

*The newsletter summarising key developments relating to long-acting injectable cabotegravir (CAB-LA) and HIV prevention*

## CAB-LA Working Group meeting dates:

### Demand Generation Working Group

3-4pm CAT/4-5pm EAT 31<sup>st</sup> August

### Engaging with Policymakers Working Group

3-4pm CAT/4-5pm EAT 1<sup>st</sup> September

## Highlights - Kigali Annual CAB Meeting

- On August 24-25, CAB members met in Kigali, Rwanda for an annual CAB meeting. Among other key topics including Advanced HIV Disease (AHD) and rollout of darunavir (DRV/r) for second-line HIV treatment, CAB members discussed research needs and priorities for a new landscape of long-acting HIV products.



## European Commission Approves Six-Monthly Lenacapavir Injections for Treatment of Multidrug Resistant HIV

Gilead [announced that the European Commission has granted Marketing Authorisation for lenacapavir](#) tablets and injections for the treatment of HIV in adults who have developed resistance to multiple HIV medications. This approval was based on evidence from the [CAPELLA study](#) where participants received lenacapavir injections every 6-months (after loading doses with oral lenacapavir tablets) in combination with a background regimen of daily oral ARVs. The study recruited participants who had multidrug-resistant HIV and were on failing therapies. Results showed no serious adverse events and saw reductions in viral load. Lenacapavir injections were administered as subcutaneous injections in the abdomen. **This is an important step forward for people with multi-drug resistant HIV who have limited treatment options.**

## Spotlight on Lenacapavir

Lenacapavir received its first regulatory approval for treatment of multi-drug resistant HIV. **However, lenacapavir is also being investigated as a six-monthly subcutaneous injections for HIV prevention in two efficacy trials: [PURPOSE-1](#) and [PURPOSE-2](#).** PURPOSE-1 is recruiting an estimated 5,010 adolescent girls and young women (AGYW) in Uganda and South Africa, while PURPOSE-2 is recruiting cisgender men, transgender women, transgender men, and gender nonbinary people who have sex with male partners in the US and South Africa. These trials are expected to reach their primary completion stages in the first quarter of 2024, meaning the product could receive first regulatory approvals for HIV prevention in 2025. If trials are successful, lenacapavir will be an important long-acting addition to the HIV prevention portfolio, expanding choice among those at risk of HIV.

## In case you missed it- UNAIDS' new podcast

- UNAIDS launched a new podcast series entitled “Against the Odds”, which aims to share stories from people around the world whose lives have been influenced by HIV/AIDS. If you haven't tuned in already, you can [catch up on the first two episodes here](#).
- The first episode, entitled “Taking a Risk”, captures Retired Justice Edwin Cameron's story of campaigning for LGBTQ+ rights and his experiences of living with HIV, whilst the second podcast, “Walking the seven wonders” features the adventures of Jonatan Montoya, who is undertaking a colossal global walk to raise awareness of HIV.



### LANDSCAPE OF INNOVATIVE TOOLS AND DELIVERY STRATEGIES

FOR ELIMINATING VERTICAL TRANSMISSION  
OF HIV, SYPHILIS, HEPATITIS B, AND CHAGAS  
IN ENDEMIC AREAS

## Unitaid's report highlights innovative approaches to eliminate vertical transmission of HIV, syphilis, hepatitis B and chagas disease

- Earlier this month, Unitaid [published a report](#) summarizing the latest evidence on key innovations and strategies to aid the elimination of HIV, syphilis, hepatitis B and chagas disease.
- The report collates information from peer-reviewed articles and semi-structured interviews spanning a variety of specialists across the four disease areas, as well as individuals from industry and academia. In addition to highlighting key epidemiological data and targets, authors also identified barriers (*page 46*) and opportunities (*page 48*) to improve access to interventions for the four diseases. A key takeaway from the report's conclusion (*page 52*) is that countries should aim to develop integrated approaches that address the needs of pregnant women and their families in a holistic, patient-centered way.

## Review of evidence for long-acting HIV prevention and treatment

- In a [review of data](#)<sup>1</sup> on cabotegravir, islatravir, and lenacapavir, authors highlight promising evidence on these long-acting products. While studies document injection site reactions among some users, overall, participants preferred long-acting treatment and prevention regimens over oral ARVs.

## Implementation Science Needs for CAB-LA

- In a new publication, WHO [summarised implementation science needs](#) for CAB-LA for HIV PrEP<sup>2</sup>.
- The article emphasizes the need to understand effective models for providing CAB-LA outside of trial settings, including for populations who were underrepresented in trials, such as sex workers, people who inject drugs and transgender men. Authors also called for more research among pregnant and breastfeeding people, and investigation of the potential for self-administering injections.

<sup>1</sup> Bernice & Kilcrease (2022). Novel and investigational HIV therapies for treatment and prevention: Focus on cabotegravir, islatravir, and lenacapavir. *Current Infectious Disease Reports*, 24, pp. 89–96

<sup>2</sup> Schmidt et al. (2022). Long-acting injectable cabotegravir: implementation science needed to advance this additional HIV prevention choice. *Journal of the International AIDS Society*, 25 (7): e25963.