PROGRESSING ACCESS TO CAB LA FOR PREP

Africa Regional PrEP Learning Network

9 September 2024

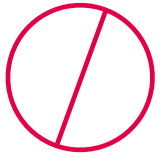
NP-GBL-CBT-PPT-240011 Sep 2024

OUR MISSION IS

ViiV Healthcare is the only biopharmaceutical company **100% focused on HIV.**

WHAT DO WE DO?

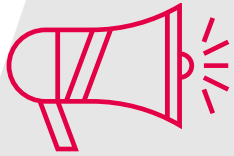
Leaving no person living with HIV behind means **playing an active role in all communities affected by HIV**.



WE TREAT.

Living with HIV is not one size fits all. **Treatments shouldn't be either.**

Our portfolio of treatments allows us to provide individual treatment options that work for all people living with HIV, no matter their story or background.



WE PREVENT.

Raising awareness and bringing preventative medicines to those who can benefit from them is a major part of what we do.

WE WORK TOWARDS A CURE.

Through our unique research partnerships, we bring together the best brains in the business, focusing on exploring every avenue, mechanism and compound **to find a cure for HIV.**

CAB LA FOR PREP ACCESS PLAN & ROADMAP

CAB LA FOR PREP L&MIC ACCESS PLAN

Today's focus

Critical Success Factors

- Activity areas that lead to sustainable in-country access
- Key updates per activity area

Partnerships, advocacy & community engagement

Global, regional, local partnerships

Community stakeholder engagement strategy

Product & clinical development	Regulatory, normative guidance & policy	Planning, coordination & financing	Supply chain & service delivery	User demand & continued use	Monitoring & evaluation
OLEs of HPTN 083 and HPTN 084 trials Q4M Ultra-long-acting formulation	Regulatory submissions & approvals (link here) WHO prequalification (PQ) WHO guidelines, national guidelines	Pricing Cost-effectiveness	Voluntary licensing (link here) Supply Implementation Science	Collaboration and partnership planning Materials for implementation	Collaboration and partnership planning

CAB LA, cabotegravir long-acting; **HPTN,** HIV Prevention Trials Network; **IS,** implementation science; **L&MIC,** low- and middle-income country; **OLE,** open-label extension; **PQ,** prequalification; **PrEP,** pre-exposure prophylaxis; **WHO,** World Health Organisation.

CAB LA FOR PREP ACCESS 10-YEAR ROADMAP

Stage 1:
Clinical research
and initial regulatory filings
2021–2022

- HPTN OLEs continue
- Initial registrations in HPTN countries
- Further submissions
- Global guidance development (e.g., WHO) and planning

Stage 2:
Catalytic phase
with ViiV product
2023–2024

- Implementation Science research projects to inform policies and guidelines
- Support roll-out in PEPFAR, Global Fund and other priority countries
- National registrations ongoing
- National guidelines developed, strategic plan inclusion (PEPFAR, Global Fund, and countries)

Stage 3:
Early scale-up
with ViiV product
2025–2027

- Scale up in first-wave countries
- Start roll-out in second wave countries

Stage 4:
Scale-up
with generic entry
2027* (earliest)

- Broader scale up enabled by additional capacity unlocked by generic entry (2027 best case scenario for generic drug [Gx] entry)

Support generic development under voluntary licences via tech transfer and know-how support

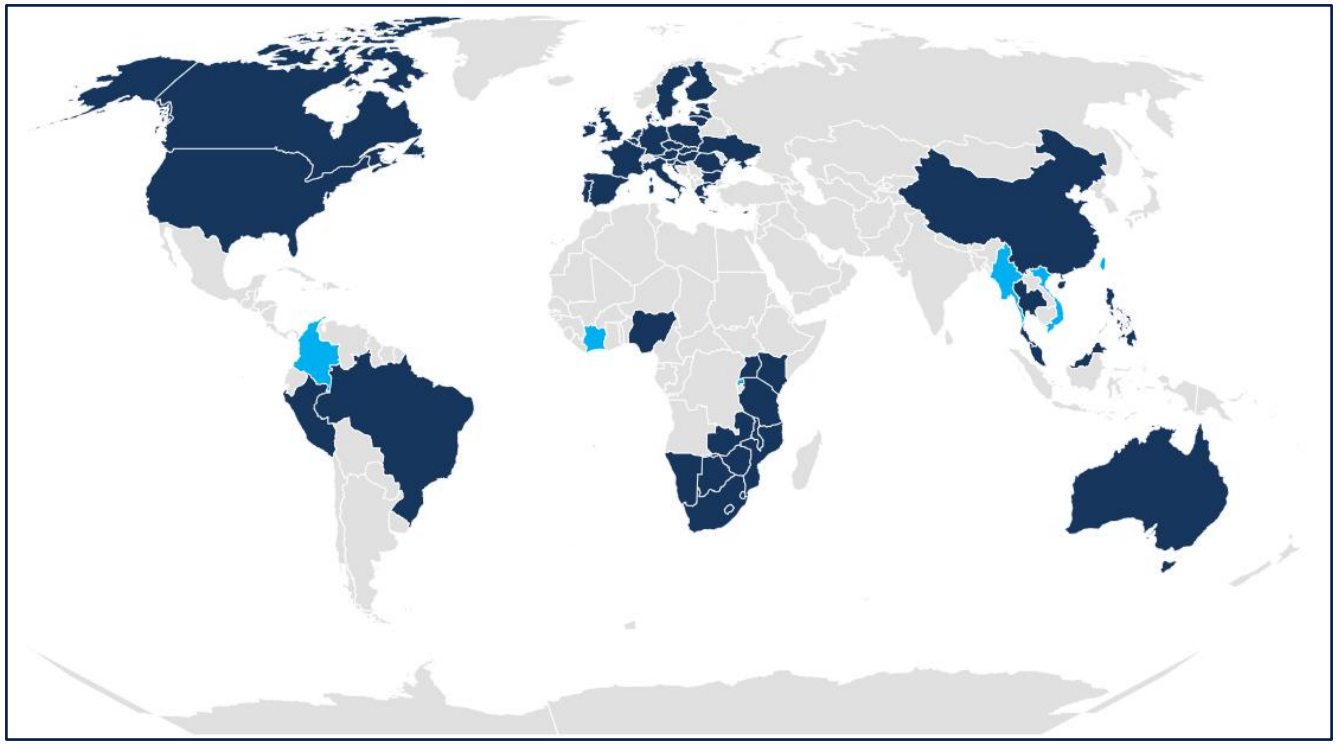
OLE, open-label extension

*2027 timeframe is a mutually agreed best estimate from MPP and ViiV

REGULATORY

VIIV REGISTRATION FOOTPRINT FOR CAB LA FOR PREP

- Geographically diverse global footprint
- Includes prioritisation for registration based on HIV burden and evaluation of PrEP readiness



Approved		
US	Zimbabwe	Australia
Malawi	South Africa*	Botswana
Brazil	Philippines	Malaysia
Peru	Zambia	EU
Nigeria	Uganda	Thailand
Mozambique	Tanzania	UK
Canada	China	Kenya
Ukraine	Namibia	

+ WHO pre-qualification

Registration submitted	
Colombia	Myanmar
Vietnam	Cote D'Ivoire
Taiwan	Rwanda

Points to note:

- Programmatic access in other countries is not necessarily dependent on registration status
- ViiV will support the use of alternative access pathways, such as import permits for programmatic access
- Will consider registering the product on a case-by-case basis

External Regulatory Affairs tracker: We improve our access to medicines (viivhealthcare.com)

*Eswatini and Lesotho recognises a South African registration, separate process will not occur.
2H, second half; **CAB LA,** cabotegravir long-acting; **EU,** European Union; **HIV,** human immunodeficiency virus; **PrEP,** pre-exposure prophylaxis; **NRA,** national regulatory agency.

SUPPLY

SUPPLY: VIIV STEPS TAKEN TO BRIDGE FROM NOW TO WHEN A VOLUNTARY LICENSEE MAY BE ABLE TO SUPPLY

	2022	2023	2024	2025	2026
PACK	Multi vial pack developed				
CAPITAL INVESTMENT	Additional mills committed	2nd Mill received, installation underway (Q3)	2nd Mill operational for supply, target end of Q3 '24		Target: 3rd Mill installation
BATCH PROCESS SCALE UP	Scale up process developed Submitted to FDA for approval	Scale up process approval received for US (Q2), Australia (Q2), South Africa (Q2)		Target approval for SSA countries*: May'25; operational use from H2'2025	

SSA = Sub-Saharan Africa

* Using Australia as reference market

VIIV SUPPLY STATUS: INCREASED SUPPLY FOR PROGRAMMATIC USE IN L&MICS

Supply	Strategy	2024	2025
Post-trial access for HPTN and other CAB for PrEP clinical trials	Continued supply	~ 12,500	Forecast ~27,000
Committed implementation studies	9 committed studies	~78,800	Forecast ~19,700

Programmatic supply	**Best endeavour to realise capacity**	**353,000 vials**	**600,000+ vials**

VOLUNTARY LICENCE & GENERICS

VOLUNTARY LICENSE AND GENERICS

*2027 timeframe is a mutually agreed best estimate from MPP and ViiV

THANK YOU