



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.



INTELLECTUAL PROPERTY LANDSCAPE

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



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).



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.



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.

mAbs/bNAbS



HIV Post-natal
Prophylaxis
(PNP)

Multiple innovators