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**Subject: Request for Waiver of Local Phase III Clinical Trial for *Lenacapavir (Capsid Inhibitor)* for prevention of HIV**

Dear Dr. Raghuvanshi,

We, the undersigned patient health groups and organizations working on HIV and AIDS from the Asia-Pacific region, would like to acknowledge and commend the Central Drugs Standard Control Organization (CDSCO), for your vital role in ensuring global access to life-saving medicines, including direct-acting antivirals for hepatitis C and antiretroviral therapies for HIV prevention and treatment. The concrete and bold steps from your end have enabled many of us and our friends and colleagues around the world to legitimately access quality-assured Indian generic medicines, with successful treatment outcomes.

We are writing to request consideration of granting a waiver for a phase III local trial for lenacapavir (300 mg oral tablets/1.5 mL injectable formulation) for HIV pre-exposure prophylaxis (PrEP).

Lenacapavir is a first-in-class, long-acting HIV capsid inhibitor that was approved for PrEP by the United States Food and Drug Administration (U.S. FDA) in June 2025 and the European Commission (EC) in August 2025, followed by other stringent regulatory authorities (e.g., Medical and Healthcare products Regulatory Agency [MHRA] in the United Kingdom, Therapeutics Goods Administration [TGA] in Australia).

The interim analysis of its multi-country phase III trial<sup>1</sup> confirmed that the study met its key efficacy endpoints of superiority for both primary and secondary endpoints. Consequently, the independent Data Monitoring Committee recommended stopping the blinded phase of the trial and offering open-label lenacapavir to all participants. The U.S. FDA designated lenacapavir under their priority review status, and their fast track and breakthrough therapy processes <sup>2,3,4</sup>. The World Health Organization also prequalified the product in just 36 days through a new, expedited abridged pathway based on a positive scientific opinion from the European Medicines Agency (EMA)<sup>5</sup>.

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<sup>1</sup> CF Kelley, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. N Engl J Med. 2024.

<sup>2</sup> US Food and Drug Administration. Priority Review [FDA website]. 2018. <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review>.

<sup>3</sup> US Food and Drug Administration. Fast Track. 2018. <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

<sup>4</sup> US Food and Drug Administration. Breakthrough Therapy. 2018. Available at: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy>

<sup>5</sup> World Health Organization, <https://extranet.who.int/prequal/news/first-lenacapavirs-prequalified#>

The global multi-centre phase III trials conducted across Africa, Asia, Latin America, and the United States, involved 8660 participants and evaluated the safety and efficacy of lenacapavir. The results demonstrated 89 to 100% superiority in reducing HIV acquisition compared to oral PrEP regimens of Tenofovir Disoproxil Fumarate and Emtricitabine or Tenofovir alafenamide (TAF) and Emtricitabine <sup>6,7</sup>. The clinical trial data, which have already supported approvals and recommendations by regulators such as the U.S. FDA and the EMA, provide sufficient evidence of the safety and efficacy of lenacapavir. Granting market authorization in India based on these existing data, without requiring additional local trials, would enable this much-needed intervention to reach millions of people in high HIV-burden countries. Imposing new local trial requirements would only delay access to lenacapavir and hinder global efforts to control HIV infections.

Scientists have indicated that, with adequate population coverage, lenacapavir could prevent up to 33% of new HIV infections in high-burden regions over the next decade, provided the drug is affordable and distributed equitably <sup>8</sup>. Achieving this impact depends on the timely approval of Indian generic formulations and the issuance of necessary documentation to allow companies to file registration dossiers with other national regulatory authorities.

We urge you to recognize the urgent need for this medicine, which is already backed by extensive research data and approvals from stringent regulatory authorities. The waiver of a local trial would ensure that lenacapavir reaches national public health programs, healthcare providers, and individuals at risk of HIV infection far more quickly. This medicine represents hope for millions around the world. That hope can only be realized through the rapid expansion of access, enabled by India's capacity for large-scale generic production.

Thanking you for your consideration.

Yours sincerely,

- i) AIDS Access Foundation, Thailand
- ii) Asia-Pacific Network of People living with HIV/AIDS, Thailand
- iii) APCASO Foundation, Thailand
- iv) APCOM Foundation, Thailand
- v) Association of People living with HIV, Pakistan
- vi) Asia-Pacific Transgender Network, Thailand
- vii) Blue Diamond Society, Nepal
- viii) Centre for Supporting Community Development Initiatives, Vietnam

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<sup>6</sup> LG Bekker, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med*. 2024.

<sup>7</sup> CF Kelley, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med*. 2024.

<sup>8</sup> Wu L, et al. Health impact, budget impact, and price threshold for cost-effectiveness of lenacapavir for HIV pre-exposure prophylaxis in eastern and southern Africa: a modelling analysis, *The Lancet HIV*, 2024.

- ix) Citizens' Health Movement Network, Thailand
- x) Deciduous for Development Group, Thailand
- xi) Diamond Friend Club, Thailand
- xii) Drug User's network, Pakistan
- xiii) Foundation for Action on Inclusion Rights, Thailand
- xiv) Global Fund Advocates Network Asia-Pacific
- xv) Health Action Coordinating Committee, Cambodia
- xvi) Health and Share Foundation, Thailand
- xvii) Hor Keaw Rainbow Group, Thailand
- xviii) Human Development Foundation, Thailand
- xix) IDUCARE, Philippines
- xx) Indian Drug Users Forum, India
- xxi) Indonesian AIDS Coalition, Indonesia
- xxii) Institute of HIV Research and Innovation, Thailand
- xxiii) Jaringan Indonesia Positif, Indonesia
- xxiv) Khmer HIV/AIDS NGO Alliance, Cambodia
- xxv) Khealang for Development Group, Thailand
- xxvi) Kidney Friends Association of Thailand, Thailand
- xxvii) Lanka Plus, Sri Lanka
- xxviii) Lighthouse Social Enterprise, Vietnam
- xxix) Little Birds Youth Network Foundation, Thailand
- xxx) LoveYourself, Inc., Philippines
- xxxi) Malaysian AIDS Council, Malaysia
- xxxii) Malaysian Treatment Access & Advocacy Group, Malaysia
- xxxiii) M-Moon Foundation, Thailand
- xxxiv) MPLUS Foundation, Thailand
- xxxv) Myanmar Positive Group, Myanmar
- xxxvi) National Association of PLWHA in Nepal, Nepal
- xxxvii) National Coalition of People Living with HIV in India, India
- xxxviii) National Community Advisory Board, Thailand
- xxxix) Network of Asian People who Use Drugs, Thailand
- xl) Network of People who Use Drugs, Bangladesh
- xli) Payoon Sri-Trang Group, Thailand
- xl ii) Peduli Hati, Indonesia
- xl iii) Persaudaraan Korban Napza Indonesia, Indonesia
- xl iv) Positive Female's Network, Pakistan
- xl v) Rainbow Dream Group, Thailand
- xl vi) Rainbow Sky Association of Thailand, Thailand
- xl vii) Recovering Nepal, Nepal
- xl viii) Recovering Nepal Women, Nepal

- xlix) Ruangaroon Group, Thailand
- l) Service Workers in Group Foundation, Thailand
- li) SISTERS Foundation, Thailand
- lii) Social Development Association, Thailand
- liii) Society for Positive Atmosphere and Related support to HIV and AIDS, Nepal
- liv) Tamtang Foundation, Thailand
- lv) Thai Network of People who Use Drugs, Thailand
- lvi) Thai National AIDS Foundation, Thailand
- lvii) Thai Network of People living with HIVAIDS, Thailand
- lviii) Thai NGO Coalition on AIDS, Thailand
- lix) The HIV Foundation Asia, Thailand
- lx) TREAT Asia, amfAR, Thailand
- lxi) VCAP Foundation, Thailand
- lxii) Vietnam Network of People Living with HIV, Vietnam
- lxiii) Wednesday Friends Club, Thailand
- lxiv) Youth Chapter, Pakistan
- lxv) Youth LEAD, Thailand

Copy for necessary action:

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