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Title: **Mass generic production of lenacapavir could cost under \$100 per person-year: the need for voluntary licensing**

Authors: A. Hill¹, J. Levi², C. Fairhead², V. Pilkington³, J. Wang⁴, M. Johnson⁵, J. Layne⁵, D. Roberts⁵, J. Fortunak⁵

¹Liverpool University, Department of Pharmacology and Therapeutics,, Liverpool, United Kingdom,

²Charité Univeristy Berlin, International Health, Berlin, Germany,

³King's College London, HIV Research Team, London, United Kingdom., United Kingdom,

⁴Oxford University Clinical Academic Graduate School, UK Medical Sciences Office, Oxford, United Kingdom,

⁵Howard University, Chemistry and Pharmaceutical Sciences,, Washington D.C., United States,

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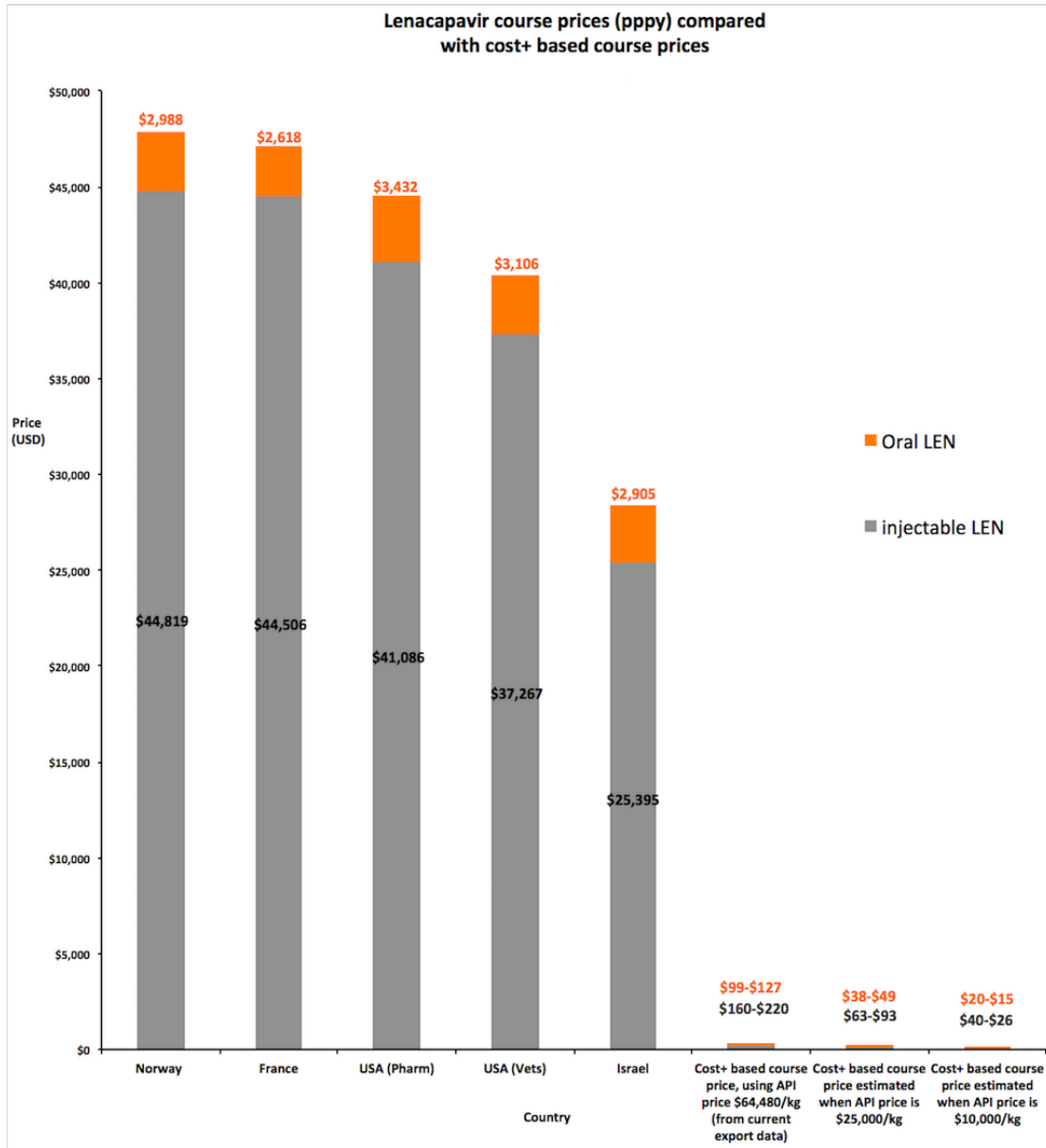
TEXT

Background: Despite improvements in access to both HIV treatment and oral PrEP, there were 1.3 million new HIV infections in 2022. If the PURPOSE trials demonstrate preventative efficacy, six-monthly lenacapavir PrEP could benefit millions of people worldwide. However, lenacapavir prices are currently up to \$44,819pppy.

Methods: We projected minimum pricing of lenacapavir based on generic mass-production and a Cost-Plus (Cost+) model. Current lenacapavir Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs) costs were obtained from export databases (Panjiva and Trade Visions LLC). Routes of synthesis (ROS) were analysed to project a Cost of Goods (COGs) for initial and increasing demand. The costs of formulation, vials and profit margins were included using standardised algorithms and Cost+ pricing. We estimated Cost+ prices with scale-up to produce sufficient doses for 1M then 10M treatment-years and compared this with current national list prices.

Results:

Lenacapavir API is currently exported for \$64,480/kg on 1kg scale. Based on the ROS and KSMs, an API COGs of \$25,000/kg is achievable for a committed demand of 1-million treatments (2000kg/year of API). An API COGs of \$10,000/kg for 10M treatment-years is achievable to drive cost reductions on further scale-up, but requires substantial improvements by manufacturers to the ROS. Including formulation, vials and profit margins, generic injectable lenacapavir could be mass-produced for \$63-93pppy for 1M treatment-years, falling to \$26-\$40pppy for 10M treatment-years. These prices require voluntary licenses and competition between generic suppliers. Current prices for 1-year of lenacapavir PrEP were \$25,395-44,819pppy in countries with available data.



Conclusions: We demonstrate that lenacapavir can be mass-produced for \$63-\$93pppy, potentially falling to \$26-\$40/pppy with scale-up. Mass-production of generic lenacapavir, under voluntary license by multiple suppliers, is required to achieve these prices. This mechanism is already in place for the mass-production of other antiretrovirals. Gilead has not yet agreed lenacapavir voluntary licenses with the Medicines Patent Pool.