

## Community Position Statement:

# DRV/r Must Urgently Become the Preferred Protease Inhibitor Used in Adult Second-Line ART

Darunavir/ritonavir (DRV/r) is a highly effective and well-tolerated protease inhibitor that has been used to treat people living with HIV (PLHIV) for over a decade. Though DRV/r has seen significant utilization in many high-income settings, this has not been the case in low- and middle- income countries (LMICs) despite DRV/r's significant benefits. As demonstrated by clinical trials including ARTEMIS and ACTG Study A5257 among others, DRV/r is superior to or equally effective as other protease inhibitors such as lopinavir/ritonavir (LPV/r) and atazanavir/ritonavir (ATV/r), while also being safer, more tolerable, and having a higher barrier to resistance.<sup>1,2</sup> DRV/r, like all antiretrovirals (ARVs), has associated risks of some side effects, but fewer treatment-limiting side effects compared to LPV/r and ATV/r.

Community members have repeatedly voiced their frustration with the severe everyday challenges imposed by the side effects of LPV/r. As two community advocates recently expressed about their experiences on LPV/r:

***“LPV/r gave me really bad nausea, like terrible. It used to make me completely sick. LPV/r was horrible, it was horrible.”*** – Woman on 2L ART for several years

***“I used to be big and healthy, but since I started taking LPV/r, regardless of how much I eat, I have lost so much weight. It’s like my body is eating itself. I look like I am malnourished. And the diarrhea has been the worst. Even after all these years, it still continues.”*** – Woman on 2L ART for over a decade

While ATV/r is more tolerable than LPV/r, other side effects such as jaundice dramatically impact recipients of care's quality of life:

***“I cannot get a girlfriend because of my yellow eyes. Every time I try to approach a girl, she laughs at me because of my yellow eyes. I wish for a treatment that will make people more comfortable with themselves. Something that won’t lower their self-esteem.”*** – Man on 2L ART for several years

The side effects from LPV/r and ATV/r have been and remain insufferable for these community members. These negative reactions continue to adversely affect their ability to work and care for themselves and their families, while also threatening their adherence.

In spite of DRV/r's notable benefits, the use of LPV/r and ATV/r as the preferred protease inhibitors in LMICs has persisted due to the lack of an affordable fixed-dose combination (FDC) of DRV/r. However, the recent development of a quality-assured FDC of DRV/r that is now available at a price below that of LPV/r paves the way for the uptake of DRV/r in LMICs to replace poorly tolerated medicines.

We, as HIV community representatives and members, have been advocating for an improved protease inhibitor for use in second-line for many years, but we acknowledged that previous manufacturing difficulties and pricing challenges prohibited DRV/r's introduction. However, there are now no remaining barriers to DRV/r adoption and utilization. We demand that all global and national stakeholders rapidly adopt, procure, and introduce DRV/r so that those PLHIV that are poorly tolerating their medicines will finally have a path to a happier and healthier life.

<sup>1</sup> Orkin et al. (2012). *HIV Medicine*. Vol. 14, Issue 1.

<sup>2</sup> Lennox et al. (2014). *Annals of Internal Medicine*. Vol. 161, Issue 7.

## A Call to Action

**We call on the World Health Organization (WHO), National Governments, and Global Procurement Agencies to immediately undertake the following actions:**

**World Health Organization:** We call on the WHO to immediately update its guidelines to include DRV/r as the preferred protease inhibitor for use in second-line. While DRV/r is listed as an alternative second-line regimen, its significant clinical benefits and recent availability at a dramatically reduced price mandate its use as the preferred second-line protease inhibitor.

**National Governments:** We call on all national governments and ministries of health to swiftly update their national guidelines to make DRV/r the preferred protease inhibitor in second-line. We also call on national governments to rapidly commence procurement, implementation planning, and transition of PLHIV on LPV/r and ATV/r to DRV/r (except for the small number of people treated for TB) so that HIV communities around the globe can soon benefit from this life-saving medicine.

**Global Procurement Agencies:** We call on major procurement agencies to make a firm directive and work with partner governments to procure DRV/r in place of ATV/r and LPV/r for second-line patients on protease inhibitors.

***We raised our voices for first-line treatment, and you answered the call. Now, for our family members, friends, and communities on second-line treatment, we are raising our voices once again for DRV/r. We urge you to act now.***

## Community Organization Endorsements

100% Life

AfroCAB Treatment Access Partnership (AfroCAB)

Associação Kuvumbana

Association of Positive Youth Living with HIV & AIDS in Nigeria (APYIN)

Association Togolaise pour le Bien-être Familial (ATBEF)

Bokk Yakaar

Coalition of Organizations of Women Living with HIV in Ivory Coast

Community Initiative for Tuberculosis, HIV/AIDS, and Malaria Plus (CITAM Plus)

Community of Women Living with HIV in Malawi (COWLHA)

Community of Zambian Women Living with HIV (COZWHA+)

Eswatini Coalition on TB

Global Coalition of Women Against AIDS in Uganda (GCOWAU)

Global Network of PLHIV (GNP+), The Netherlands HIV i-Base

International Community of Women Living with HIV (ICW) - Kenya Chapter

Lean on Me Foundation

Lesotho Network of People Living with HIV and AIDS

Nairobi Youth Advisory Council

National Network of Tanzania Women with HIV/AIDS (NETWO+)

Network of Zambian People Living with HIV (NZP+)

Nyamira Post-HIV Test Group

Pan-Africa Positive Women Coalition - Eastern Africa Regional

Pan-African Positive Women's Coalition

Pan-African Positive Women's Coalition - Zanzibar

Pan-African Treatment Access Movement

Pangaea Zimbabwe Aids Trust (PZAT)

Partnership of Women Against HIV/AIDS in Tanzania

People Plus

Phakama Africa

PLAN Health Advocacy and Development Foundation

Positive Response for Treatment Access Adherence and Support Foundation

Positive Women Together in Action of Eswatini

Princes of Africa Trust

Sauti Skika Adolescents Living with HIV Network

Tanzania National Network of Girls and Young Women

Affected and Living with HIV/AIDS (TANGYWA+)

Treatment Action Group (TAG)

UK Community Advisory Board

Ushering Hope Trust

Women Fighting AIDS in Tanzania (WOFATA)

WOTE Youth

Y+ Kenya

Zimbabwe National Network of People Living with HIV

Zimbabwe Young Positives (ZY+)

## Individual Signatories

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