resistant to current antibiotics. Furthermore, due to gepotidacin's mechanism of action, blocking bacterial DNA replication by inhibiting two vital enzymes, mutations in both enzymes are needed to significantly affect susceptibility to gepotidacin. This gives hope that this drug will stay effective as resistance would be harder to develop. A recent press release from GSK announced that the EAGLE-1 trial met its primary efficacy endpoint, with gepotidacin (oral, two doses of 3,000mg) demonstrating non-inferiority to intramuscular (IM) ceftriaxone (500mg) plus oral azithromycin (1,000mg), a leading combination treatment regimen for gonorrhoea.

PRIORITY LIST

WATCHLIST



PANDEMIC & EPIDEMIC THREATS

Epidemics are an unexpected, often sudden, increase of a specific illness within a community or region. Pandemics are when an epidemic occurs worldwide, crossing international borders and affecting a large number of people. A number of communicable diseases can be significant health threats at the local, regional and global level and lead to epidemics or pandemics. Epidemics and pandemics can be prevented and mitigated through a range of measures, such as good hygiene, social distancing, medicines and vaccination. Pandemics pose a significant threat to global health security. By actively engaging in pandemic preparedness, MPP contributes to the resilience of healthcare systems and helps mitigate the impact of future health crises. MPP works with innovators and pharmaceutical companies to expedite the development and manufacturing of medical countermeasures. By facilitating intellectual property licensing and technology transfer, MPP can support the production of these life-saving tools in LMICs and contribute to ensuring that pandemic-related products are accessible to governments and healthcare systems, especially in low- and middle-income countries, in an equitable manner.

Among the epidemic threats, MPP has been monitoring the influenza space. Seasonal influenza is an acute respiratory infection caused by influenza viruses which circulate in all parts of the world. It represents a year-round disease burden. It causes illnesses that range in severity and sometimes lead to hospitalization and death. Worldwide, influenza epidemics are estimated to result in about 3 to 5 million cases of severe illness, and about 290,000 to 650,000 respiratory deaths annually. Given its potential impact on eventual influenza pandemics, MPP has added baloxavir marboxil as a priority product for in-licensing.

Given the current situation in the pandemic and epidemic threats, MPP has identified one medicine as a priority for influenza. The relevant change in this report compared to the previous MPP prioritisation is the addition of baloxavir marboxil for influenza.

baloxavir marboxil *Roche*

Baloxavir marboxil, an oral one-dose, one-time treatment for influenza, could serve, in addition to its use in seasonal influenza, as a valuable tool in pandemic preparedness in the event of a novel and highly virulent influenza strain.

As a drug in a new class of antiviral treatment for influenza, it could provide an additional layer of defence and an option against viruses resistant to existing antivirals.

PRIORITY LIST

WATCHLIST



MATERNAL HEALTH

In 2023, MPP joined forces with Ferring Pharmaceuticals through a formal agreement to broaden access to heat-stable carbetocin (HSC). This innovative drug is vital for preventing post-partum haemorrhage, a serious condition that leads to the death of approximately 66,500 women annually in low- and middle-income countries. HSC, which has been recognised as essential by the EML core list since 2019, matches oxytocin in effectiveness and safety, and crucially, does not require refrigeration. This is particularly beneficial in regions with limited resources.

Currently, we are not specifically prioritising medicines within the maternal health area. However, it is important to note that our prioritization process is dynamic and conducted on a rolling basis. New candidates for in-licensing could be considered and added to our priority or watch lists at any time, should they meet our framework criteria.

Non-communicable diseases (NCDs) are the leading cause of death among women, accounting for three-quarters of female deaths each year. Breast and cervical cancers are the most diagnosed and deadly cancers for women globally, with a significant number of these deaths occurring in underprivileged areas. To address these challenges, MPP is focusing on specific treatments, including the immune checkpoint inhibitor class and five other products that are key in combating breast and cervical cancers. This targeted approach is part of MPP's commitment to improving healthcare outcomes for women around the world.



CHILDHOOD ONSET DISEASES

Across most disease areas in which MPP has been working on, access to appropriate medicines for children lags behind that for adults, and in many cases important medicines are not available in formulations that can be taken easily by young children.

Since its inception, MPP has prioritised working with manufacturers on bringing quality-assured paediatric formulations to market, including accelerating their development and facilitating uptake. This contribution has increasingly taken place in partnership with other key stakeholders in the paediatric field.

Moving forward, MPP will continue to place particular focus on addressing the needs of children across all disease areas in which it operates. Its contribution in paediatrics will be framed in alignment with the Global Accelerator for Paediatric Formulations Network (GAP-f) a WHO network of which MPP is a founding member, to ensure that the most-needed, optimal paediatric formulations are prioritised, developed, and made available to children swiftly and efficiently.

This chapter provides a summary of MPP priorities and watchlist in the field of childhood onset diseases. The relevant changes in this report compared to the previous MPP prioritisation are: The addition of nirsevimab to the priority list and of clesrovimab to the watchlist for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease, and the addition of elexacaftor/tezacaftor/ivacaftor on the watchlist for the management of cystic fibrosis.

RESPIRATORY SYNCYTIAL VIRUS

Respiratory syncytial virus (RSV) is a virus that causes acute respiratory infection in individuals of all age groups.

While most infants and young children experience mild, cold-like symptoms, some infants, especially with their first infection, develop lower respiratory tract disease such as pneumonia and bronchiolitis (swelling of the small airway passages in the lungs), that often leads to an emergency department or physician office visit.

Infants have the highest incidence of severe disease, peaking at 1 to 3 months of age. Premature infants, and those with chronic lung disease of prematurity or significant congenital heart disease, are at highest risk for severe RSV disease. RSV caused an estimated 101,400 deaths in children under five in 2019.

nirsevimab *Astrazeneca/Sanofi*

Nirsevimab is a monoclonal antibody with activity against RSV. Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. One dose of nirsevimab administered to infants as a single intramuscular injection prior to, or during RSV season, may provide protection during the RSV season.

clesrovimab *MSD*

Clesrovimab is a monoclonal antibody with activity against Respiratory Syncytial Virus (RSV). Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. Although the product is still in development, one dose of clesrovimab administered to infants as a single intramuscular injection may provide protection against RSV.

PRIORITY LIST

WATCHLIST



CYSTIC FIBROSIS

Cystic fibrosis is a rare, progressive, life-threatening disease, caused by mutations in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene that results in the formation of thick mucus that builds up in the lungs, digestive tract, and other parts of the body. It leads to severe respiratory and digestive problems as well as other complications such as infections and diabetes.

There is no cure and people with cystic fibrosis receive daily treatments depending on the severity of their symptoms. There are no global annual deaths estimates for cystic fibrosis and related life expectancy, but it is generally assumed that in the absence of CFTR modulators, the median life expectancy for cystic fibrosis would be around 24.5 years (compared to 46 in presence of CFTR).

elexacaftor/tezacaftor/ivacaftor *Vertex*

The combination of the active substances elexacaftor, ivacaftor and tezacaftor is the first triple combination therapy available to treat patients with the most common cystic fibrosis mutation.

It is approved for use in patients 12 years and older with cystic fibrosis who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which is estimated to represent 90% of the cystic fibrosis population.

SICKLE CELL DISEASE

In 2019, sickle cell disease (SCD) was responsible for 47,932 deaths and saw 605,000 new births with the condition, bringing the total number of people living with SCD to 5.69 million. Approximately 90% of those affected by sickle cell disease reside in low- and middle-income countries (LMICs)

Notably, sub-Saharan Africa bears the highest SCD prevalence, with approximately 80% of cases occurring in this region. The mortality rate for children under five years of age in this region ranges from 50% to 80%.

voxelotor *Pfizer*

Voxelotor is a haemoglobin oxygen-affinity modulator approved by the United States Food and Drug Administration (USFDA) in 2019 for the treatment of sickle cell disease.

Voxelotor has a different mode of action from that of conventional standard of care therapies, which makes it relevant as additional treatment or in case of intolerance.

PRIORITY LIST

WATCHLIST



ONCOLOGY

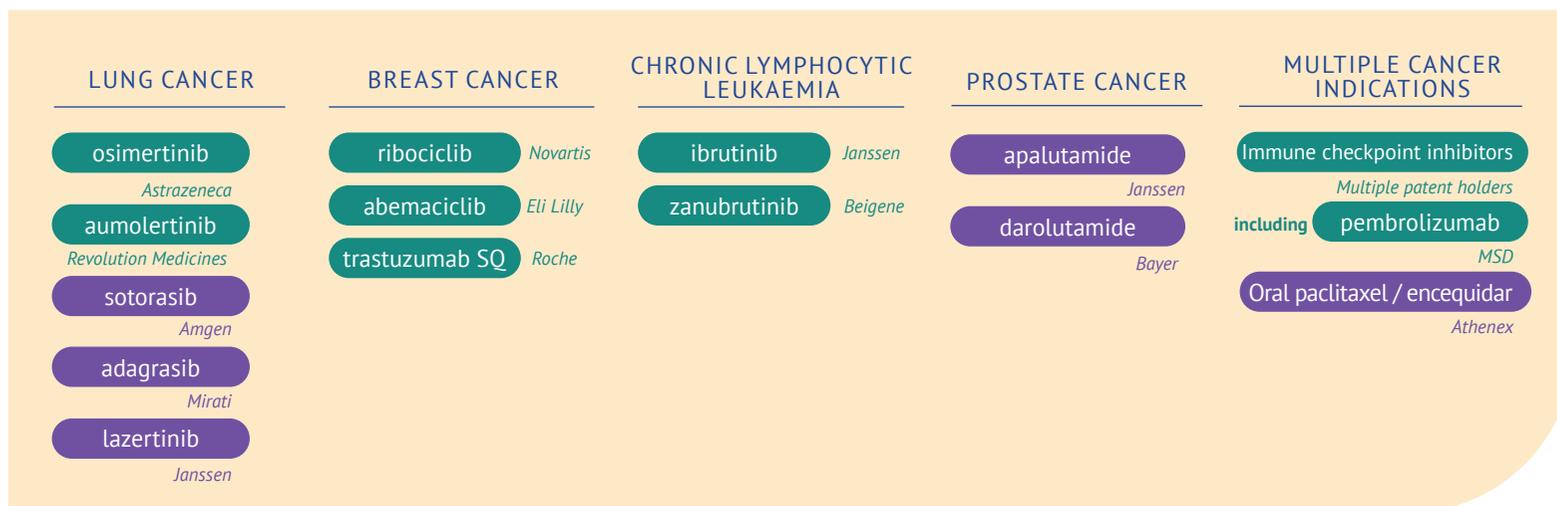
Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths. Among the prevalent cancer types, breast, lung, colon and rectum, prostate, stomach, liver, cervix uteri and skin cancers stood out as the most frequently encountered. Many cancers can be cured if detected early and treated effectively.

Many health systems in low- and middle-income countries remain ill-equipped to cope with this growing health crisis. Consequently, a significant portion of cancer patients worldwide continues to face significant barriers to accessing timely and high-quality diagnosis and treatment.

This chapter provides a summary of MPP priorities and watchlist respectively, in the field of oncology.

Relevant changes in the 2024 MPP prioritisation report compared to the previous year are:

- addition of pembrolizumab as a priority within the class of the immune checkpoint inhibitors;
- addition of subcutaneous trastuzumab to the priority list;
- removal of furmonertinib and enzalutamide from the watchlist due to patent expiry and patent coverage respectively;
- removal of oral docetaxel + encequidar from the watchlist as its development seems halted.





LUNG CANCER

Lung cancer arises from the rapid and unregulated proliferation of abnormal cells in the lungs, posing a significant threat to health and carrying a high risk of fatality.

The two most common forms of lung cancer are: non-small cell lung carcinoma (NSCLC), which is prevalent and tends to develop at a gradual pace, and small cell lung carcinoma (SCLC), which is rarer but usually exhibits a rapid growth rate. In low- and middle-income countries (LMICs), there were 1.2 million incident cases of non-small cell lung cancer (NSCLC) in 2020.

Unfortunately, around 70% of NSCLC cases are diagnosed in advanced stages, such as locally advanced or metastatic.

aumolertinib

Revolution Medicines

Aumolertinib is a 3rd generation Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR TKI), that has demonstrated significant benefits compared to standard first-line treatments of 1st and 2nd generations in the WHO Essential Medicines List for the treatment of non-small cell lung cancer.

Aumolertinib is under review for approval by the European Medicines Agency (EMA).

adagrasib

Mirati

Adagrasib is an oral Kirsten Rat Sarcoma Virus (KRAS) inhibitor that received approval by the Food and Drug Administration (FDA) for the treatment of non-small cell lung cancer (NSCLC) in 2022 and showcases durable clinical benefits in patients.

lazertinib

Janssen

Lazertinib is an investigational 3rd generation Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR TKI), presenting superiority over the 1st generation of EGFR TKI. Lazertinib has a strong potential as alternative option for lung cancer treatment.

osimertinib

Astrazeneca

Osimertinib is a 3rd generation Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR TKI) approved by the Food and Drug Association and the European Medicines Agency.

It has demonstrated significant benefits compared to standard first-line treatments of 1st and 2nd generations in the WHO Essential Medicines List (EML) for the treatment of non-small cell lung cancer.

The EML committee called on MPP to explore licensing opportunities for osimertinib.

sotorasib

Amgen

Sotorasib is an oral Kirsten Rat Sarcoma Virus (KRAS) inhibitor, that received accelerated approval by the Food and Drug Administration (FDA) for the treatment of non-small cell lung cancer (NSCLC) in 2021. A recent study showed that sotorasib offered significant benefits compared to the standard intravenous treatment.

PRIORITY LIST

WATCHLIST



Breast cancer is the most commonly occurring cancer in women. In 2022, there were over 2.29 million new cases of breast cancer in women, leading to an estimated 669,418 deaths, many of which disproportionately occurred in low-resource settings.

There are four main female breast cancer subtypes, including the following in order of prevalence: HR+/HER2-, HR-/HER2-, HR+/HER2+, HR-/HER2+.

- HR stands for hormone receptor.
- HR+ means that tumour cells have receptors for the hormones estrogen or progesterone, which can promote the growth of HR+ tumours.
- HER2 stands for human epidermal growth factor receptor 2.
- HER2+ means that tumour cells make high levels of a protein called HER2/neu, which has been shown to be associated with certain aggressive types of breast cancer.

abemaciclib *Eli Lilly*

Abemaciclib is an oral cyclin-dependent kinase 4 and 6 (CDK 4/6) inhibitor, approved by the Food and Drug Administration for the treatment of HR+/HER2- advanced breast cancer, recommended as the preferred option in the treatment of advanced breast cancer. CDK 4/6 inhibitors are the recommended preferred option in the treatment of advanced breast cancer.

The Essential Medicines List expert committee recognised its potential for future inclusion and recommended to MPP to explore licensing opportunities.

Abemaciclib has a similar safety profile to ribociclib but with a different dosing regimen, making it an alternative of interest.

ribociclib *Novartis*

Ribociclib is an oral Cyclin-Dependent Kinase 4 and 6 (CDK 4/6) inhibitor, approved by the USFDA for the treatment of HR+/HER2- advanced breast cancer.

The Essential Medicines List expert committee recognised its potential for future inclusion and recommended to MPP to explore licensing opportunities.

trastuzumab SQ *Roche*

Trastuzumab subcutaneous is a monoclonal antibody approved by the USFDA in 2019 for the treatment of HER2+ over-expressing breast cancer. It is the same monoclonal antibody as intravenous trastuzumab with the advantage of being easier and more rapid to administer.



CHRONIC LYMPHOCYTIC LEUKAEMIA

Chronic Lymphocytic Leukaemia (CLL) is the most common form of leukaemia, accounting for 25% to 30% of all leukaemia cases in Western countries. In 2019, CLL resulted in 44,612 deaths worldwide. Regarding incidence rates in 2019, CLL affected 1.34 individuals per 100,000 in the global population, with rates of 1.13 in high-income countries, 0.45 in middle-income countries, and 0.28 in low-income countries. Central Sub-Saharan Africa is experiencing the fastest growth in disease rates, with deaths increasing by 2.8% each year and the impact on daily life growing by 2.66% annually.

CLL predominantly occurs in older individuals, peaking in the elderly population, with a median age at diagnosis of 71 years in Europe. Furthermore, the incidence of CLL is approximately twice as high in males compared to females.

ibrutinib

Janssen

Ibrutinib is a Bruton's Tyrosine Kinase Inhibitor (BTKi) approved by the Food and Drug Administration in 2013 and added to the complimentary list of the Essential Medicines List for the treatment of CLL. Ibrutinib demonstrated major benefits compared to chemo-immunotherapy. The Essential Medicines List expert committee recommended to MPP to explore licensing opportunities.

zanubrutinib

Beigene

Zanubrutinib is a Bruton's Tyrosine Kinase Inhibitor (BTKi) approved by the USFDA in 2023 for the treatment of CLL. Recognising the emerging important role of BTKi as a therapeutic class in the treatment of CLL, the EML Committee advised that it would consider an application for zanubrutinib as therapeutic alternative for inclusion and recommended to MPP to explore it for licensing.

PROSTATE CANCER

Prostate cancer made up 7.3% of all new cancer cases in 2020, accounting for 14.1% of all new male cancer diagnoses.

Notably, cancer incidence rates have been on the rise in various sub-Saharan African populations. Men of African descent face nearly double the risk of being diagnosed with prostate cancer before the age of 45 compared to Caucasian men.

apalutamide

Janssen

Apalutamide is a 2nd generation androgen receptor antagonist approved by the USFDA in 2018. As a class of drugs, 2nd generation androgen receptor antagonists improve overall survival in prostate cancer patients. Apalutamide is a strong potential alternative candidate.

darolutamide

Bayer

Darolutamide is a 2nd generation androgen receptor antagonist approved by USFDA in 2019. As a class of drugs, 2nd androgen receptor antagonists improve overall survival in prostate cancer patients. Darolutamide is a strong potential alternative candidate.

PRIORITY LIST

WATCHLIST



MULTIPLE CANCER INDICATIONS

Immune checkpoint inhibitors

Multiple patent holders

Immune checkpoint inhibitors (ICIs) represent a revolutionary advance in the field of oncology, offering a new horizon in the treatment of cancer by immunotherapy. These monoclonal antibodies block proteins that would prevent the immune system from attacking cancer cells. The best-known representatives of this class are PD-1 and PD-L1 inhibitors. The versatility of ICIs has led to their approval for the treatment of a wide range of cancers, and the pipeline of new ICIs is robust and promising.

The importance of ICIs in this context is underlined by the World Health Organization's (WHO) Essential Medicines List (EML) Committee, which has recognised their importance by including certain ICIs on the list of essential medicines for the treatment of cutaneous melanoma. This reflects their therapeutic value and their potential for wider application. In particular, ICIs have shown that they can play an essential role in the fight against certain types of breast and cervical cancer, which remain the most diagnosed and deadliest forms of cancer for women in low- and lower-middle-income countries (LMICs).

The WHO EML Committee recommended continuing to work on strategies to improve the affordability of these medicines, and also suggested considering licensing to MPP, as our support for technology transfer could contribute to successful implementation by reducing the development time and costs of biosimilar versions for use in low- and middle-income countries. In line with these efforts, MPP has strategically prioritised ICIs as a class, with pembrolizumab presented as an example/priority.

The ICI class includes

pembrolizumab

MSD

Pembrolizumab as a single agent reduces the risk of death in non-small cell lung cancer patients by 40%, significantly extending survival by more than a year with fewer side effects compared to traditional chemotherapy. Pembrolizumab is also indicated against several other cancers.

Oral paclitaxel / encephaloidar

Athenex

The intravenous formulation of paclitaxel was added to the EML in 2011 and used in the treatment protocols for many cancers. Pending confirmation of its safety and efficacy, this new mode of oral administration, currently under development, could be particularly promising for LMIC settings, and therefore have been included in the watchlist.

PRIORITY LIST

WATCHLIST



DIABETES, CARDIOVASCULAR & METABOLIC DISORDERS

Cardiovascular diseases (CVDs) stand as the leading global cause of death, accounting for 32% of all deaths in 2019, with an estimated 17.9 million lives lost. Over three-quarters of CVD deaths occur in low- and middle-income countries. These diseases were responsible for 38% of the 17 million premature deaths (those under 70 years old) attributed to noncommunicable diseases in 2019. Early detection of cardiovascular disease is paramount to initiate timely management through counselling and medication. Despite high-quality scientific evidence of the benefits of different classes of drugs in preventing and controlling cardiovascular disease, their current use remains low.

Currently, 537 million adults (10.5% of the global population) are grappling with diabetes. Projections indicate that this number will climb to 643 million by 2030. Approximately 240 million individuals worldwide live with undiagnosed diabetes, meaning nearly one out of every two adults is oblivious to their condition. Notably, 90% of these undiagnosed cases are concentrated in low- and middle-income countries (LMICs). Type 1 diabetes afflicts over 1.2 million children and adolescents, with 54% of them under the age of 15. Type 2 diabetes is the most common type of diabetes, accounting for over 90% of all diabetes worldwide. Globally, the prevalence of type 2 diabetes is high and rising across all regions and has also become a concern in children and young people as a result of an increasing prevalence of obesity.

This chapter provides a summary of MPP priorities and watchlist in the diabetes, cardiovascular and metabolic disorders field. No medicine was identified as priority, but two classes of products are now included in the priority list: the incretin-based therapies and in the watchlist: the cardiovascular fixed-dose combination therapies.

In the 2024 report, empagliflozin and canagliflozin were removed from the priority list due to the expiration of dapagliflozin's patent and the inclusion of this drug class with a square-box indication in the EML.

incretin-based therapies

Multiple patent holders

The incretin hormones are gut hormones that amplify nutrient-induced insulin secretion in response to meal intake. Incretin peptides, principally Glucagon-like Peptide-1 (GLP-1) and Gastric Inhibitory Polypeptide (GIP), regulate islet hormone secretion, glucose concentrations, lipid metabolism, gut motility, appetite and body weight, and immune function, providing a scientific basis for utilising incretin-based therapies in the treatment of type 2 diabetes.

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) have proven efficacy in type 2 diabetes mellitus (T2DM) management as they effectively reduce glycaemia and weight while posing a low risk of hypoglycaemia.

Some GLP-1 RAs also have documented beneficial effects on the cardiovascular system, chronic kidney disease and non-alcoholic fatty liver disease.

cardiovascular fixed-dose combination therapies

Multiple patent holders

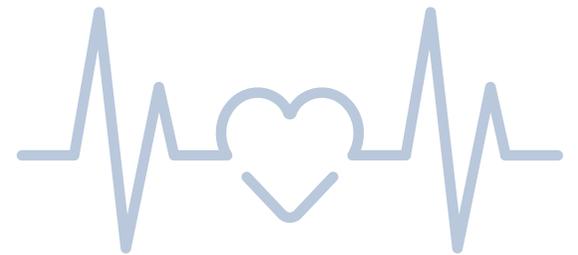
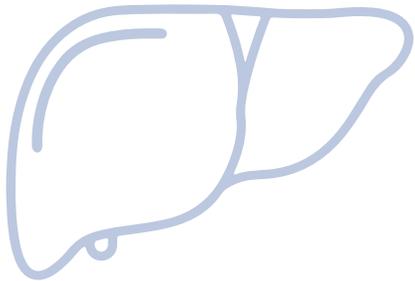
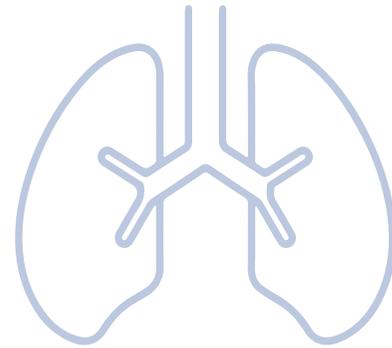
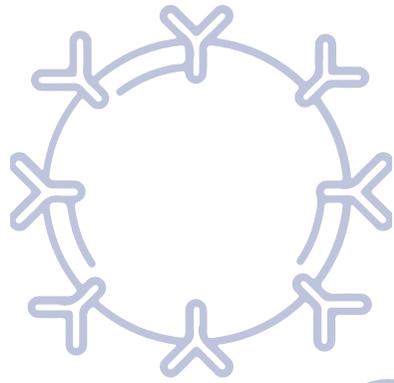
Fixed-dose combination medicines, or polypills, have been proven to simplify treatment, enhance adherence, and better manage risk factors for cardiovascular disease.

These polypills combine cholesterol-lowering drugs, blood pressure medications, and aspirin as needed and significantly reduce morbidity and mortality from atherosclerotic cardiovascular diseases. Effective management of cardiovascular diseases could prevent millions of deaths over the next decades.

The demonstrated benefits and cost-effectiveness of these combinations earned them an inclusion in the WHO Essential Medicines List in 2023.

PRIORITY LIST

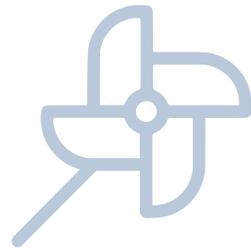
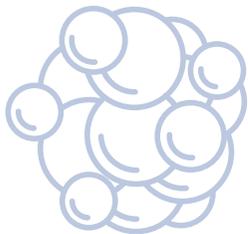
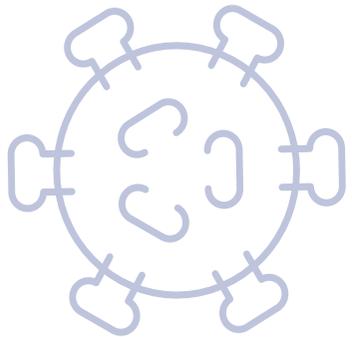
WATCHLIST

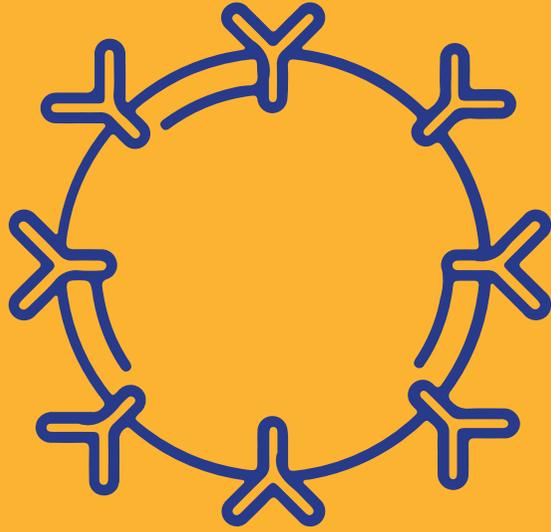


Products snapshots

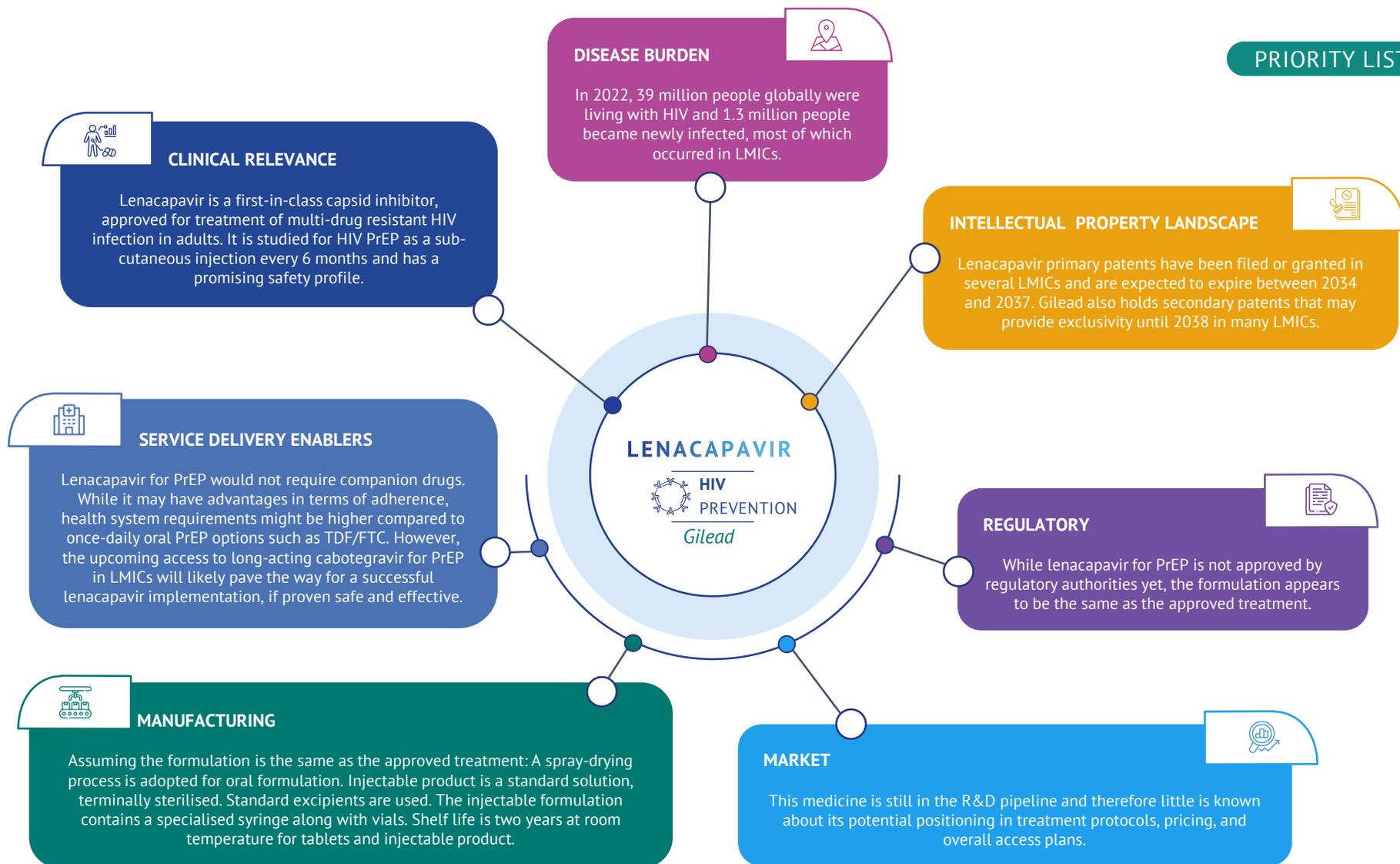
In this chapter we provide additional information on the medicines listed previously.

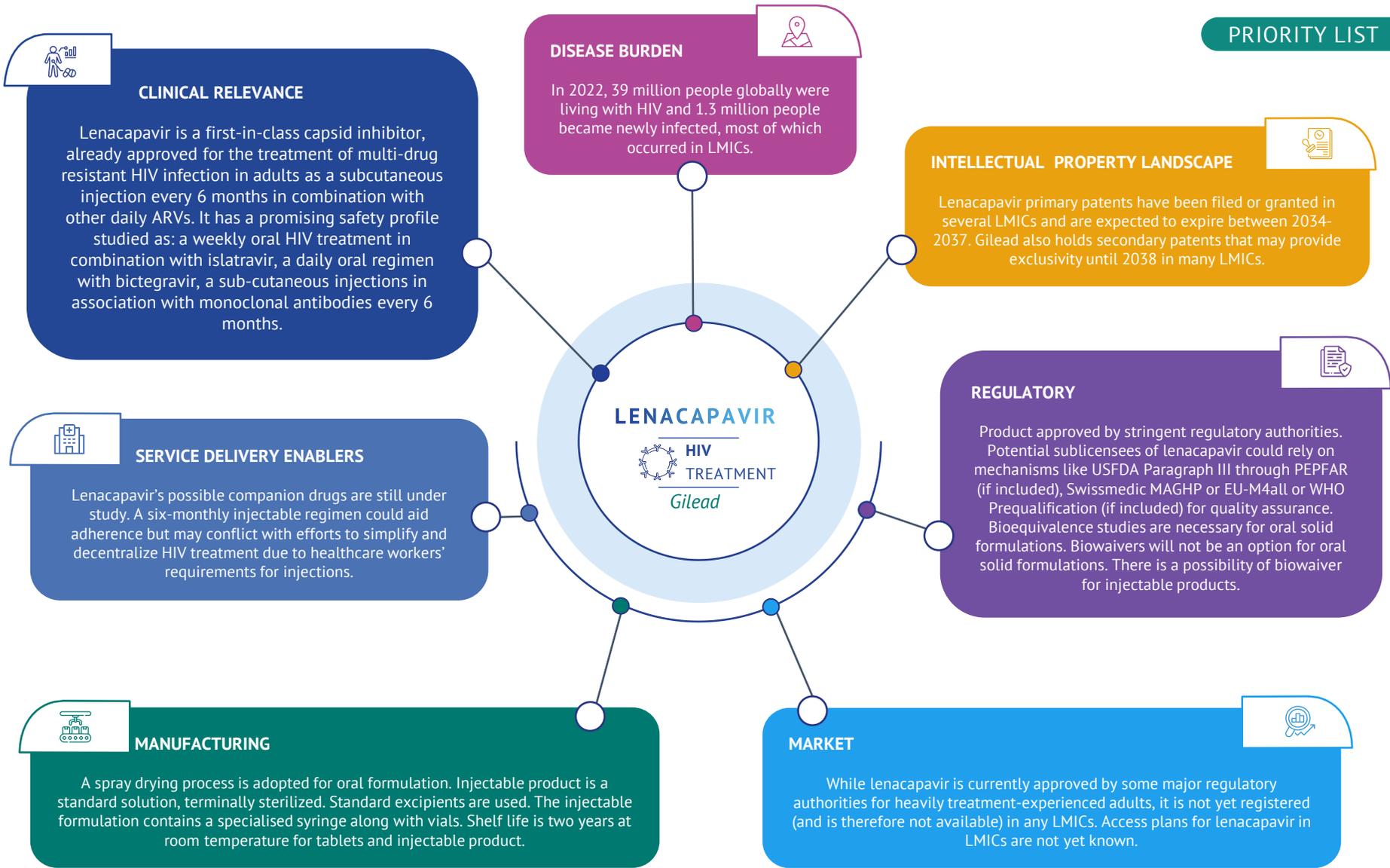
The detailed analysis is presented as a graphic snapshot following the prioritisation framework structure. Snapshots contain plain language key messages for each of the prioritisation criteria that MPP has evaluated.



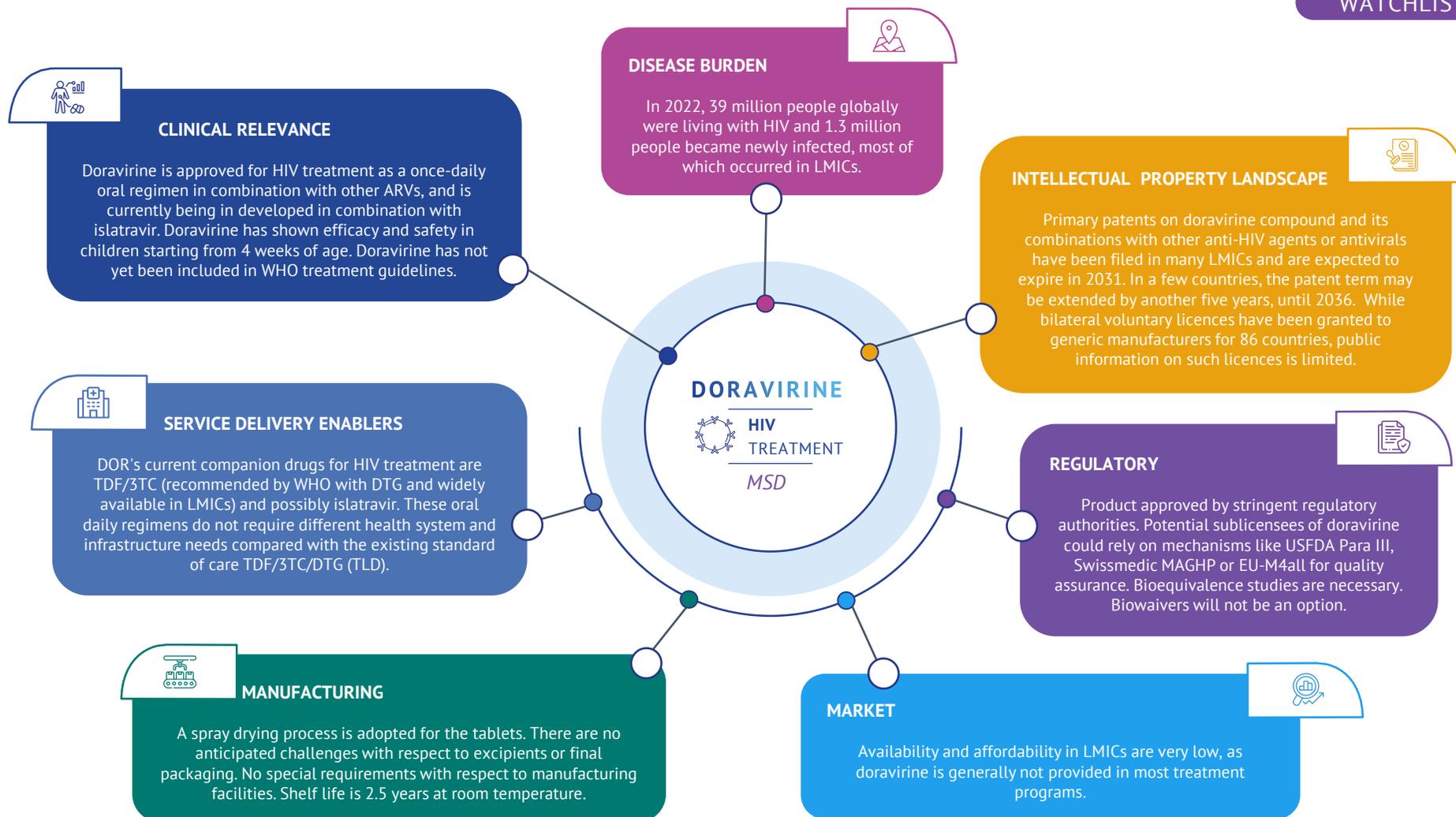


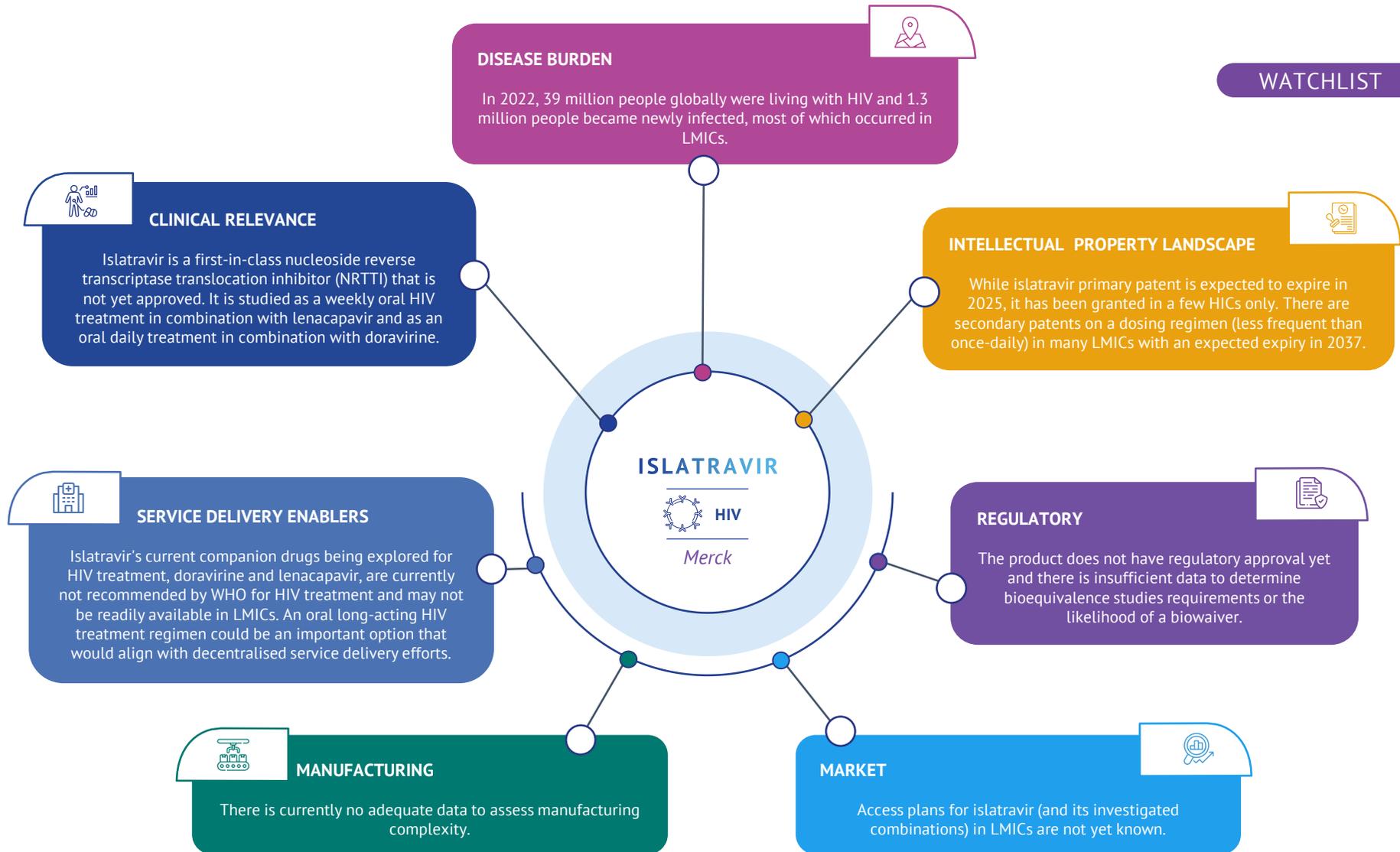
HIV











DISEASE BURDEN

About 500 children are newly infected with HIV every day. As of 2018, of the estimated nearly 38 million people worldwide living with HIV, approximately 1.7 million are children under 15 years of age. Since 2010, new HIV infections among children have declined by 41%, but only half (54%) of all children living with HIV are getting treatment and 100,000 children died of AIDS-related illnesses in 2018.

CLINICAL RELEVANCE

mAbs/bNAbS for PNP are still in early research, and clinical evidence in the field of prevention is limited; nonetheless, mAbs/bNAbS for PNP hold significant potential, owing to the ease of a single injection and a favorable safety profile.

SERVICE DELIVERY ENABLERS

mAbs/bNAbS for HIV post-natal prophylaxis are likely to be injectables administered intramuscularly or intravenously and require cold chain storage. As such, supply chain, health facility, and healthcare worker requirements may be minimised through the integration of mAbs/bNAbS in national neonate immunization packages and corresponding administration at birth (for infants born to mothers living with HIV).

MANUFACTURING

Complex manufacturing process since the products are biotherapeutics. The products are still early in development and technical details are likely product-specific.

MARKET

Post-natal prophylaxis strategies are likely to be implemented in countries with high HIV burden, mostly LMICs.

INTELLECTUAL PROPERTY LANDSCAPE

The patent landscape, likely to be complex, will depend on the specific candidates selected.

REGULATORY

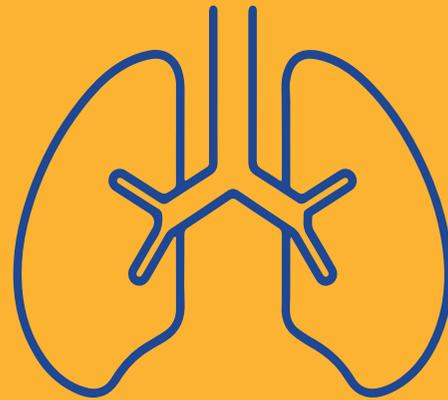
There are currently no approved mAbs/bNAbS for HIV post-natal prophylaxis. Potential licensees could rely on mechanisms like EU-M4 all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment likely to be done. Clinical trial waivers would likely not be an option. There could be additional regulatory complexities if a combination of bNAbS is used.

mAbs/bNAbS

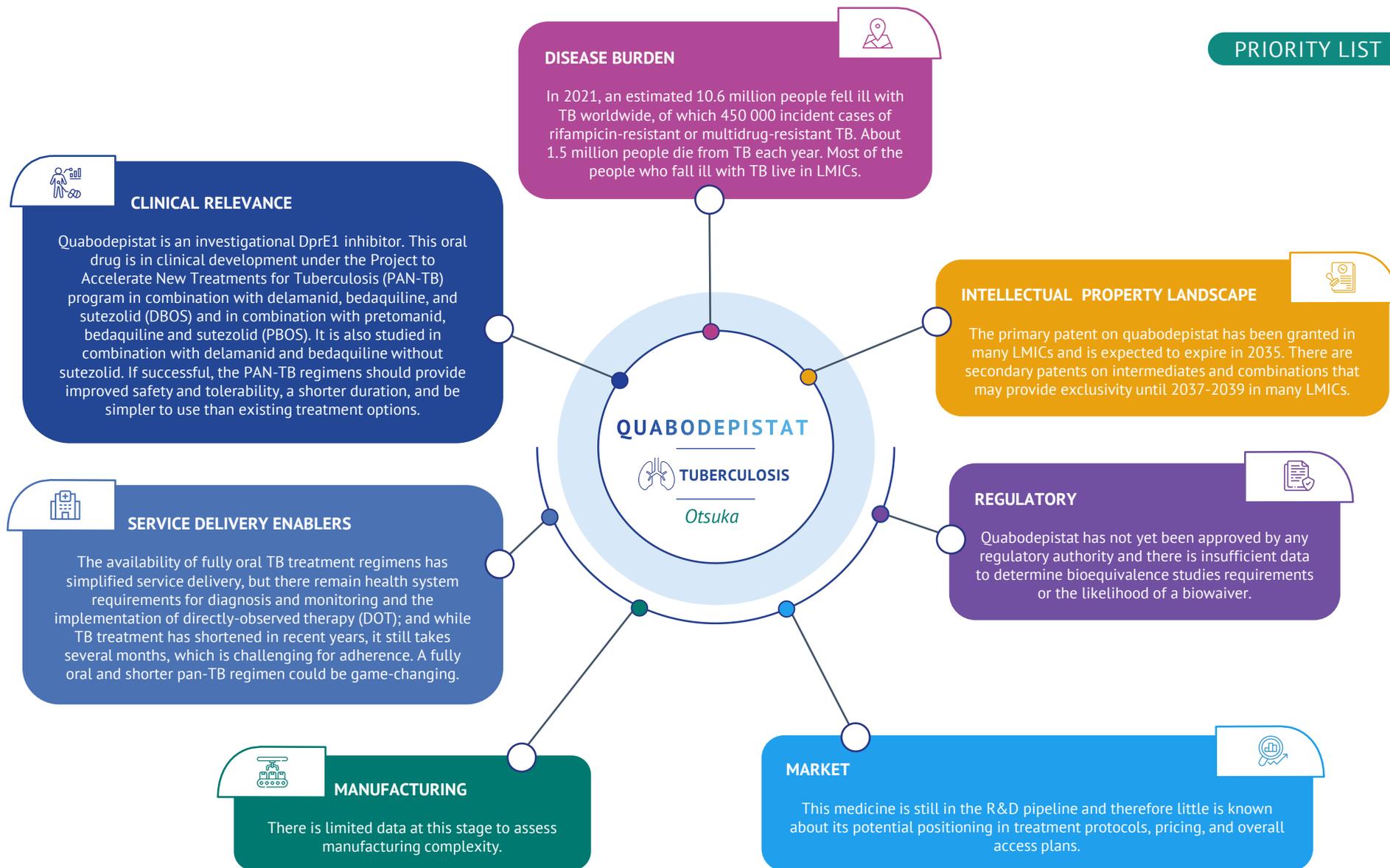


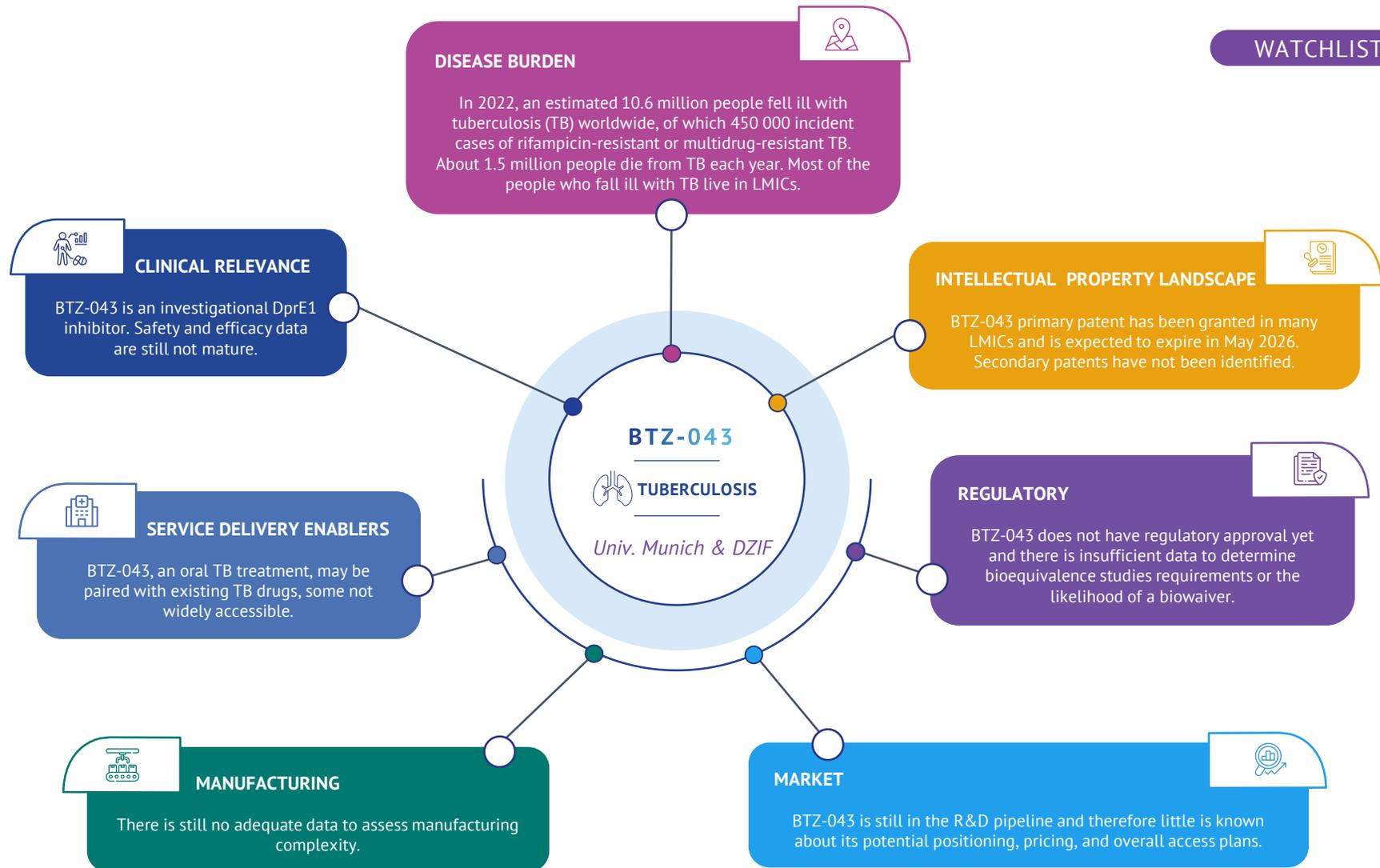
HIV Post-natal-
Prophylaxis
(PNP)

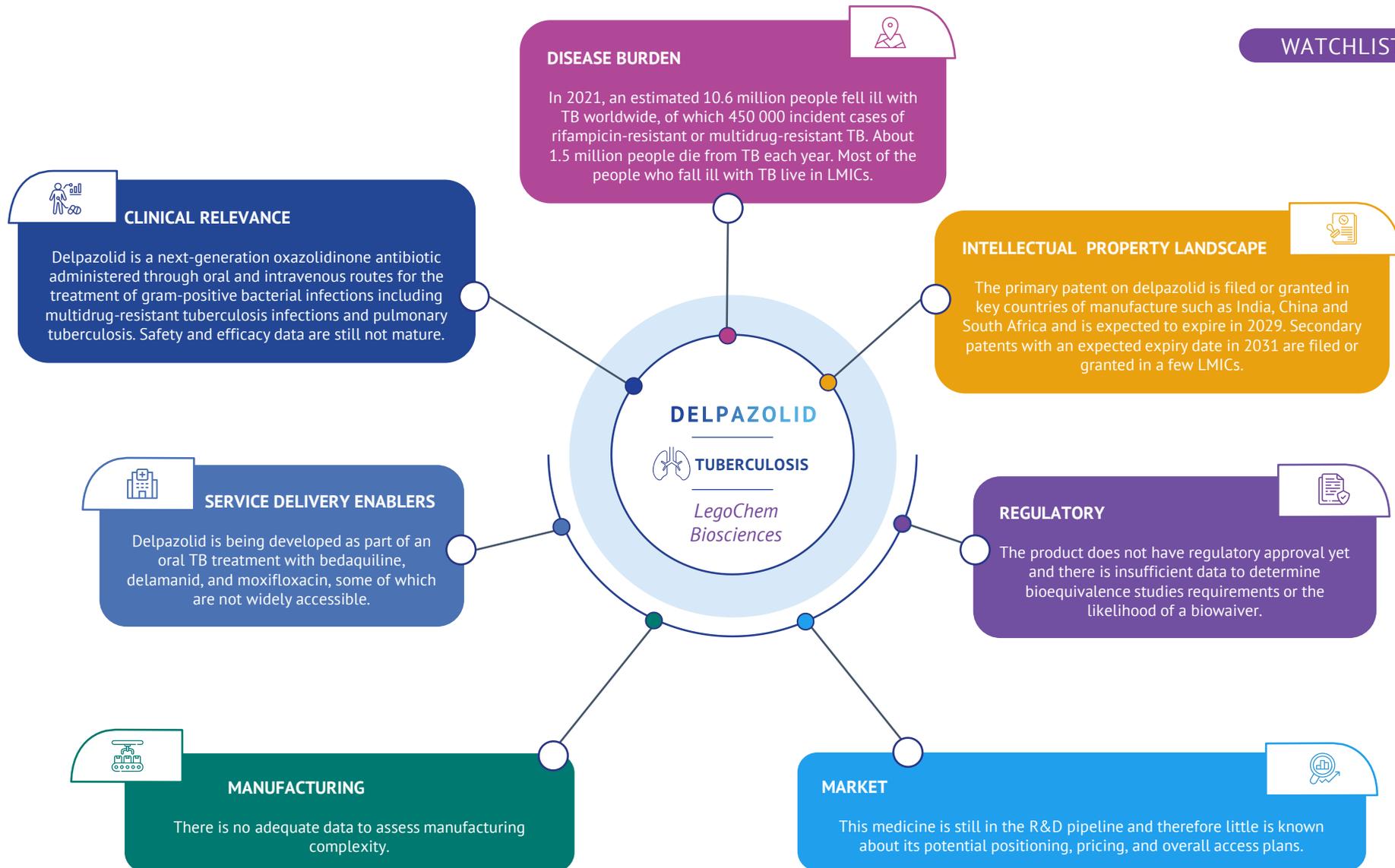
Multiple innovators

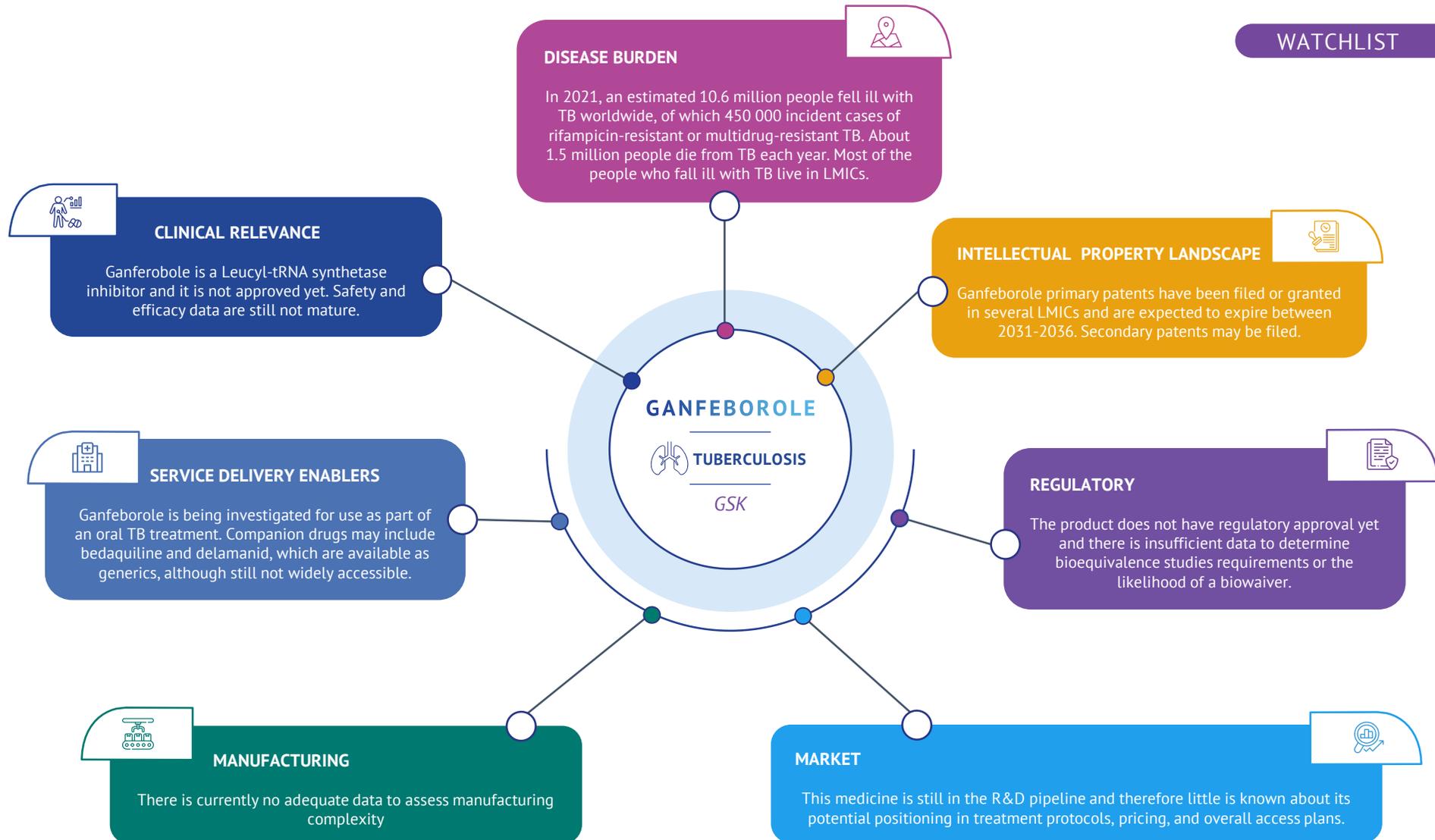


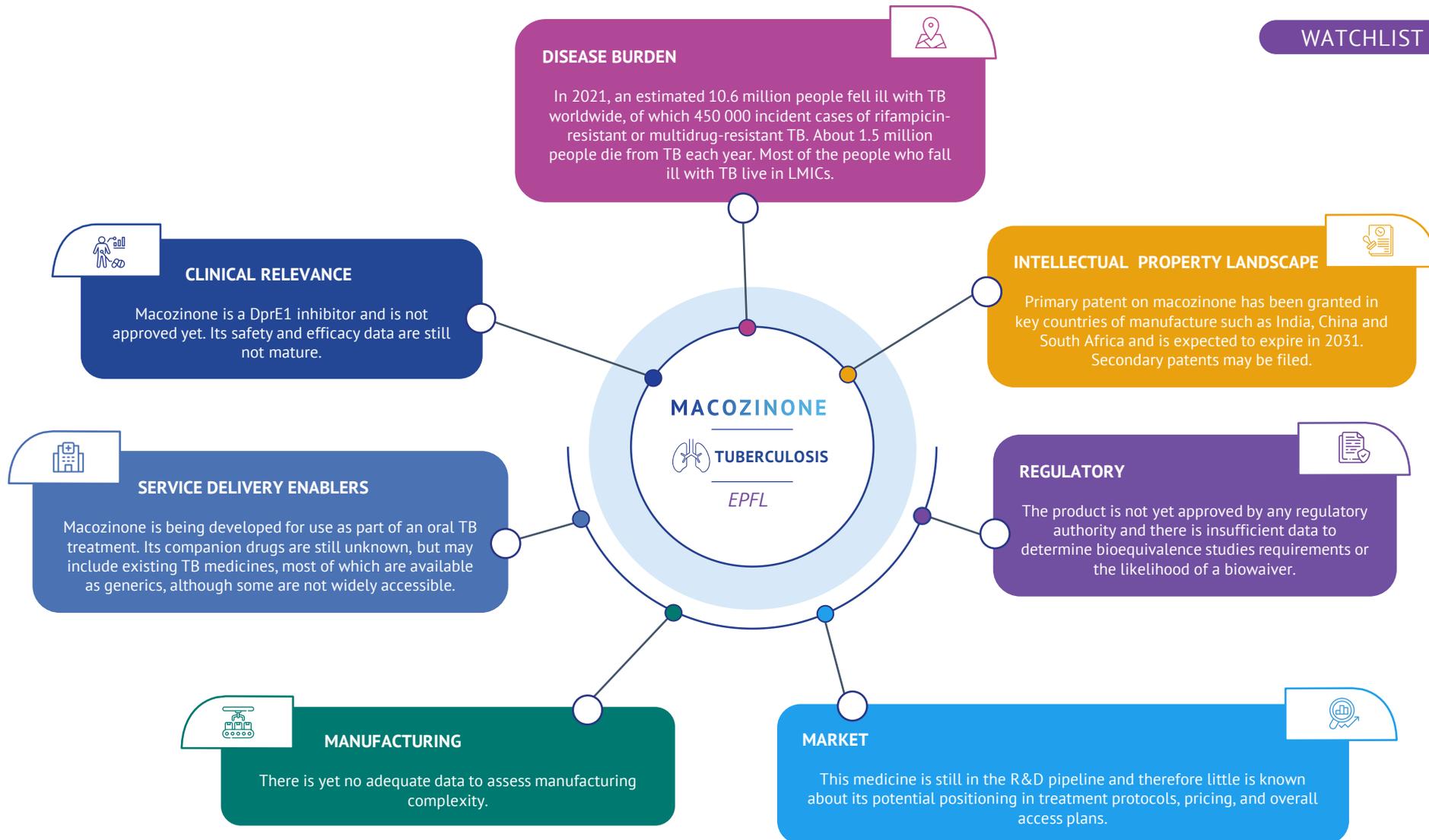
TUBERCULOSIS

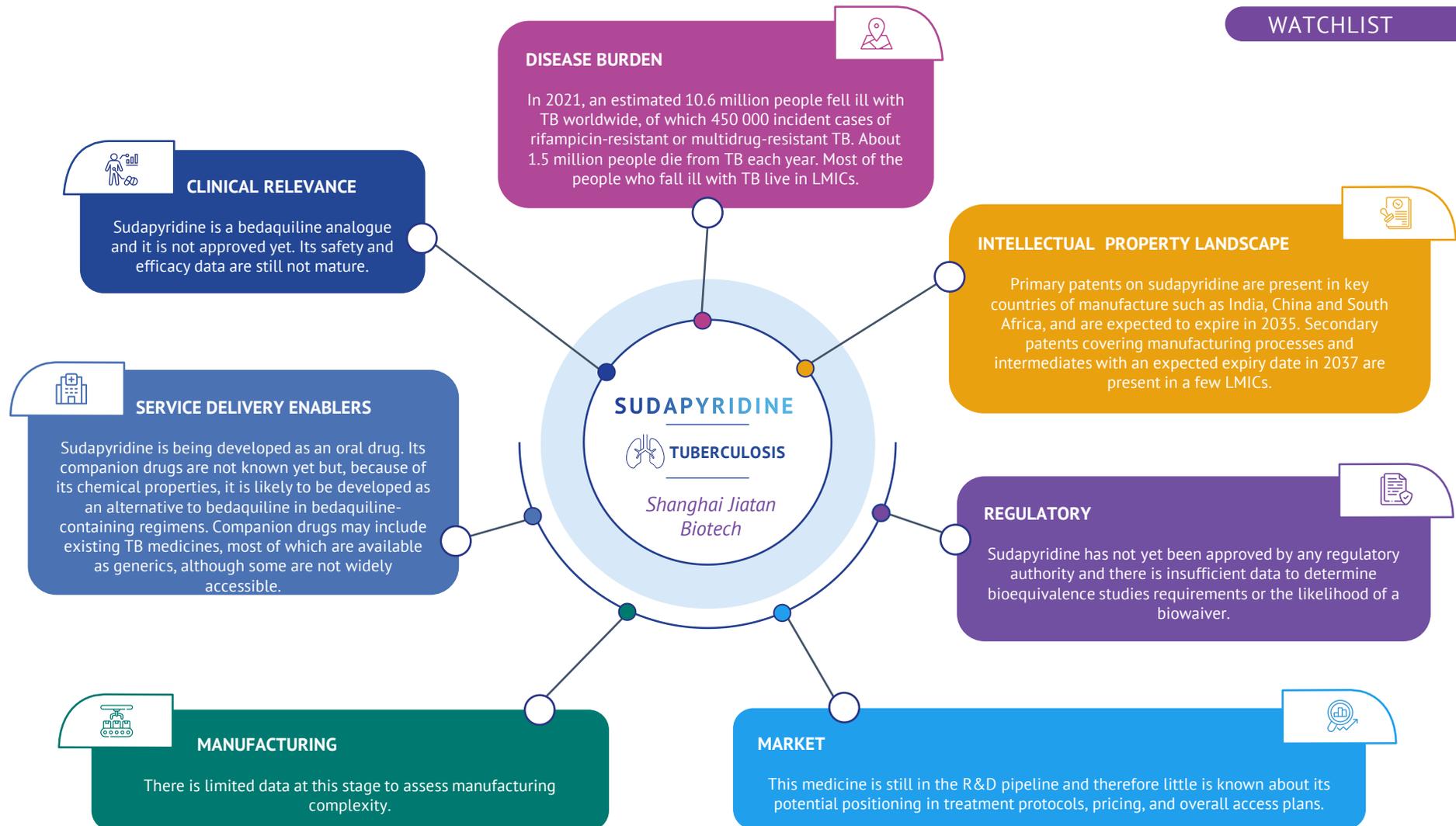


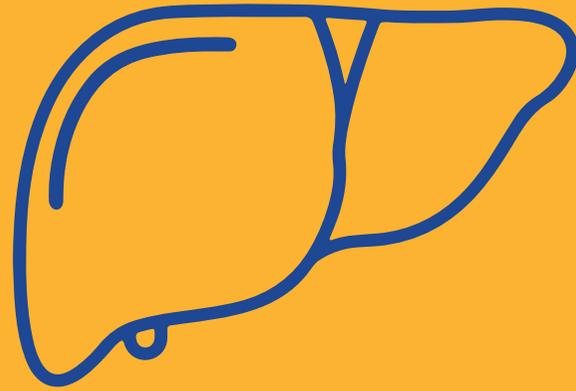




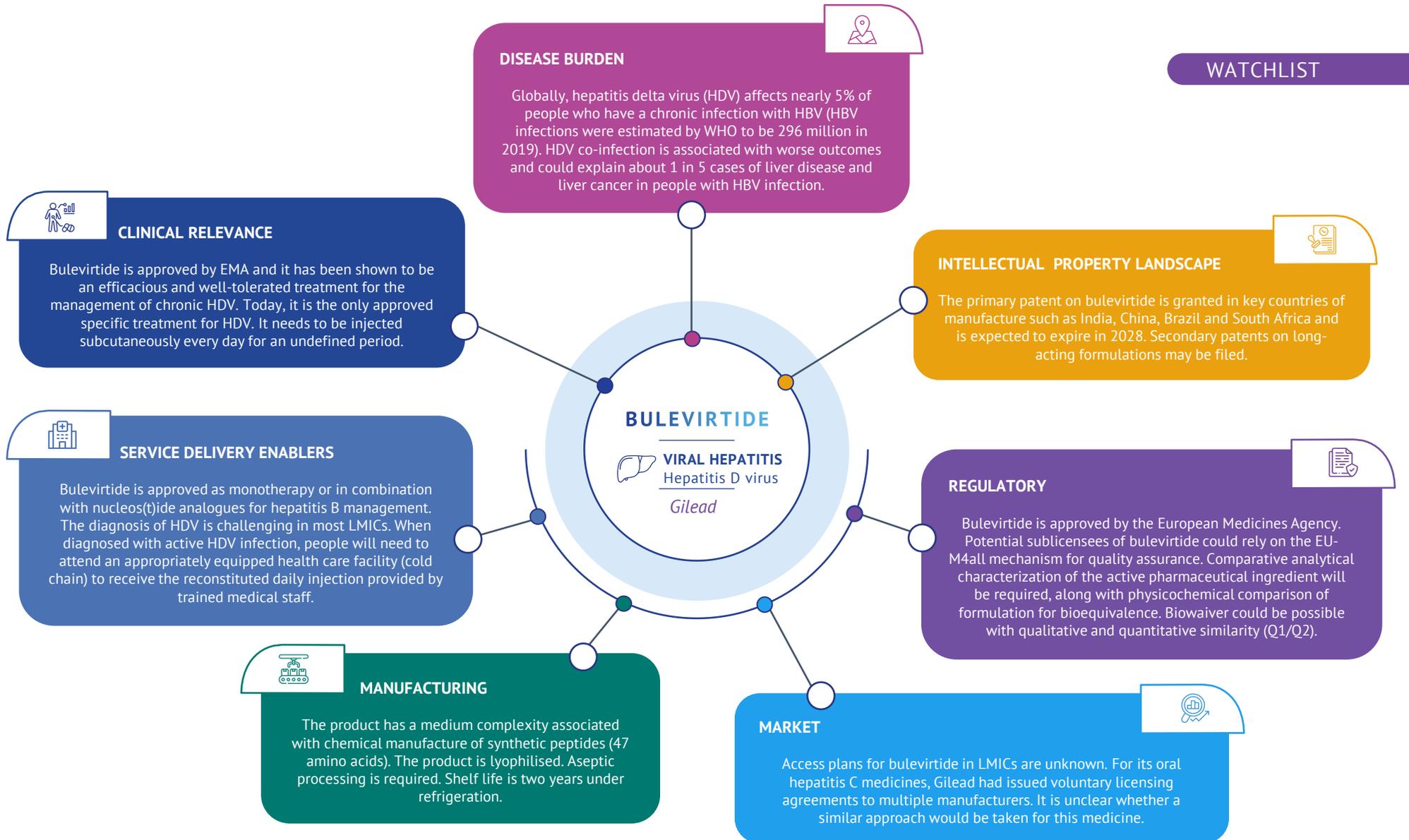


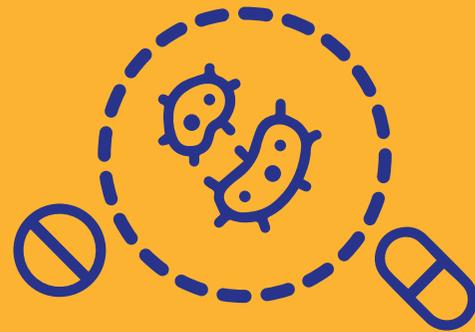






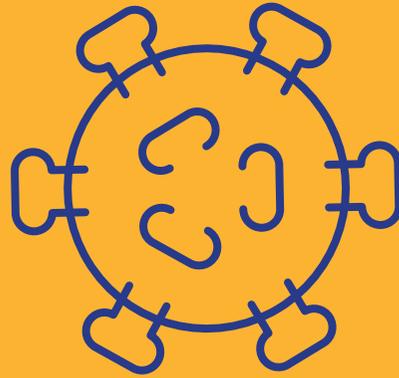
VIRAL HEPATITIS





OTHER INFECTIOUS DISEASES





PANDEMIC & EPIDEMIC THREATS

DISEASE BURDEN

Worldwide, influenza annual epidemics are estimated to result in about 3 to 5 million cases of severe illness, and about 300 to 600 thousand respiratory deaths.

CLINICAL RELEVANCE

Baloxavir marboxil is approved by FDA for both the treatment and the prevention of influenza. A single-dose of baloxavir marboxil is safe and has superior efficacy to placebo and similar efficacy to oseltamivir (administered twice daily for 5 days) for ameliorating influenza symptoms in high-risk outpatients, with an 86% reduction in risk of developing clinical influenza. Baloxavir marboxil could prove to be a useful tool for addressing pandemic preparedness.

INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on baloxavir marboxil have been filed or granted in several LMICs and they are expected to expire between 2030-2036. Secondary patents may provide exclusivity in a few LMICs until 2037.



SERVICE DELIVERY ENABLERS

Single oral administration, with no requirements for companion drugs, simplifies treatment delivery. Influenza testing is not mandatory, and prescription could be based on clinical judgment.

REGULATORY

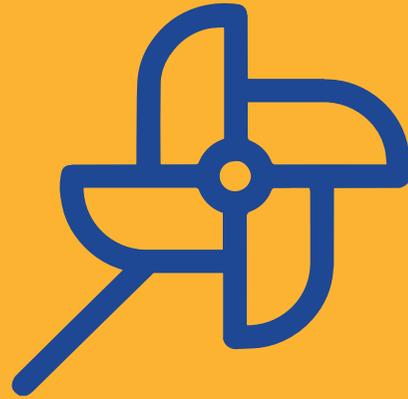
Product approved by stringent regulatory authorities. Potential sublicensees of baloxavir marboxil could rely on mechanisms like USFDA Para III, Swissmedic MAGHP, EU-M4all or WHO Prequalification (if included) for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

The production involves a standard manufacturing process for tablets. There are no challenges with respect to excipients or final packaging. Probable occupational exposure band (OEB) category 4, special facility might be required. Shelf life is at least three years at room temperature.

MARKET

The product is currently available in a small number of LMICs at prices that are generally higher than oseltamivir. Based on an analysis of data of sales in HICs and UMICs where it is available, its price would be beyond the reach of most people and could potentially constitute a constraint on the ability of health systems in LMICs to respond to a possible influenza pandemic outbreak.



CHILDHOOD ONSET DISEASES

DISEASE BURDEN

Respiratory Syncytial Virus (RSV) is a leading cause of respiratory disease globally. RSV has been estimated to cause 34 million acute lower respiratory tract infections (LRTI) in young children annually, with over 3 million severe cases requiring hospitalization, and between 66,000 to 199,000 fatalities, 99% of which are in low- and middle-income countries (LMICs).

CLINICAL RELEVANCE

Nirsevimab showed efficacy versus placebo with respect to the medically attended RSV LRTI (relative risk reduction 79,5%), the RSV LRTI hospital admission (77,3%), and severe RSV (86%).

INTELLECTUAL PROPERTY LANDSCAPE

Patents covering nirsevimab have been filed or granted in several LMICs and they are expected to expire between 2028 and 2035. Secondary patents covering a formulation and a treatment regimen with expiry dates in 2038 and 2040 were filed in several LMICs.

SERVICE DELIVERY ENABLERS

Nirsevimab is an injectable monoclonal antibody, administered intramuscularly that requires cold chain storage. As such, supply chain, health facility, and healthcare worker requirements may be minimised through the integration of nirsevimab in national neonate immunization packages and corresponding administration at birth, especially as nirsevimab injection is deemed compatible with concomitant newborn vaccine injections.

REGULATORY

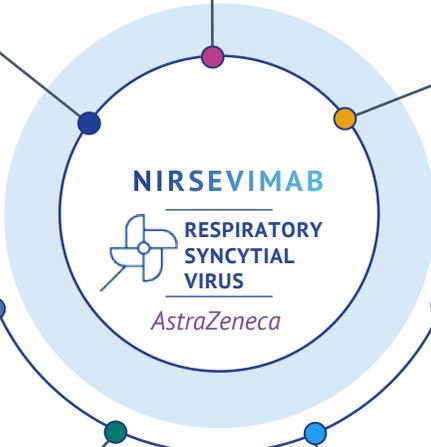
Nirsevimab is approved by stringent regulatory authorities. Potential licensees could rely on mechanisms like EU-M4aII for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Clinical trial waivers would not be an option.

MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. No challenges with respect to excipients. Final pack is pre-filled syringe (PFS), which would be considered as a device. Shelf life is two years under refrigeration.

MARKET

Nirsevimab is scarcely available even in private sectors in developed countries and there is no presence in LMICs. Nirsevimab's price is estimated to be high (inherent to most monoclonal antibodies) and there is currently no information on access strategies for LMICs.



DISEASE BURDEN

Respiratory Syncytial Virus (RSV) is a leading cause of respiratory disease globally. RSV has been estimated to cause 34 million acute lower respiratory tract infections (LRTI) in young children annually, with over 3 million severe cases requiring hospitalization, and between 66,000 to 199,000 fatalities, 99% of which are in low- and middle-income countries (LMICs).

CLINICAL RELEVANCE

Preliminary data shows that a single dose of clesrovimab could provide 74.2% efficacy for the prevention of medically attended lower respiratory tract RSV infection for a duration of 5 months in infants. However, these data are preliminary and more evidence on efficacy is needed.

INTELLECTUAL PROPERTY LANDSCAPE

Patents covering clesrovimab have been filed or granted in more than fifty LMICs and they are expected to expire in 2036. Secondary patents may be filed

CLESROVIMAB



SERVICE DELIVERY ENABLERS

Clesrovimab is an injectable monoclonal antibody, likely to be administered intramuscularly and requires cold chain storage. As such, supply chain, health facility, and healthcare worker requirements may be minimised through the integration of clesrovimab in national neonate immunization packages and corresponding administration at birth.

REGULATORY

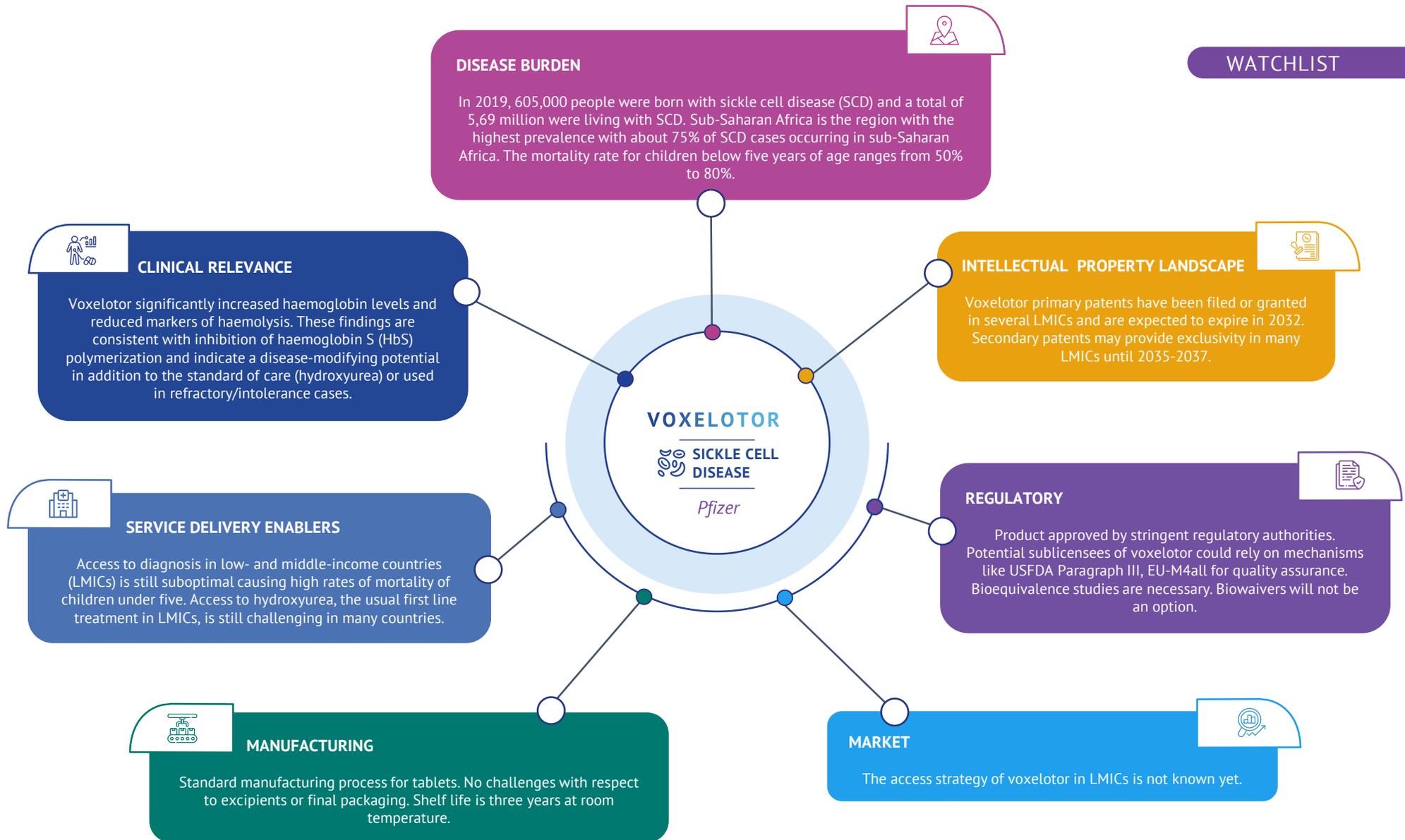
Clesrovimab is not approved by any stringent regulatory authorities. Potential licensees could rely on mechanisms like EU-M4 all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment likely to be done. Clinical trial waivers likely would not be an option.

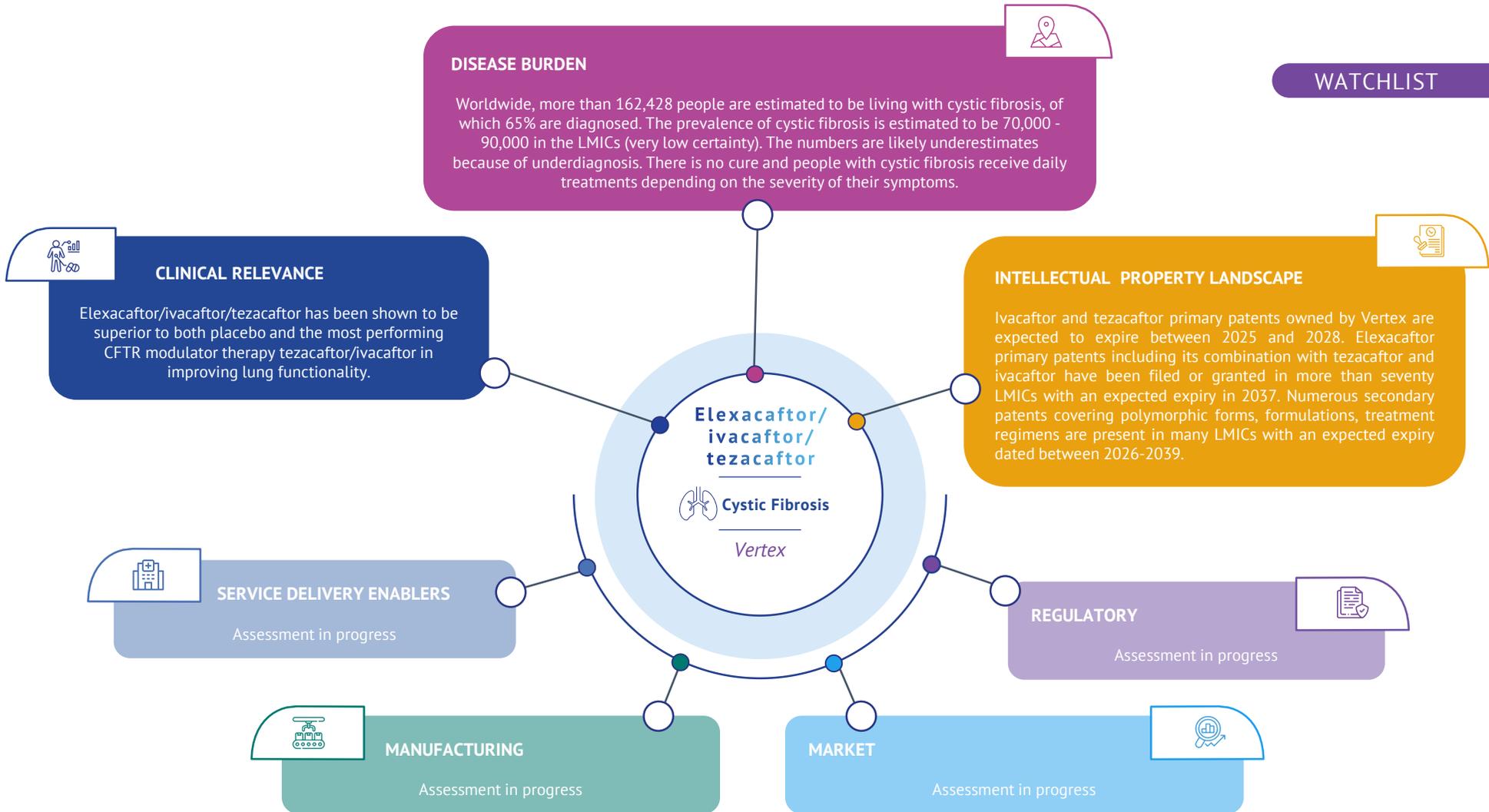
MANUFACTURING

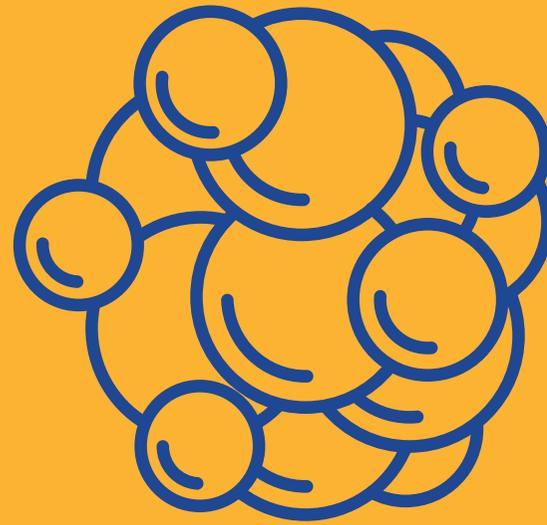
Complex manufacturing process since product is a monoclonal antibody. The product is still early in development and technical details are likely product specific

MARKET

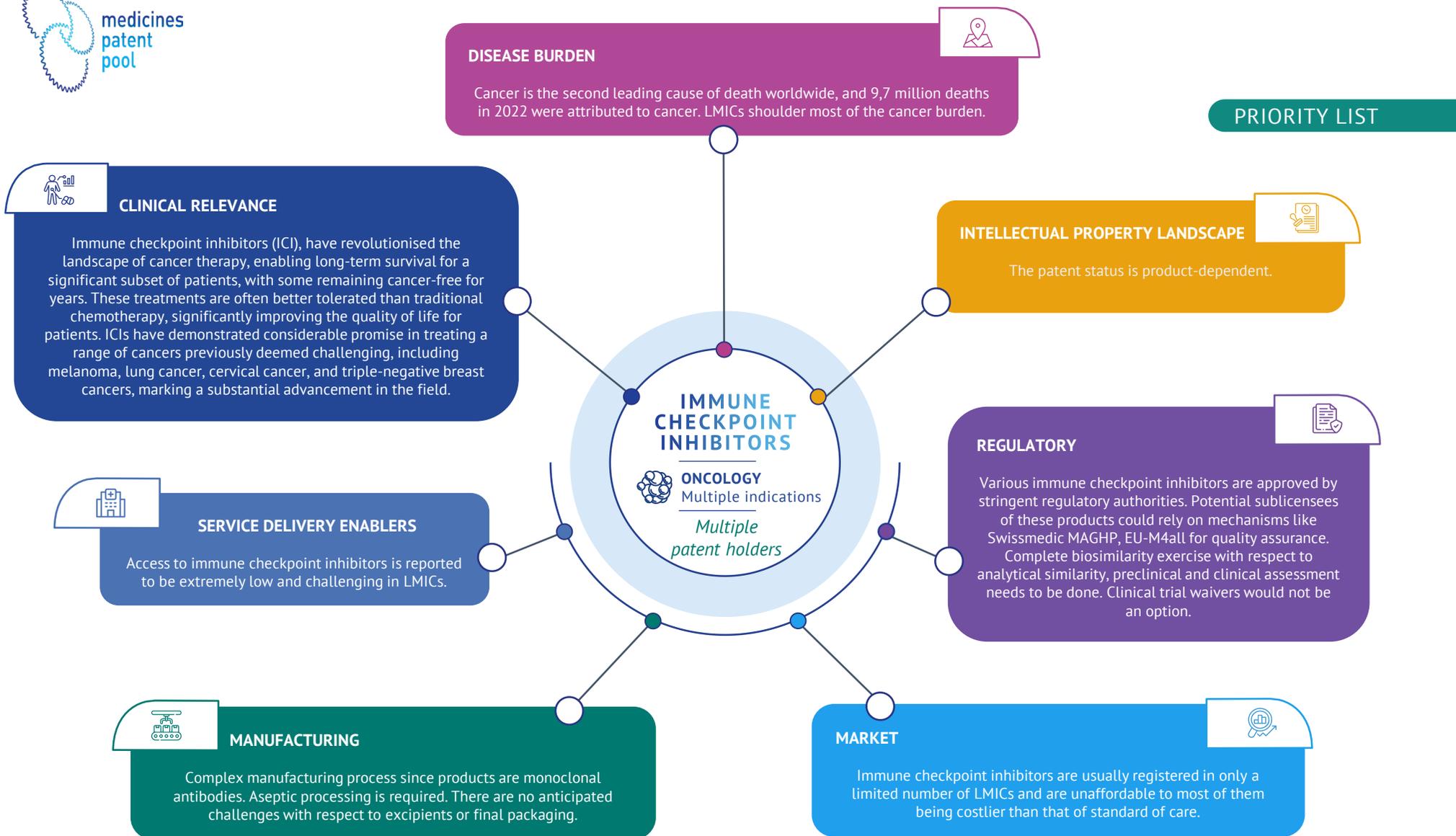
Clesrovimab is not available yet in HIC or LMICs. Clesrovimab's price is estimated to be high (as most of monoclonal antibodies) and there is currently no information on access strategies for LMICs.







ONCOLOGY





DISEASE BURDEN

Lung cancer is the most diagnosed and the first cause of death from cancer worldwide, with an estimated 2.5 million new cases and 1.8 million related deaths in 2022. 80% are classified as non-small cell cancers (NSCLC). The EGFR mutation is present in 30% of these cases and almost 60% of these cases are diagnosed in advanced stages.

CLINICAL RELEVANCE

Aumolertinib, an investigational 3rd generation epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI), has demonstrated a consistent benefit in the time a patient can live without disease progression and a lower rate of adverse events leading to permanent discontinuation compared to gefitinib.

INTELLECTUAL PROPERTY LANDSCAPE

Aumolertinib compound patent is expected to expire in 2035, and it has been granted in key countries of manufacture such as India, China and South Africa. Secondary patents may provide exclusivity in few LMICs until 2036-2039

SERVICE DELIVERY ENABLERS

Lung cancer is still underdiagnosed in many LMICs, especially where there is a higher burden of tuberculosis. While basic imaging tests are available in the public sector of LMICs, patients are often identified at an advanced/metastatic setting. EGFR PCR testing is becoming increasingly available also in the public sector of some LMICs, also thanks to the availability of generic first and second generation of EGFR TKIs.



REGULATORY

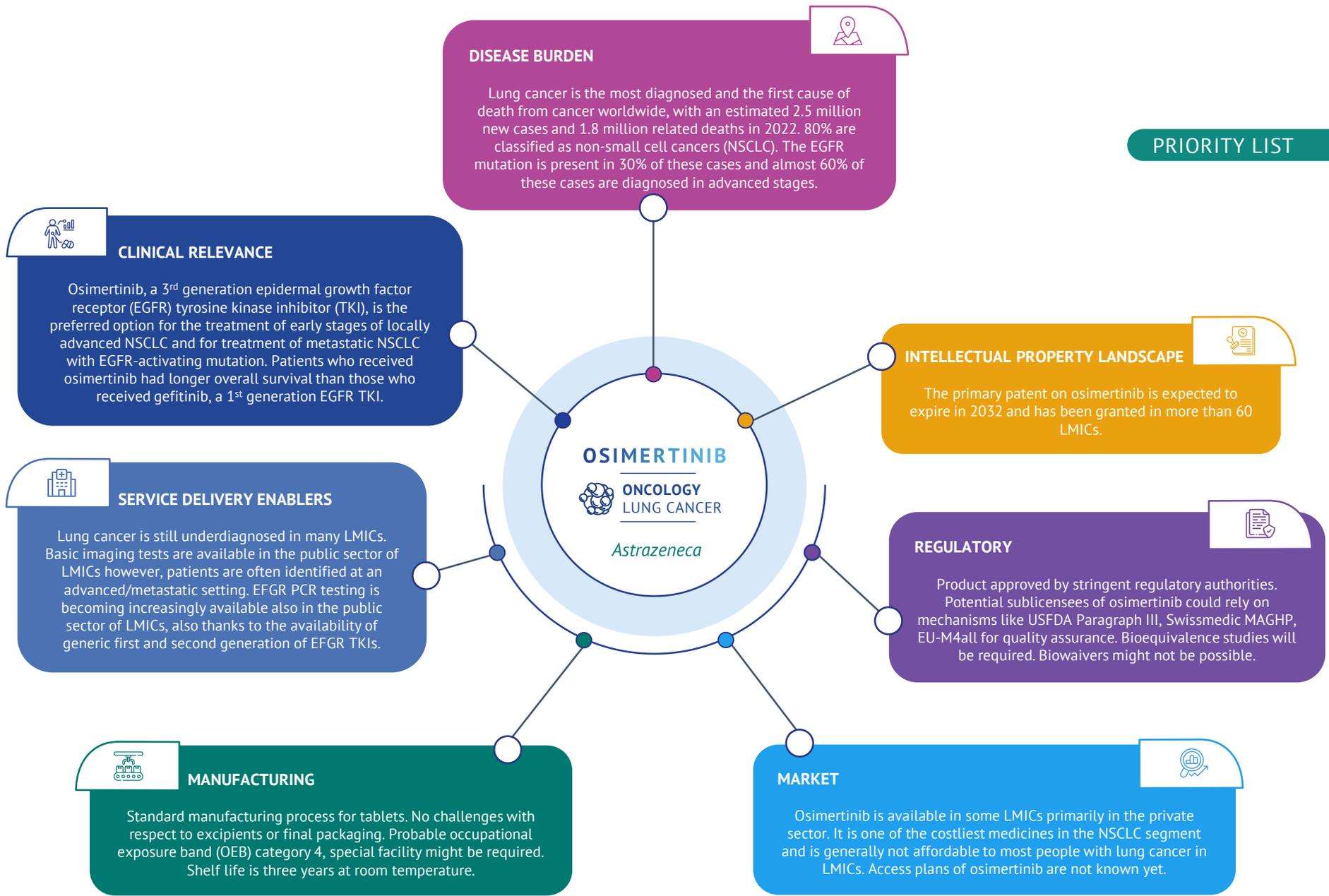
Aumolertinib does not have stringent regulatory authorities (SRA) approval yet and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

There are currently limited data available to assess the manufacturing complexity of aumolertinib.

MARKET

Aumolertinib is currently approved only in very few countries. Access plans for it in LMICs are currently unknown.



DISEASE BURDEN

Lung cancer is the most diagnosed and the first cause of death from cancer worldwide, with an estimated 2.5 million new cases and 1.8 million related deaths in 2022. 80% are classified as non-small cell cancers (NSCLC). The EGFR mutation is present in 30% of these cases and almost 60% of these cases are diagnosed in advanced stages.

CLINICAL RELEVANCE

Osimertinib, a 3rd generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), is the preferred option for the treatment of early stages of locally advanced NSCLC and for treatment of metastatic NSCLC with EGFR-activating mutation. Patients who received osimertinib had longer overall survival than those who received gefitinib, a 1st generation EGFR TKI.

SERVICE DELIVERY ENABLERS

Lung cancer is still underdiagnosed in many LMICs. Basic imaging tests are available in the public sector of LMICs however, patients are often identified at an advanced/metastatic setting. EGFR PCR testing is becoming increasingly available also in the public sector of LMICs, also thanks to the availability of generic first and second generation of EGFR TKIs.

MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable occupational exposure band (OEB) category 4, special facility might be required. Shelf life is three years at room temperature.

MARKET

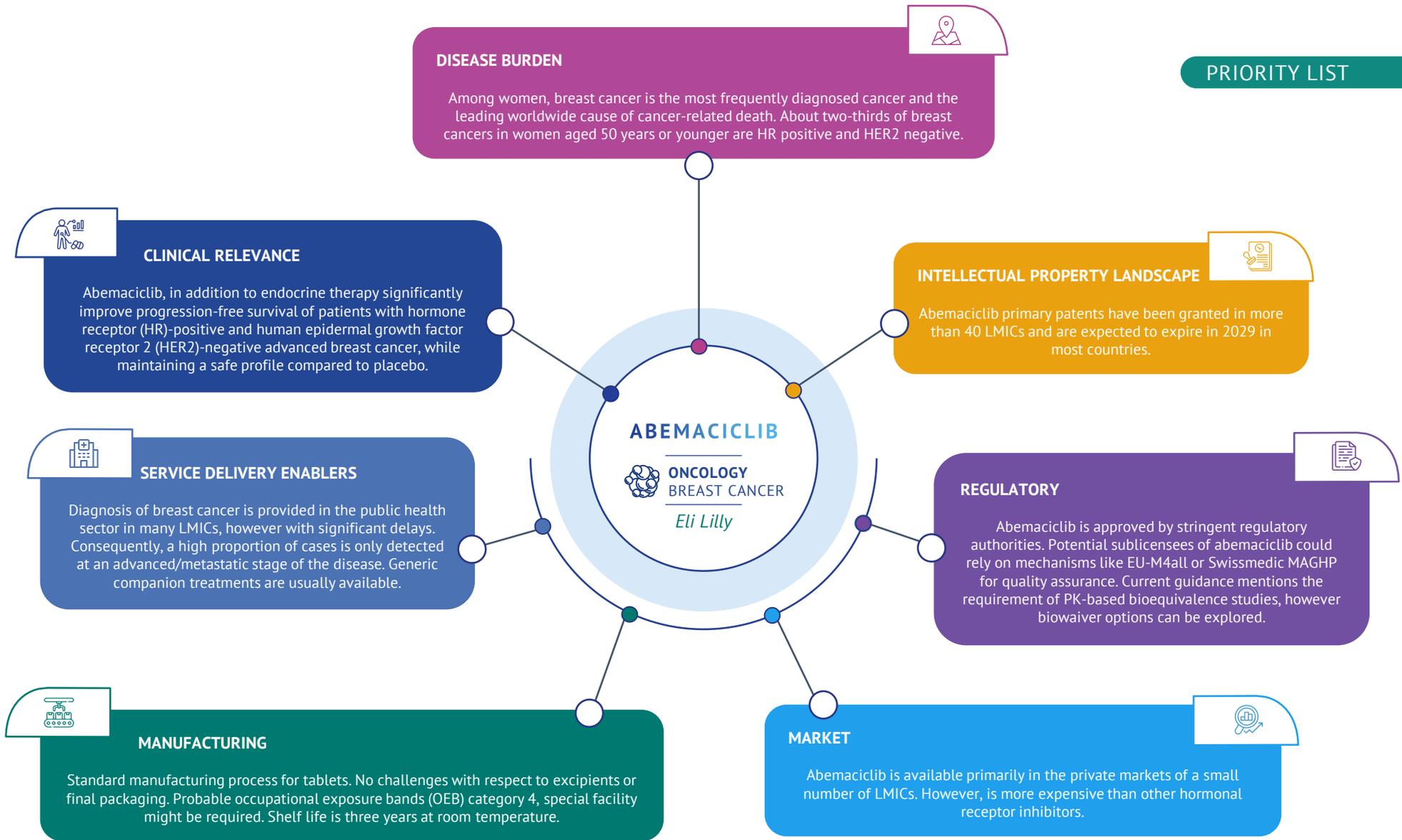
Osimertinib is available in some LMICs primarily in the private sector. It is one of the costliest medicines in the NSCLC segment and is generally not affordable to most people with lung cancer in LMICs. Access plans of osimertinib are not known yet.

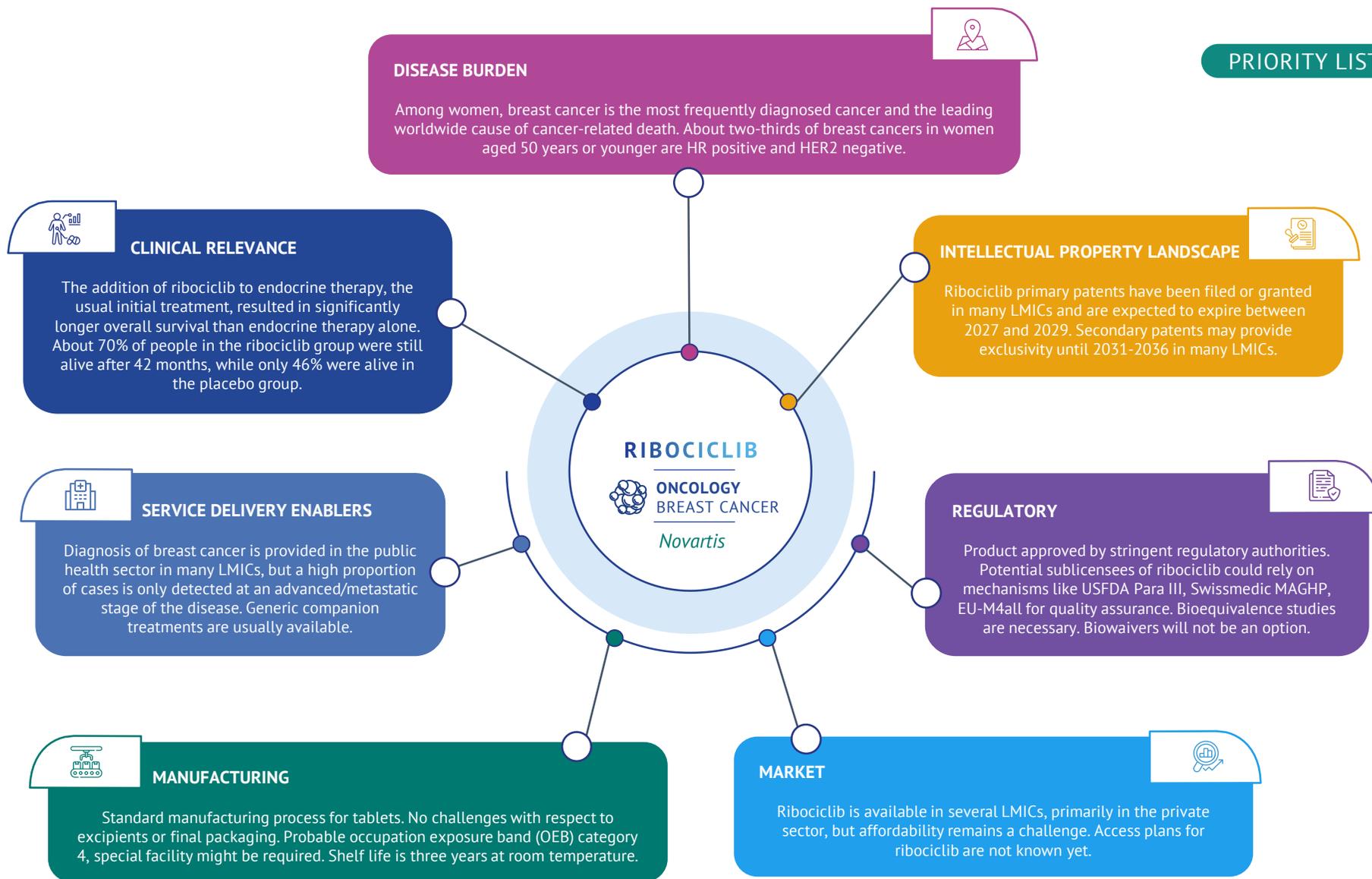
INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on osimertinib is expected to expire in 2032 and has been granted in more than 60 LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of osimertinib could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies will be required. Biowaivers might not be possible.





DISEASE BURDEN

There were more than 2.3 million new cases of breast cancer in 2022 globally. In LMICs, the majority of the patients are diagnosed at an advanced/metastatic stage and at least 30% of cases are characterised by overexpression of human epidermal growth factor receptor 2 (HER2 positive).

CLINICAL RELEVANCE

Cancer-free survival is significantly improved in HER2-positive breast cancer patients who receive one year of trastuzumab treatment after adjuvant chemotherapy. The subcutaneous administration method is quicker, saving time and money to health systems, and is preferred by patients compared to the intravenous formulation.

INTELLECTUAL PROPERTY LANDSCAPE

Trastuzumab primary patents expired in 2012. Secondary patents on the subcutaneous formulation have been filed and granted widely in LMICs and are expected to expire in 2030.

SERVICE DELIVERY ENABLERS

Diagnosis of breast cancer is provided in the public health sector in many LMICs, but a high proportion of cases is only detected at an advanced/metastatic stage of the disease. Generic companion treatments are usually available. The subcutaneous formulation could simplify service delivery and enable more people to be treated with the existing health infrastructure in LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees could of trastuzumab subcutaneous could rely on mechanisms like Swissmedic MAGHP, EU-M4all or WHO PQ (if included in pilot program) for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Phase III clinical trial waiver might be possible if there is already an approved intravenous product by the applicant.

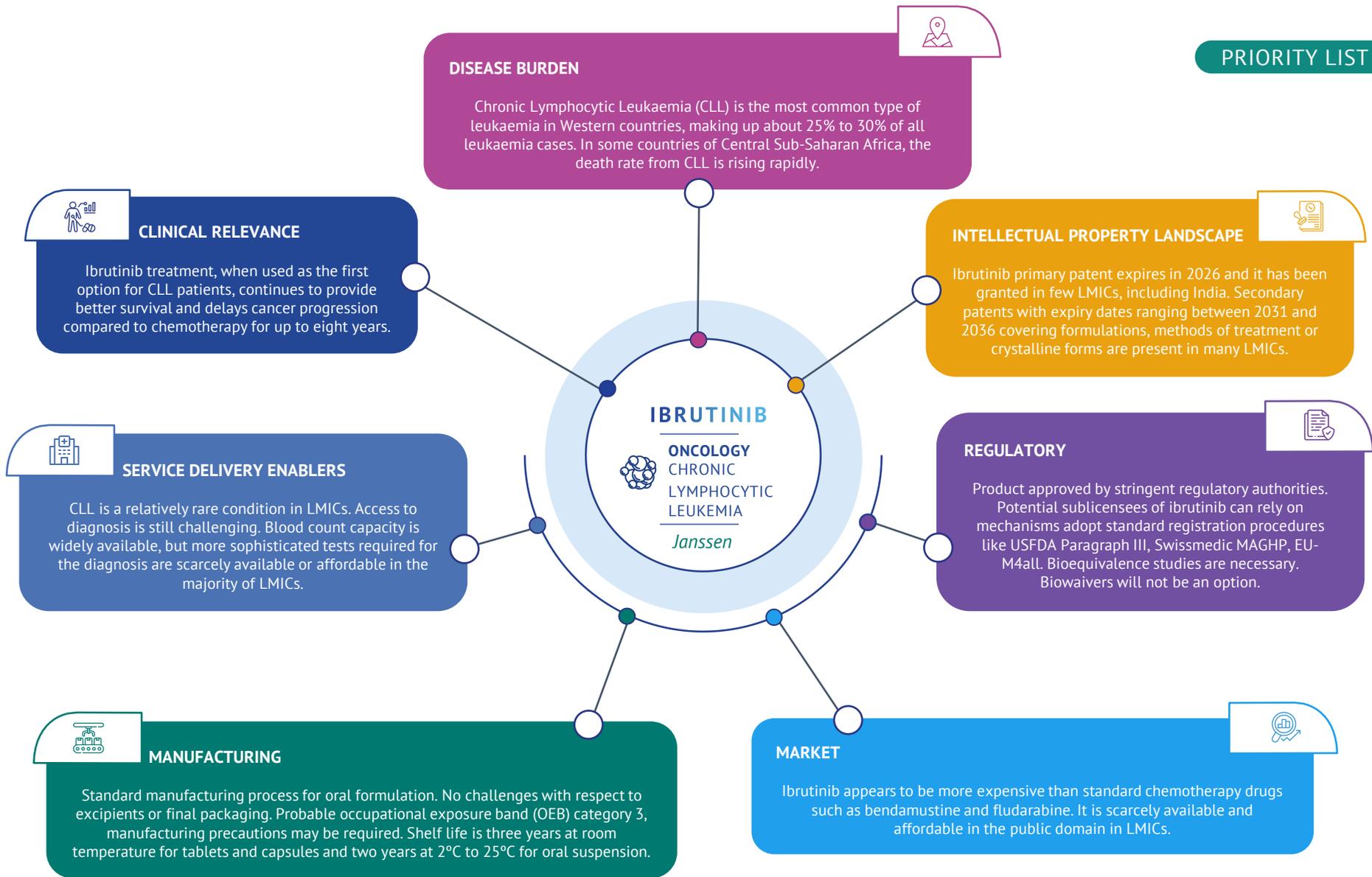


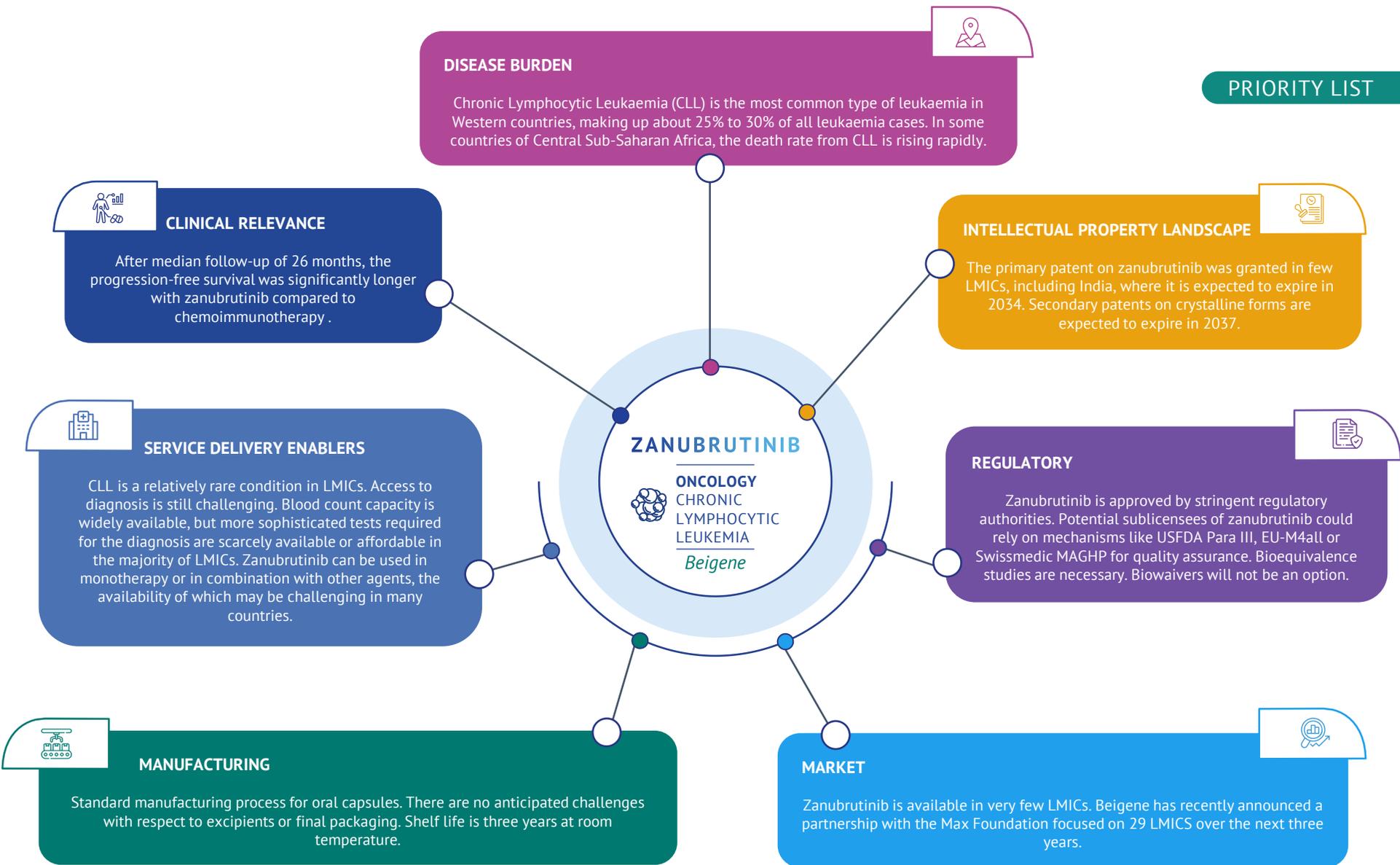
MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. Occupation exposure band (OEB) level 3, manufacturing precautions necessary. Hyaluronidase, a biologic, is added as excipient. There are no anticipated challenges with respect to final packaging. Shelf life is 21 months under refrigeration.

MARKET

While biosimilar formulations of intravenous trastuzumab are available in many LMICs, subcutaneous formulation availability is very limited and hence its access in many LMICs, despite its advantages for patients and health systems.







DISEASE BURDEN

Lung cancer is the most diagnosed and the first cause of death from cancer worldwide, with an estimated 2.5 million new cases and 1.8 million related deaths in 2022. 80% are classified as non-small cell cancers (NSCLC). The EGFR mutation is present in 30% of these cases and almost 60% of these cases are diagnosed in advanced stages.

CLINICAL RELEVANCE

Lazertinib, a 3rd generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), demonstrated significant improvement in the time a patient can live without disease progression compared with gefitinib, a 1st generation EGFR TKI.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on lazertinib has been granted in many LMICs including India and is expected to expire in 2034. There are secondary patents that may provide further exclusivity until 2038-2041 in many LMICs.

LAZERTINIB
ONCOLOGY
LUNG CANCER
Janssen

SERVICE DELIVERY ENABLERS

Lung cancer is still underdiagnosed in many LMICs. Basic imaging tests are available in the public sector of LMICs; however, patients are often identified at an advanced/metastatic stage. EGFR PCR testing is becoming increasingly available also in the public sector of LMICs, also thanks to the availability of generic first and second generation of EGFR TKIs.

REGULATORY

Lazertinib is only approved in the Republic of Korea so far and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

There is currently limited data to assess the manufacturing complexity of lazertinib.

MARKET

Although the product got its first approval in 2021, it is still pricier than first-generation EGFR TKI inhibitors. There is no information on its access and availability in LMICs

DISEASE BURDEN

Lung cancer is the most diagnosed and the first cause of death from cancer worldwide, with an estimated 2.5 million new cases and 1.8 million related deaths in 2022. 80% are classified as non-small cell lung cancers (NSCLC). Activating mutations in KRAS (Kirsten rat sarcoma virus) viral oncogene homologue are found in 25 to 30% of NSCLC.

CLINICAL RELEVANCE

Sotorasib significantly increased the time a patient, with advanced NSCLC presenting the KRAS mutation, can live without disease progression and had a more favourable safety profile compared with docetaxel, a conventional chemotherapy drug.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on sotorasib has been granted in many LMICs and is expected to expire in 2038. Several secondary patents on crystalline forms and processes are expected to expire between 2039 and 2040.

SOTORASIB
ONCOLOGY
LUNG CANCER
Amgen

SERVICE DELIVERY ENABLERS

Lung cancer is still underdiagnosed in many LMICs. Basic imaging tests are available in the public sector of LMICs however, patients are often identified at an advanced/metastatic setting. PCR testing capacity is becoming increasingly available also in the public sector of LMICs.

REGULATORY

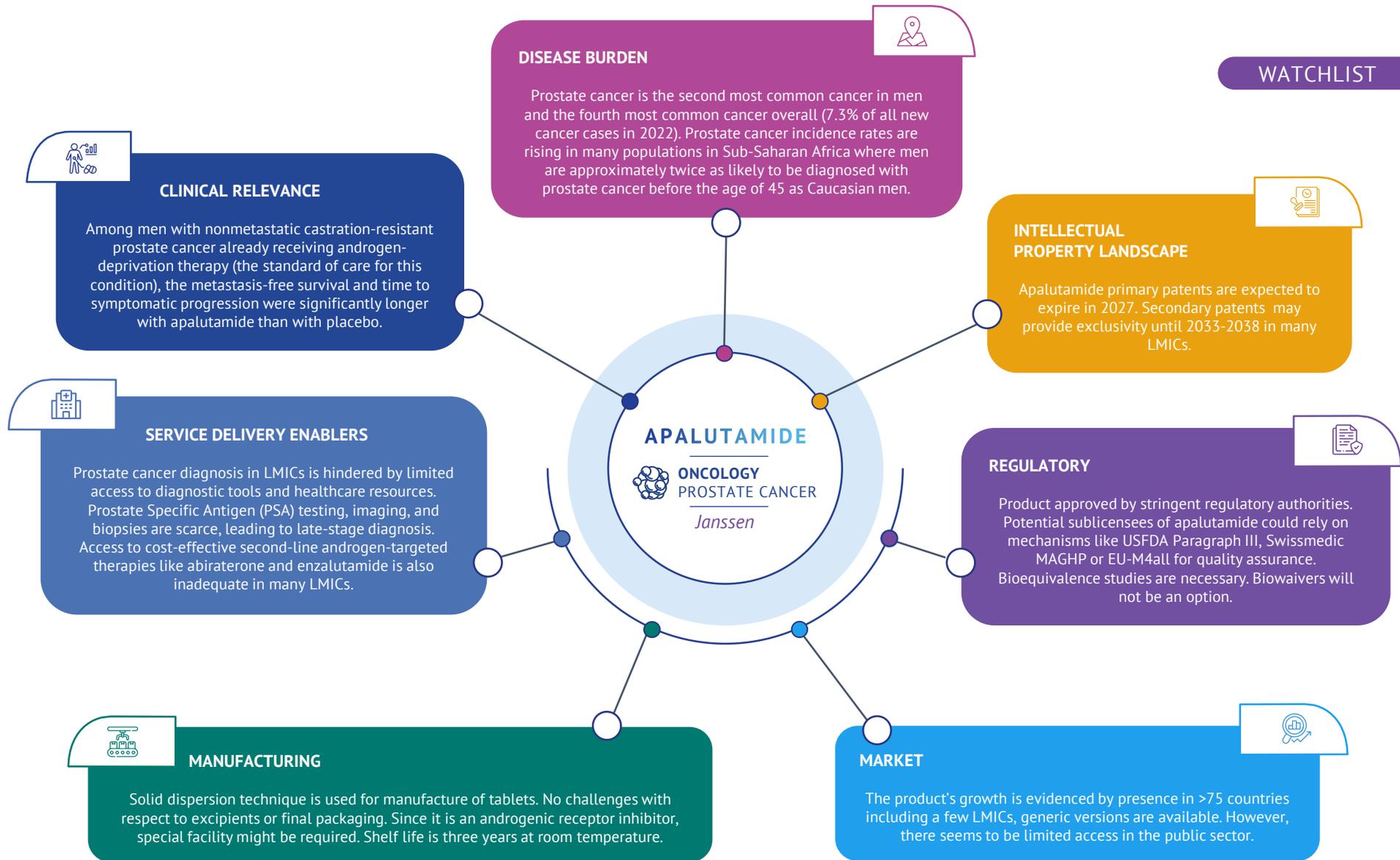
Product approved by stringent regulatory authorities. Potential sublicensees of sotorasib could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable Occupational Exposure Band (OEB) category 3, manufacturing precautions necessary. Shelf life is three years at room temperature.

MARKET

Sotorasib is currently available in very few LMICs and is generally pricier than standard of care. Access plans are currently unknown.



DISEASE BURDEN

Prostate cancer is the second most common cancer in men and the fourth most common cancer overall (7.3% of all new cancer cases in 2022). Prostate cancer incidence rates are rising in many populations in Sub-Saharan Africa where men are approximately twice as likely to be diagnosed with prostate cancer before the age of 45 as Caucasian men.

CLINICAL RELEVANCE

Among men with nonmetastatic castration-resistant prostate cancer already receiving androgen-deprivation therapy (the standard of care for this condition), the metastasis-free survival and time to symptomatic progression were significantly longer with apalutamide than with placebo.

INTELLECTUAL PROPERTY LANDSCAPE

Apalutamide primary patents are expected to expire in 2027. Secondary patents may provide exclusivity until 2033-2038 in many LMICs.

SERVICE DELIVERY ENABLERS

Prostate cancer diagnosis in LMICs is hindered by limited access to diagnostic tools and healthcare resources. Prostate Specific Antigen (PSA) testing, imaging, and biopsies are scarce, leading to late-stage diagnosis. Access to cost-effective second-line androgen-targeted therapies like abiraterone and enzalutamide is also inadequate in many LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of apalutamide could rely on mechanisms like USFDA Paragraph III, Swissmedic MAGHP or EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

Solid dispersion technique is used for manufacture of tablets. No challenges with respect to excipients or final packaging. Since it is an androgenic receptor inhibitor, special facility might be required. Shelf life is three years at room temperature.

MARKET

The product's growth is evidenced by presence in >75 countries including a few LMICs, generic versions are available. However, there seems to be limited access in the public sector.

APALUTAMIDE

ONCOLOGY
PROSTATE CANCER
Janssen

DISEASE BURDEN

Prostate cancer is the second most common cancer in men and the fourth most common cancer overall (7.3% of all new cancer cases in 2022). Prostate cancer incidence rates are rising in many populations in Sub-Saharan Africa where men are approximately twice as likely to be diagnosed with prostate cancer before the age of 45 as Caucasian men.

CLINICAL RELEVANCE

Among men with nonmetastatic castration-resistant prostate cancer already receiving androgen-deprivation therapy (the standard of care for this condition), the percentage of patients who were alive at three years was significantly higher among those who received darolutamide than among those who received placebo.

INTELLECTUAL PROPERTY LANDSCAPE

Darolutamide primary patent has been granted in many LMICs and is expected to expire in May 2030. The patent term has been extended in few LMICs until 2035. Secondary patents have not been identified in LMICs.

DAROLUTAMIDE

ONCOLOGY
PROSTATE CANCER
Bayer

SERVICE DELIVERY ENABLERS

Prostate cancer diagnosis in LMICs is hindered by limited access to diagnostic tools and healthcare resources. PSA testing, imaging, and biopsies are scarce, leading to late-stage diagnosis. Access to cost-effective second-line androgen-targeted therapies like abiraterone and enzalutamide is also inadequate in many LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of darolutamide could rely on mechanisms like USFDA Para III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable occupational exposure band (OEB) category 3 manufacturing precautions might be required. Shelf life is three years at room temperature.

MARKET

Darolutamide's growth is evidenced by its availability in more than 80 countries including some LMICs. However, it is scarcely available in the public domain and there seems to be no information on its access strategies in LMICs.

DISEASE BURDEN

Cancer is the second leading cause of death worldwide, and 9,7 million deaths in 2022 were attributed to cancer. Low-and-middle-income countries (LMICs) shoulder most of the cancer burden.

CLINICAL RELEVANCE

Paclitaxel is part of the taxane class which is used in oncology treatments for a variety of cancers, including breast, lung, prostate, stomach and ovarian cancers, among others and is an integral part of the standard of care. An oral formulation of paclitaxel, enabled by encequidar, a novel P-glycoprotein pump inhibitor, is attractive due to its ease of administration, which could include the option for patients to take it at home without requiring intravenous access.

INTELLECTUAL PROPERTY LANDSCAPE

While paclitaxel is off patent and encequidar primary patent is to expire in early 2024, Hanmi owns patents on paclitaxel oral formulation as well as on the combination that have been filed or granted in many LMICs with an expected expiry in 2036. Additional secondary patents on encequidar have been filed in many LMICs and are expected to expire between 2031 and 2033.

SERVICE DELIVERY ENABLERS

Service delivery enablers change according to the type of cancer assessed. In general, capacity of cancer diagnosis is slowly improving in LMICs. Oral therapies represent an opportunity to facilitate the delivery of treatment.

REGULATORY

Oral paclitaxel has not yet been approved by any regulatory authority and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

There is currently limited data available to assess the manufacturing complexity of oral paclitaxel.

MARKET

This medicine is still in the research and development pipeline and therefore little is known about its potential positioning in treatment protocols, pricing, and overall access plans

**ORAL
PACLITAXEL +
ENCEQUIDAR**

**ONCOLOGY
MULTIPLE
INDICATIONS**
Athenex



**DIABETES,
CARDIOVASCULAR
& METABOLIC
DISORDERS**

DISEASE BURDEN

Type 2 diabetes (T2DM), the most prevalent form of diabetes globally, represents over 90% of cases and is on the rise in all demographics, including children and adolescents, partly due to increasing obesity rates. Those with diabetes have a higher risk of developing cardiovascular diseases.

CLINICAL RELEVANCE

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) stand at the forefront of diabetes management by playing not only a pivotal role in glycaemic control but also in promoting weight loss. Beyond their metabolic effects, some GLP-1 RAs have also been associated with a reduction of the risks of cardiovascular events in patients.

INTELLECTUAL PROPERTY LANDSCAPE

The patent status is product dependent.

SERVICE DELIVERY ENABLERS

While new agents are effective and safe in achieving diabetes control, LMICs still rely on older drug classes mainly due to cost. Increased access to better medicines for the control of diabetes may help fill the treatment-to-control gap (where nearly 40% of treated patients do not achieve control), while other efforts should also aim at increasing diagnosis (where more than 50% of all patients are missed).

REGULATORY

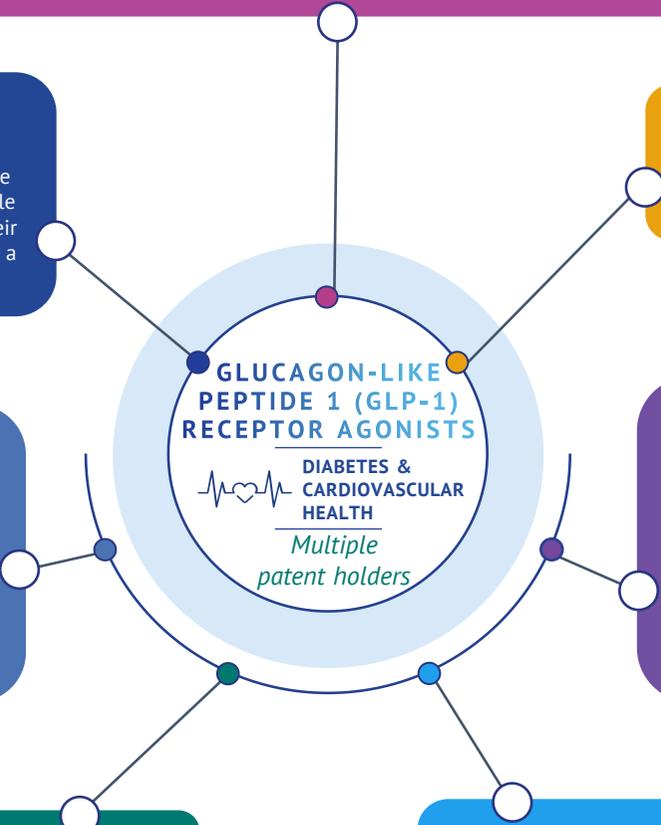
Various GLP-1 receptor agonists are approved by stringent regulatory authorities. Potential sublicensees of these products could rely on mechanisms like Swissmedic MAGHP, EU-M4all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Clinical trial waivers would not be an option.

MANUFACTURING

The manufacturing processes are product dependent.

MARKET

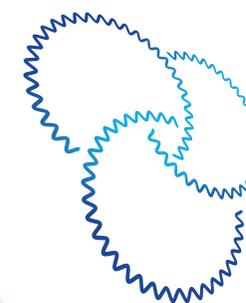
There is currently low access to GLP-1 receptor agonists in several LMIC markets and pricing is relatively high compared to other therapies used in diabetes that are now genericised.



Annex:

Prioritisation framework

PRODUCT ASSESSMENT FRAMEWORK TO GUIDE PRIORITISATION EXERCISE



medicines
patent
pool

The assessment framework proposed to be applied to each product has the following arborescence:



Each sub-criteria is accompanied by an explanation of how the information gathered will likely be used in assessing the potential of an MPP intervention for the product in question. The final decision on product prioritisation is at the discretion of the prioritisation committee.

ASSESSMENT FRAMEWORK

1. PUBLIC HEALTH CONSIDERATIONS



1.1. Disease burden

- 1.1.2. Prevalence & incidence
- 1.1.3. Treatment options
- 1.1.4. Disease severity
- 1.1.5. Epidemic risk



1.2. Clinical relevance

- 1.2.1. Safety
- 1.2.2. Efficacy
- 1.2.3. Posology & method of administration
- 1.2.4. Cross-disease impact

2. ACCESS CONSIDERATIONS



2.1. Intellectual property landscape

- 2.1.1. Years to patent expiry of API
- 2.1.2. Geographical coverage of patents
- 2.1.3. Secondary patents
- 2.1.4. Multiple patent owners



2.2. Service delivery enablers

- 2.2.1. Diagnostic
- 2.2.2. Companion drugs
- 2.2.3. Health system requirements



2.3. Manufacturing

- 2.3.1. Manufacturing simplicity
- 2.3.2. Presentation & storage



2.4. Regulatory

- 2.4.1. Regulatory pathway
- 2.4.2. Regulatory cost & complexities
- 2.4.3. Probability of biowaiver /Clinical trial waiver



2.5. Market

- 2.5.1. Affordability & Availability of candidate
- 2.5.2. Commercial potential for MPP Generics' network
- 2.5.3. Impact

1. PUBLIC HEALTH CONSIDERATIONS



1.1. Disease burden

CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
1	Prevalence/incidence	BURDEN OF DISEASE IN LMICS (GLOBAL OR LOCAL)	The burden of the disease in LMICs (global) or in specific LMIC regions or countries (local).
2	Prevalence/incidence	BURDEN OF DISEASE IN SPECIFIC POPULATIONS	The burden of the condition in key populations (PLHIV, pregnant and lactating individuals, pediatric populations, and adolescents, people who inject drugs (PWID), incarcerated individuals, sex workers, and any other vulnerable groups).
3	Treatment options	LACK OF ALTERNATIVE TREATMENTS	Whether there is a lack of alternative treatment for the product-specific indication.
4	Disease severity	DISABILITY-ADJUSTED LIFE YEARS (DALYs)	Disability-adjusted life years (DALYs) as a measure of disease severity.
5	Disease severity	NUMBER OF DEATHS	Yearly estimated deaths linked directly or indirectly to the condition.
6	Epidemic risk	EPIDEMIC/PANDEMIC RISK	Whether there is a risk for imminent or future outbreaks of the disease.



1.2. Clinical relevance

CRITERIA FOR PRODUCT'S ASSESSMENT

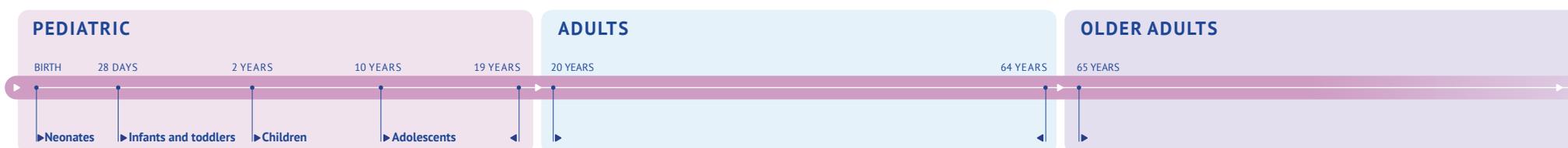
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
7	Safety	SAFETY/TOLERABILITY	Overall safety and tolerability profile of the product.
8	Safety	DRUG-DRUG INTERACTIONS (DDI) WITH HIGH-BURDEN DISEASES REGIMENS	Drug-drug interactions (DDI) with standard of care (SoC) for high-burden infectious diseases such as HIV, TB, and Hepatitis C, and other DDIs.
9	Safety	PRODUCT-INDUCED ADVERSE EVENTS	Whether the product causes adverse events (e.g. hepatotoxicity, nephrotoxicity, weight gain, hypertension).



CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
10	Safety	SPECIAL ADMINISTRATION RESTRICTIONS	Special administration restrictions such as fasting, or requirements for food intake.
11	Efficacy	EFFICACY	Overall efficacy compared to SoC. Efficacy should be ideally superior to the SoC. If the efficacy is comparable to SoC, then an additional advantage should be present. If the efficacy is inferior to the SoC, then product should be excluded from the evaluation.
12	Efficacy	ADHERENCE	Facilitated adherence to the product compared to SoC (from user/caregiver perspective).
13	Efficacy	GENETIC BARRIER TO RESISTANCE	When relevant. Whether there is a high genetic barrier to resistance, especially important for long/life treatment duration.
14	Efficacy	KNOWN RESISTANCE MUTATIONS	When relevant. Whether the product has known significant viral/bacterial resistance mutations of concern.
15	Efficacy	SPECTRUM	When relevant. Whether the product covers several diseases or all disease sub-types (e.g. Hepatitis C pan-genotypic treatment, multi-purpose technology, latent and active TB, several sexually transmitted infections (STIs), several cancers, etc.).
16	Efficacy	INNOVATIVE PRODUCT	Whether the product is innovative (such as a new promising mechanism of action, breakthrough therapy designation, orphan drug designation etc.).
17	Posology & method of administration	DOSAGE	Dosage for each indication (e.g. mg, mg/kg, mg/m2).
18	Posology & method of administration	LENGTH OF THE TREATMENT	Duration of the treatment for the main and secondary indications.
19	Posology & method of administration	FREQUENCY OF ADMINISTRATION	The frequency of dosing (e.g. once or twice daily or every 6 months).
20	Posology & method of administration	AVAILABILITY OF A PEDIATRIC FORMULATION	Whether a pediatric formulation/development program is available.
21	Posology & method of administration	METHOD OF ADMINISTRATION	Route of administration and concise instructions for correct administration and use.
22	Cross-disease impact	CROSS-DISEASE IMPACT	Synergies with other health areas i.e., whether the product could be used across several diseases.

We used the following age ranges:



2. ACCESS CONSIDERATIONS



2.1. Intellectual property landscape

CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
23	Years to patent expiry of API	YEARS TO PATENT EXPIRY OF API	Number of years of blocking patent protection left on the API.
24	Geographical coverage of patents	GEOGRAPHICAL COVERAGE OF PATENTS (INCLUDING SECONDARY PATENTS)	Country scope: how many LMICs are covered.
25	Secondary patents	SECONDARY PATENTS	Specific secondary patents (e.g. formulation, process, method of treatment, platforms) or patent thicket (e.g. biologics).
26	Multiple patent owners	MULTIPLE PATENT OWNERS	If multiple patent owners, might be lengthier to find an agreement with all the involved parties.



2.2. Service delivery enablers

CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
27	Diagnostic	REQUIREMENTS FOR DIAGNOSIS	Diagnostic requirements for the diagnosis of the disease.
28	Diagnostic	ACCESS TO DIAGNOSIS	It includes an evaluation on availability/affordability/status awareness of the diagnosis. It also includes and info on whether the diagnosis is generally available in the public sector or only in the private one. A subset of countries is taken as a proxy.
29	Diagnostic	REQUIREMENTS FOR TREATMENT ELIGIBILITY/ TREATMENT MONITORING	Additional diagnostic requirements required to define eligibility to treatment candidate compared to SoC (e.g. sequencing) / requirement for treatment monitoring (e.g. viral testing).
30	Companion drugs	COMPANION DRUG REQUIREMENTS	Need of companion treatments.
31	Companion drugs	ACCESS TO COMPANION DRUGS	Access (availability and affordability) to companion treatment/s.
32	Health system requirements	HEALTH SYSTEM AND INFRASTRUCTURE NEEDS	Additional requirements for the proper and safe use of the candidate e.g. specific treatment efficacy and/or safety requirements/staff training/facilities.



2.3. Manufacturing

CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
33	Manufacturing simplicity	MANUFACTURING	This includes the simplicity of the manufacturing process generally for this class of molecules. Small molecules chemically manufactured are classified as "not particularly complex for manufacturing". Synthetic proteins or nucleic acids are considered as "partially complex manufacturing" as it is less standard process than small molecules and requires generally aseptic filling which demands specific competencies. Recombinant proteins are classified as "complex manufacturing" as these involve cell growth steps and precise characterization tools needing specific competencies, and it generally also requires aseptic filling. Any specificity of this product within its category is ranked in the criteria as "standard manufacturing operations".
34	Manufacturing simplicity	MANUFACTURING OPERATIONS	Compared to the general simplicity to manufacture this category of product, any complexity to manufacture this specific product is ranked here (e.g., non-standard manufacturing step requiring specific competency or investment).
35	Manufacturing simplicity	MANUFACTURING FACILITY	Special requirements in terms of manufacturing facilities are captured here. Higher value of MPP intervention is attributed to products with no specific facility requirement other than basic good manufacturing practices (GMP), for example non-sterile products. Medium rating is attributed to products which require some additional control in terms of facility, like requirement of grade C area for sterile products which can be sterilised by terminal sterilisation. Lower value of MPP intervention is attributed to products which would require aseptic processing (Grade A), or special containment like hormones or oncology products with occupational exposure limits (OEL) classification of 4 or 5, thus making likely more challenging the identification of manufacturers and potentially the implementation of the production.
36	Manufacturing simplicity	EXCIPIENTS	If the excipients are well known (pharmacopeia), neither costly nor difficult to supply, the MPP intervention would be considered of high value as the implementation would be facilitated. If the excipient is used only in a few medical products or its cost impacts significantly on the cost of goods or the low availability can hinder the supply of the medical product, it would likely result in more difficulties in supplying the excipients or in affecting the product pricing.
37	Presentation and storage	SHELF-LIFE AND STORAGE CONDITIONS	Higher value of MPP intervention is for products with a shelf-life of at least two years at room temperature. A more moderate value would be for products with a shelf-life between one year (excluded) and two years at non-controlled temperature or storage at controlled temperature (e.g. 2-8°C). Lower value for MPP intervention could be for products with a shelf-life lower than one year (included) or with storage in frozen conditions (e.g. -20°C) as it would likely complexify the product distribution.
38	Presentation and storage	MEDICAL DEVICE	Tablets, pills, and vials presentations are considered as standard and would be in principle facilitated by an MPP intervention. Pre-filled syringes (PFS) are considered a medium standard. Intranasal medical devices, insulin pens, or patches are considered non-standard as they require specific equipment, access to specific and potentially costly devices and could imply specific regulatory requirements. In such situations, the potential impact of an MPP intervention needs to be evaluated on a case-by-case basis. This classification could be revised based on the deeper impact of the different medical devices and other potential variables.



CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
39	Regulatory pathway	REGULATORY PATHWAY FOR THE LICENSEES	Probable regulatory pathway for the licensee. Higher rating is attributed to products where the originator product is already approved by SRA/WHO PQ, where the generics have regulatory pathways. Lower rating is attributed to products where the originator is not filed with any regulatory authority, where there is apparently no pathway for the licensee to file their product. Medium rating is attributed to products where the originator has approval in non-SRA countries, but no approval in SRA/WHO PQ. In such cases, potential sub-licensees would need to wait to have the originator product approved with SRA /WHO PQ to file their own product.
40	Regulatory cost and complexities	COST AND COMPLEXITIES OF REGULATORY FILING	The costs associated with regulatory filing are to be assessed separately here. This includes the cost of development, including possible studies (bioequivalence (BE), pre-clinical, clinical, etc.), cost of reference listed drug (RLD), etc. Simple generic products could be rated as high (since they have less complexities). Complex generic products like long-acting therapeutics, or complex dosage forms could be treated as with moderate complexity. Sometimes, simple generic products might need population studies which might add complexity to BE studies and could be included in this category. Biotherapeutics, which require a biosimilarity package, wherein a battery of preclinical and clinical studies are required, could be categorised as high level of complexity.
41	Probability of biowaiver / clinical trial waiver	PROBABILITY OF BIOWAIVER /CLINICAL TRIAL WAIVER	This aspect gets assessed in regulatory cost but needs to be understood separately if a biowaiver/clinical trial waiver is possible. High probability of biowaiver is there for oral solids of BCS Class I, or solutions. Moderate probability for biowaiver is where a molecule might have a probability of biowaiver/clinical trial waiver but there could be other studies/justifications required. For biotherapeutics, some less complex molecules with a PD marker might be included in this category. Low probability of biowaiver is applicable to BCS Class II /IV molecules. Complex biotherapeutics like mAbs would also fall in this category.



CRITERIA FOR PRODUCT'S ASSESSMENT

N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
42	Affordability/availability of the candidate	CANDIDATE-PRODUCT'S AVAILABILITY IN LMICS	Availability of target product in LMICs to assess impact of voluntary licensing and business case.
43	Affordability/availability of the candidate	CANDIDATE-PRODUCT'S AFFORDABILITY IN LMICS	Affordability of target product in a sample of countries with reference to SoC, to assess impact of voluntary licensing and business case.
44	Commercial potential for MPP generic manufacturers' network	COMPANY COMMERCIAL FOOTPRINT	Commercial reach of company across the targeted MPP territories to understand if an in-house access program can reach people in need.
45	Commercial potential for MPP generic manufacturers' network	MARKET SIZE	Annual sales of the product globally and in a sample of territories to understand generic business case and impact on originator profit and loss.
46	Commercial potential for MPP generic manufacturers' network	EXISTENCE, AVAILABILITY AND PRICE OF ALTERNATIVE OF MARKETED TREATMENTS	To assess need and business case for originators.
47	Commercial potential for MPP generic manufacturers' network	EXISTENCE AND AVAILABILITY OF ALTERNATIVE TREATMENTS IN PIPELINE	Existence and availability of alternative therapies in development to focus our priorities and generic interest.
48	Commercial potential for MPP generic manufacturers' network	PRODUCT ATTRACTIVENESS FOR THE LICENSEES	Commercial attractiveness in terms of potential sales and volumes (which could be considered as a proxy for generic manufacturers potentially interested in developing the product).
49	Commercial potential for MPP generic manufacturers' network	PROCUREMENT	Whether there are any established procurement mechanisms available for this type of product.
50	Commercial potential for MPP generic manufacturers' network	COMPETITIVE PRODUCTS (INCLUDING ALREADY EXISTING GENERIC VERSIONS OF THE CANDIDATE AND SAME CLASS PRODUCTS)	Market share according to what is in the pipeline.
51	Impact	POTENTIAL SAVING FOR PUBLIC HEALTH	Commercial impact that generic manufacturers would create after MPP intervention. Whether MPP would be improving the <i>status quo</i> for patients and governments.

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Abbreviations and acronyms

3TC	lamivudine
AMR	antimicrobial resistance
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
ARV	antiretroviral
BCS	biopharmaceutical classification system
BE	bioequivalence
BIC	bictegravir
bNAbs	broadly neutralising antibodies
BTkI	Bruton's Tyrosine Kinase Inhibitor
CAB	cabotegravir
CAB-LA	cabotegravir long-acting
CFTR	cystic fibrosis transmembrane conductance regulator
CADO	Conference on Antiretroviral Drug Optimization
CAP	community advisory panel
CDK 4/6	Cyclin-dependent kinase 4 and 6
CHAI	Clinton Health Access Initiative
CKD	chronic kidney diseases
CLHIV	children living with HIV
CLL	chronic lymphocytic leukemia
CROI	Conference on Retroviruses and Opportunistic Infections
CVD	cardiovascular disease
DALYs	disability-adjusted life years
DDI	drug-drug interactions
DOT	directly observed therapy
DTG	dolutegravir
EASL	European Association for the Study of the Liver
EGFR	Epidermal Growth Factor Receptor
EMA	European Medicines Agency
EML	Essential Medicines List
ESMO	European Society for Medical Oncology

EU-M4All	The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'.
FDC	Fixed dose combination
GAP-f	Global Accelerator for Paediatric Formulations
GLP-1 RA	Glucagon-like peptide-1 receptor agonists
GMP	Good manufacturing practices
HbS	Sickle haemoglobin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDV	Hepatitis Delta Virus
HER2	human epidermal growth factor receptor 2
HIC	High-income countries
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
HR	Hormone Receptor
HSC	Heat-stable carbetocin
IAS	International AIDS Society
ICI	Immune checkpoint inhibitors
IDF	International Diabetes Federation
IM	Intramuscular
INSTI	Integrase strand transfer inhibitor
IP	Intellectual property
ISL	islatravir
IV	intravenous
KRAS	Kirsten rat sarcoma virus
LEN	lenacapavir
LA	long-acting
LMICs	Low- and middle-income countries
LRTI	Lower respiratory tract infections

MAGPH	Marketing Authorisation for Global Health Products
mAbs	Monoclonal antibodies
MDR-TB	Multi-drug-resistant tuberculosis
MPP	Medicines Patent Pool
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NCD	Non-communicable diseases
NMPA	China National Medical Products Administration
NSCLC	Non Small Cell Lung Cancer
OEB	Occupational Exposure Bands
OEL	Occupational Exposure Limits
PADO	Paediatric Antiretroviral Drug Optimization
PAN-TB	Project to Accelerate New Treatments for Tuberculosis
PCR	Polymerase Chain Reaction
PD	Pharmacodynamics
PD-1	Programmed cell Death 1
PD-L1	Programmed cell Death Ligand 1
PEPFAR	President's Emergency Plan for AIDS Relief
PK	Pharmacokinetics
PLHCV	People living with HCV
PLHIV	People living with HIV
PNP	Post-natal prophylaxis
PPH	Post-partum haemorrhage
PrEP	Pre-Exposure Prophylaxis
PSA	Prostate-Specific Antigen
PWID	People who inject drugs
Q1	qualitative sameness
Q2	quantitative sameness
RMNCH	Reproductive, maternal, newborn and child health
RPV	Rilpivirine
RR-TB	Rifampicin-resistant tuberculosis
RSV	Respiratory Syncytial Virus
SAP	Scientific Advisory Panel
SCD	Sickle Cell Disease

SDC	Swiss Agency for Development Cooperation
SoC	Standard of care
SQ	subcutaneous
SRA	Stringent Regulatory Authorities
SSA	sub-Saharan Africa
STI	sexually transmitted infections
Swissmedic MAGHP	Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products
T1DM	Type 1 Diabetes
T2DM	Type 2 Diabetes
TAF	tenofovir alafenamide
TB	Tuberculosis
TDF	tenofovir disoproxil fumarate
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
TLD	tenofovir/lamivudine/dolutegravir
TKI	tyrosine kinase inhibitor
UHC	Universal Health Coverage
UK	United Kingdom
UNAIDS	Joint United Nations Programme on HIV/AIDS
USD	United States Dollar
USFDA	The United States Food and Drug Administration
Para III	Paragraph III Certification means a certification that a generic applicant seeks FDA approval of its abbreviated new drug application (ANDA) as of the date a patent listed in the Orange Book for a relevant new drug application (NDA) expires.
UTI	Urinary tract infection
UUG	Uncomplicated urogenital gonorrhoea
WHO	World Health Organization
WHO-PQ	WHO Pre-Qualification of Medicines Programme

Acknowledgments

MPP would like to acknowledge the valuable support of the experts of its **Scientific and Community Advisory Panels (SAP & CAP)** in informing the prioritisation exercise.

MPP was founded by:



MPP's activities are undertaken with the financial support of :



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