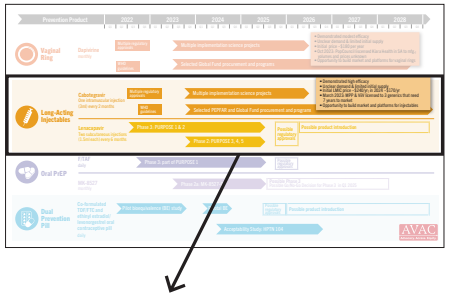
Overview of Lenacapavir (LEN) for PrEP Trials

- Initial data
- Possible data
- Possible earliest regulatory submissions
- Possible earliest regulatory approval and market entry with product from Gilead
- 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	**5,010**	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	**3,000**		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	**250**			Currently recruiting; estimated study completed date early 2028				
PURPOSE 4 **HPTN 103** Phase 2 Injectable lenacapavir	People who inject drugs	US	**250**			Currently recruiting; estimated study completed date mid-2027				
PURPOSE 5 Phase 2 Injectable lenacapavir	Cisgender men who have sex with men, Transgender women, Transgender men, Gender non-binary	France and UK	**262**			Enrollment expected to begin in the second half of 2024				

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