Where We Are Now with LEN for PrEP





Global Fund & PEPFAR announce coordination to reach 2 million people with LEN for PrEP



WHO guidelines development group to review evidence and formulate clinical guidance



FDA grants Gilead **Priority Review status** of LEN for PrEP



FDA grants approval of LEN for PrEP



WHO guidelines and recommendations announced at IAS in Kigali



Gates Foundation

Unitaid Gates Foundation and **Unitaid** announce investments in generic LEN, with expected price of \$40 PPPY in LMIC in 2027

Funding freezes, litigation, widespread closures, and confusion jeopardize scaled LEN procurement



Dec 17 2024

Dec 19 2024

Jan 28-30 2025

Feb 3 2025

Feb 18 2025

Feb 24 2025

Jun 18 2025

July 9 2025

July 14 2025

July 25 2025

Aug 26 2025

Sept 4 2025

Sept 24 2025





Gilead submits new drug application to U.S. Food and Drug **Administration** for twice-yearly lenacapavir for HIV prevention



Gilead submits marketing authorization application to the **European Medicines** Agency



European Medicines Agency agrees to accelerated review of LEN for PrEP





Gilead and Global Fund announce access agreement and finalize initial supply for nine priority countries



EMA annnounces recommendation of market authorization of LEN for PrEP, two months ahead of schedule



PEPFAR recommits to partnership with Gilead in coordination with the Global Fund to deliver LEN for PrEP

PEPFAR, Global Fund and governments can begin to procure

