

## ViiV Healthcare and the Medicines Patent Pool sign new voluntary licensing agreement to expand access to innovative long-acting HIV prevention medicine

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**LONDON and GENEVA, 28 July, 2022** - ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, and the Medicines Patent Pool (MPP) today announced the signing of a new voluntary licensing agreement for patents relating to cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP) to help enable access in least developed, low-income, lower middle-income and Sub-Saharan African countries<sup>1,2</sup>.

Through this agreement, selected generic manufacturers will have the opportunity to develop, manufacture and supply generic versions of cabotegravir LA for PrEP, the first long-acting HIV prevention medicine, in 90 countries, subject to required regulatory approvals being obtained. It is expected that this agreement will help to enable at-scale access to generic cabotegravir LA for PrEP. This announcement comes just seven months after the first regulatory approval of cabotegravir LA for PrEP in the world, by the US Food and Drug Administration (US FDA).

Each year, there are approximately 1.5 million new cases of HIV worldwide<sup>3</sup>, most of which occur in resource-limited countries, with women and adolescent girls disproportionately impacted. While oral PrEP options are available in many countries, challenges with adherence and stigma have limited their impact in some populations. Access to an effective long-acting HIV prevention option could significantly contribute towards the goal of ending the epidemic.

The new voluntary licence announced today builds on a long-standing partnership between ViiV Healthcare and MPP, which has been highly successful in facilitating the manufacture and sale of generic versions of oral ViiV Healthcare medicines in countries most affected by HIV and least able to pay for treatment and care. In particular, voluntary licensing has enabled access to generic products containing another of ViiV Healthcare's innovative medicines, dolutegravir, for at least 20 million people living with HIV in low- and middle-income countries, as of December 2021<sup>4</sup>.

**Deborah Waterhouse, CEO at ViiV Healthcare said,** "Today's announcement represents a potentially game-changing moment in HIV prevention. Enabling at-scale access to generic cabotegravir LA for PrEP could play a significant role in averting the transmission of HIV, particularly amongst women and adolescent girls, and help end the HIV epidemic. I am proud that through our long-standing partnership with MPP, we continue to play our part in widening access for people in resource-limited countries to new innovative medicines."

**Charles Gore, MPP Executive Director said,** "We are delighted to sign this voluntary licence with ViiV for cabotegravir LA for PrEP. Long-acting technologies open up a whole new dimension that facilitates medicine uptake, and this product brings a much-needed option for those at risk. This licence was negotiated in double-quick time and is another example of MPP's continued commitment to making innovation available and affordable in low- and middle-income countries in

the shortest possible time. Rapid access to new technologies is our only hope of hitting the Sustainable Development Goal targets.”

This voluntary licence forms part of a holistic approach to enable at-scale access to cabotegravir LA for PrEP in least developed, low-income, lower middle-income and Sub-Saharan African countries<sup>1</sup>. There are complexities and considerations that need to be managed to support the manufacturing and roll out of a generic long-acting injectable. Compared to oral PrEP options, cabotegravir LA for PrEP is more complex to manufacture and there is an evolving and less well-defined demand for the product. These are challenges not only for ViiV but also for any potential generic partners. ViiV Healthcare and MPP will now work closely with stakeholders and generic manufacturers selected through MPP’s expression of interest process to enable access to generic cabotegravir LA for PrEP as soon as possible.

Cabotegravir LA for PrEP is a long-acting injectable which has recently gained its first regulatory approval for use in HIV prevention the USA for at risk adults and adolescents weighing at least 35kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to receiving it. It is not currently approved for use in HIV prevention anywhere outside of the USA. ViiV Healthcare has submitted marketing applications in a number of countries including the majority of countries where the clinical trials were conducted, with further registrations planned. ViiV Healthcare is also working with stakeholders, including global health agencies, non-governmental organisations, governments and community partners to understand country-specific contexts and is supporting implementation science projects that will provide critical information on the feasibility, acceptability and scalability to deliver successful introduction of cabotegravir LA for PrEP into national programmes, which would be needed to enable any future generic version of the product.

#### **Partner quotes:**

“Long-acting PrEP has the potential to transform HIV prevention efforts, but only if it is made widely available at affordable prices. Unitaid welcomes the news of this voluntary licence, agreed in record time, which gives people at risk of infection additional options so they can choose the HIV prevention method that works for them. Developing solutions that respond to different needs and preferences is critical to averting new infections globally.”

**Dr Philippe Duneton, Executive Director, Unitaid**

Unitaid created the MPP to facilitate access conditions for critical medicines in 2010 and continues to be MPP’s principal funder. A new coalition to accelerate access to long-acting PrEP, convened by Unitaid and partners, is working to develop and implement coordinated strategies to overcome access challenges to new PrEP options.

“This is really welcome news and a next important step along the road to ensuring the promising innovation of injectable PrEP is made accessible to all who would benefit from it even those from the least well-resourced regions. We know primary prevention is key to controlling HIV globally but to get the most from innovation we need access and scale up.”

**Linda-Gail Bekker, Director of the Desmond Tutu HIV Centre at the University of Cape Town**

“Afrocab Treatment Access Partnership and our many community partners welcome this announcement regarding the generic licensing of CAB-LA. CAB-LA will undoubtedly have a transformative impact on HIV prevention efforts in our communities. We are pleased to see that

Afrocab's and community partners' advocacy around CAB-LA access did not go unheard. Today's announcement is an exciting milestone, but we know much work is still needed to ensure CAB-LA is widely available in our settings. We now eagerly and anxiously await a bridging price to make CAB-LA accessible in LMICs NOW. We look forward to working with all stakeholders to ensure that the promise of CAB-LA is realised."

**Jacque Wambui from Kenya, AfroCAB**

## Notes to Editors

### About the Medicines Patent Pool

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with 15 patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, three long-acting technologies, two oral antiviral treatments for COVID-19 and 12 COVID-19 technologies. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs and SDC.

For more information on Medicines Patent Pool and its licences, please visit [www.medicinespatentpool.org](http://www.medicinespatentpool.org)

### About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of becoming infected with HIV. Shionogi joined as shareholders in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

For more information on the company, its management, portfolio, pipeline, and commitment, please visit [www.viivhealthcare.com](http://www.viivhealthcare.com).

### About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com/company](http://gsk.com/company)

### Medicines Patent Pool enquiries:

Gelise McCullough +41 79 685 64 36 (Geneva)

Ibon Villelabeitia +41 79 292 54 26 (Geneva)



[Press@medicinespatentpool.org](mailto:Press@medicinespatentpool.org)

**ViiV Healthcare enquiries:**

Media enquiries:	Catherine Hartley	+44 7909 002 403	(London)
	Rachel Jaikaran	+44 7823_532_755	(London)

**GSK enquiries:**

Media enquiries:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Madeleine Breckon	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)

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2. Country classifications as defined by the United Nations: [LDCs at a Glance | Department of Economic and Social Affairs \(un.org\)](https://www.un.org/development/desa/policy/lDCs-at-a-glance/)
3. <https://www.unaids.org/en/resources/fact-sheet>
4. Medicines Patent Pool 'Access to Medicines tracker'. Data as of December 2021. <https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>