

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 guidelines

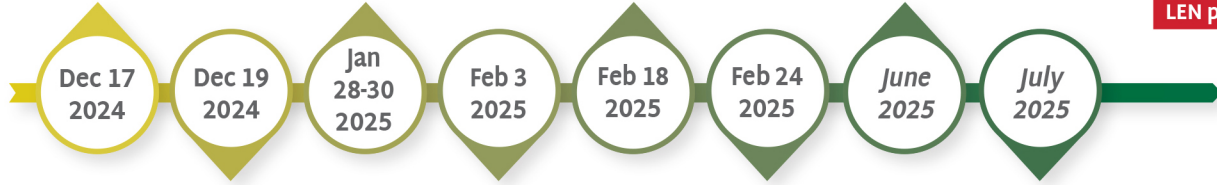


FDA grants Gilead Priority Review status of LEN for PrEP



FDA decision on priority review of LEN for PrEP is expected by June 19th

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

June 2025

July 2025



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



EUROPEAN MEDICINES AGENCY
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Gilead submitted marketing authorization application to the European Medicines Agency



EUROPEAN MEDICINES AGENCY
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European Medicines Agency agrees to accelerated review of LEN for PrEP



World Health Organization

WHO guidelines and initial regulatory approvals are expected around the time of IAS in Kigali



PEPFAR and Global Fund can procure after regulatory approvals & WHO recommendation

