European AIDS Treatment Group

Brussels, October 18th 2021

Open Statement on Access to Long-acting Injectable Cabotegravir for HIV Prevention in Europe

As organisations delivering services and advocating for the right to health of populations most affected by HIV, we are very concerned about the lack of submission for registration of ViiV's injectable Cabotegravir for the prevention with the European Medicines Agency (EMA) and other regulatory authorities in Europe. We ask for public commitment and transparency from ViiV.

ViiV submitted Cabotegravir for PrEP to the FDA on 29 September 2021 and it was granted priority review (a fair decision looking at the clinical trials results). On 21 December, it was approved by FDA.

We welcome the agreement with the Medicine Patent Pool for the voluntary licencing of Cabotegravir for PrEP.

Given the long time needed for the registration, reimbursement, and prices negotiations, it is critically urgent for ViiV to file at EMA to prevent a very long delay before LAI Cabotegravir reaches the people who will benefit most from it. It will then be equally important for EMA to provide for a fast-track approval process to minimise further delay. We also expect health authorities at country level to act affirmatively to open access to long acting injectables for PrEP and add it to the basket of HIV prevention options.

European countries still have some way to go to deliver adequate combination programmes, including PrEP, to key affected communities and at the scale needed. From the start, our organisations have been a strong supporter of oral PrEP as a novel tool in combination prevention programmes. Yet, several groups experience barriers to continued oral use and will benefit from long-acting injectable PrEP. Also, consistent with the decentralisation of care for PrEP through community-based organisations to better serve some populations, we strongly believe people must be able to access the PrEP options that work for them. This includes innovative tools such as the long-acting injectable Cabotegravir. Not opening the pathway to introduce a medical tool responding to an unmet medical need is ethically wrong and we ask for ViiV and other players to live up to their public health responsibilities.

We call on ViiV to file for registration of long-acting injectable Cabotegravir for the prevention of HIV with the European Medicines Agency (EMA) and other regulatory authorities.

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Signing organisations

AIDS Action Europe

Aidsfonds

Apoyo Positivo

Adhara/Sevilla Checkpoint

ARAS – Romanian Association Against AIDS

BCN Checkpoint (Projecte dels NOMS-Hispanosida)

Czech AIDS Help

DCAB - Deutsches Expertennetzwerk HIV/Hepatitis e.V.

ECOM - Eurasian Coalition on Health, Rights, Gender and Sexual Diversity

ESWA – European Sex Workers' Rights Alliance

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Grupo de Trabajo sobre Tratamientos del VIH (gTt)

GAT - Grupo de Ativistas em Tratamentos

HivNorway

PrEP in Italia

Red Ribbon Istanbul Association

ReShape/International HIV Partnerships

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About the European AIDS Treatment Group:

The European AIDS Treatment Group (EATG) is a patient-led NGO that advocates for the rights and interests of people living with or affected by HIV/ AIDS and related co-infections within the WHO Europe region. Founded in 1992, the EATG is a network of more than 150 members from 45 countries in Europe. Our members are PLHIV and representatives of different communities affected by HIV/AIDS and co-infections. EATG represents the diversity of more than 2.3 million people living with HIV (PLHIV) in Europe as well as those affected by HIV/AIDS and co-infections. For more information, please visit www.eatg.org