Overview of Lenacapavir (LEN) for PrEP Trials

Legend:
- ⭐ (green) Initial data
- ⭐ (black) Possible data
- ✔ (blue) Possible earliest regulatory submissions
- ✔ (red) Possible earliest regulatory approval and market entry with product from Gilead
- ✦? (green) Possible earliest generic manufacturer(s)
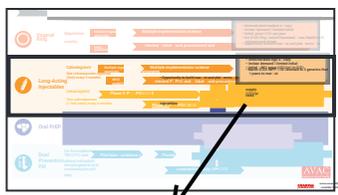
Trial	Population	Location	Size	2022	2023	2024	2025	2026	2027	2028
PURPOSE 1 Phase 3 Injectable lenacapavir & oral F/TAF	Cisgender adolescent girls and young women	South Africa and Uganda	5,345		Initial results released in June 2024 demonstrated no infections in the LEN arm ⭐	✔	✔		✦?	
PURPOSE 2 Phase 3 Injectable lenacapavir	Cisgender men who have sex with men, Transgender women, Transgender men, Gender non-binary	US, South Africa, Peru, Brazil, Mexico, Argentina, and Thailand	3,271		Initial results released in September 2024 demonstrated LEN reduced HIV infections by 96% compared to background HIV incidence ⭐					
PURPOSE 3 HPTN 102 Phase 2 Injectable lenacapavir	Cisgender women	US	253			Enrolment complete; estimated study completed date early 2028 ⭐				
PURPOSE 4 HPTN 103 Phase 2 Injectable lenacapavir	People who inject drugs	US	181			Enrolment complete; estimated study completed date late 2028 ⭐				
PURPOSE 5 Phase 2 Injectable lenacapavir	Cisgender men who have sex with men, Transgender women, Transgender men, Gender non-binary	France, and UK	268			Enrolment complete; estimated study completed date late 2028 ⭐				
PURPOSE 365 Phase 3 Injectable lenacapavir	Diverse population of people who would benefit from PrEP	US	300				Currently recruiting; estimated study completion date 2028 ⭐			

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February 2026