

Community Position Statement: CAB-LA must be immediately licensed to generic suppliers to enable affordable, widespread access for all people at risk of HIV

The development of cabotegravir long-acting injectable (CAB-LA) for HIV prevention comes at crucial time in HIV prevention. In 2020 alone, there were 1.5 million new HIV infections, leading the world to miss global targets by an excess of one million new infections. We witnessed the results of these failures in our own communities – **globally, around 5,000 young women aged 15-24 years, including our young daughters, sisters, friends, and neighbors, were newly infected with HIV every week.**¹ CAB-LA, with its high efficacy, strong tolerability, and bimonthly dosing, offers a vital tool our communities urgently need.

Today, the available options for HIV prevention in our settings are limited. While oral pre-exposure prophylaxis (PrEP) is both safe and effective, the requirement for daily pill-taking is not ideal for many of our community members; oral PrEP's efficacy and overall utilization are limited by the adherence challenges associated with daily-pill taking and the stigma that arises due to the inability to discreetly use oral tablets. People with PrEP experience have said:

*“People start rumours about you being HIV positive, if you take pills every day” –VOICE-D Trial Participant, Age 36, Zimbabwe*²

*“Taking PrEP [pills daily], in fact it is a burden, it is not easy. I prefer you inject me instead of giving me pills”. – Young woman in Kisumu County, Kenya, Age 23*³

CAB-LA offers a critically needed option for individuals at risk of HIV infection for whom daily PrEP use is not preferred or feasible. Administered through an intramuscular injection once every two months (after an initial two doses one month apart), CAB-LA resolves many barriers associated with daily pill use and has the potential to transform HIV prevention efforts. Users of long-acting injectable antiretrovirals (ARVs) for HIV treatment have already voiced the drastic improvement in quality of life they've experienced transitioning from daily oral tablets to long-acting injections:

“I don't have to be connected to a pill bottle, and I no longer have any anxiety within myself about taking my pill. When we think about what it means for adherence to go from 365 pills to 6 shots, it's revolutionary. We need to do everything we can do to make sure everyone has access to that.” – Long-Acting Injectable HIV Treatment User (from Community Forum Webinar)

For years, we have advocated for a diversity of HIV prevention options that respond to the needs, lifestyles, and unique experiences of our community members at greatest risk for HIV infection. The availability of affordable, widespread access to CAB-LA will represent an important step in this direction.

Achieving affordable and widespread access to CAB-LA, as with the vast majority of HIV products in low- and middle-income countries, necessitates its producers, ViiV Healthcare and GlaxoSmithKline (GSK), undertake rapid generic licensing with a broad geographic scope, effective technology transfer to additional

¹ UNAIDS. Fact Sheet – World AIDS Day 2021. [Link](#).

² Luecke, EH et al. 2016. Stated product formulation preferences for HIV pre-exposure prophylaxis among women in the VOICE-D (MTN-003D) study. *Journal of the International AIDS Society*, 19: 20875. <https://doi.org/10.7448/IAS.19.1.20875>

³ Pintye, Jillian et al. 2021. Influences on Early Discontinuation and Persistence of Daily Oral PrEP Use Among Kenyan Adolescent Girls and Young Women: A Qualitative Evaluation from a PrEP Implementation Program. *JAIDS Journal of Acquired Immune Deficiency Syndromes*. doi: 10.1097/QAI.0000000000002587

manufacturers (if requested), and extensive country registrations. For dolutegravir (DTG), WHO's recommended first line HIV treatment, this process resulted in DTG access in almost 100 countries and a price decrease of over 80% with generic production when compared to the innovator non-profit price.⁴ In 2021, over 18 million people are estimated to be accessing generic dolutegravir, a reality not possible without a wide-ranging, affordable, and secure generic supply. Following this pathway for CAB-LA would similarly ensure it has the geographic scope, supply security, and price that are essential for addressing the substantial unmet need for HIV prevention in our communities.

Shamefully, ViiV and GSK have not yet licensed CAB-LA. As a result, without urgent action, generic CAB-LA's introduction in our communities could be delayed by nearly a decade, if not longer. ViiV and GSK's decision not to license marks a disgraceful change in practice for companies well-aware that licensing is an essential tool to support widespread access to HIV products. By choosing a path of profit over lives, they betray our communities. Their memories cannot be this short: They cannot have forgotten the lessons well-learned by pharmaceutical companies during the peak of the HIV crisis. Their inaction means an early opportunity for widespread generic CAB-LA access has already been lost. Furthermore, we fear that the decision to not license CAB-LA sets a dangerous precedent which could threaten generic licensing of other critical HIV products. It is essential that ViiV and GSK immediately grant a broad generic license for CAB-LA, support effective technology transfer as requested, and pursue widespread product registration in all high-burden HIV countries.

While generic licensing, technology transfer, and broad registration are critical first steps, ViiV and GSK's actions cannot end there. In the near-term, ViiV and GSK must also support access to an affordable bridging supply of CAB-LA so that the millions of our currently at-risk community members are able to use this life-altering product without having to wait for the successful completion of a technology transfer and manufacturing scale-up, processes that take years. Furthermore, ViiV and GSK must also engage in ongoing research and evidence generation. Insights from these projects will bolster health systems to deliver CAB-LA at scale, ensuring that CAB-LA quickly reaches our communities who need it most.

The arrival of CAB-LA marks a turning point in the fight against HIV. For years, we have waited patiently for this moment even as we watched our families, neighbors, and communities be transformed forever. We will not wait any longer. We demand ViiV and GSK stand with us and support generic access for CAB-LA.

A Call to Action

We call on ViiV and GSK to immediately initiate the following actions:

- Grant a publicly available, transparent, and public health-oriented license for CAB-LA to multiple generic suppliers, with a broad geographic scope (at least as broad as ViiV's license for DTG) and flexible, access-enabling terms.
- Conduct technology transfers (only if requested by the generic manufacturers) to ensure efficient, high-quality production and regulatory approval of generic CAB-LA.
- Ensure widespread registration of CAB-LA in high-burden countries.
- Facilitate access to a truly affordable bridging product in the near-term, and engage in ongoing evidence generation to support CAB-LA implementation.

⁴ The lowest innovator non-profit price for DTG 50mg (30 tablets) is \$20.11 while the first generic DTG 50mg (30 tablets) produced by Aurobindo entered the market priced at \$3.67.

Community Organization Endorsements

ABPF Benin
Activist Education and Development Centre
Afrique Arc-En-Ciel (AAEC)
Afrocab Treatment Access Partnership
Aides
Association of Positive Youths Living with HIV In Nigeria (APYIN)
Association Des Femmes Actives Et Solidaires (AFASO)
Association Espoir Pour Demain (AED)
Association Féminine Vision Positive (AFVIPO)
Association of Women Living with HIV In Senegal
Association Pour Le Bien-Etre Familial/Naissances Désirables DRC
Association Sante Scolaire (SASCO)
Association Togolaise Pour Le Bien Etre Familial (ATBEF)
AYARHEP
Bokk Yakaar
CBO 7 Days
Cbo Gà Vàng
Club Des 7 Jours
Coalition Of Women Living with HIV In Malawi (COWLHA)
Coalition PLUS
Community Of Women Living with HIV Lesotho
Concern Citizen of Shuni Progressive Union
CONERELA+
COLTMR CI
DACASA
Discordant Couple's Welfare Group
Emthonjeni Counseling and Training
Global Coalition of Women Against AIDS In Uganda (GCOWAU)
GNP+
Good Health Community Programmes
ICHANGE
ICW CA
ICW CI
ICW EA
ICW Togo
Long-Acting Technologies CAB (LAT CAB)
Lean On Me Foundation
Lesotho Network of People Living With HIV/AIDS
Liberia Network of Persons Living with HIV (LIBNEP+)
LVCT Health
MILOGO
National Network of Positive Women Ethiopians
National Network of Tanzania Women with HIV And AIDS (NETWO+)
Network Of African People Living with HIV West Africa, NAP+WA
Network Of People Living With HIV/AIDS In Nigeria (NEPWHAN)
Pan-African Treatment Access Movement
Pangaea Zimbabwe
PEPFAR DOD
Planned Parenthood Association of Ghana (PPAG)
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
Positive Response for Treatment Access, Adherence, and Support Foundation
REBAP+
RECAP+
Rede Moçambicana De Pessoas Vivendo Com HIV (MONET+)
Take Care of Human Being (TAHBE)
Tororo Forum for People Living with HIV Network
Treatment Action Group
Uganda Network on Ethics, Law & HIV/AIDS (UGANET)
UK Community Advisory Board
UMATI
Venus Social Enterprise
Vietnam Network of Young Key Affected Populations
Women Fighting AIDS In Kenya (WOFAK)
Y+ Kenya
Youth Arise Against HIV/TB In Kisumu

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