

## **Communique of the Kigali Dolutegravir Stakeholder Meeting of African Women**

### **Living with HIV**

We, the thirty-nine women living with HIV representing 18 countries, met in Kigali on July 13 and 14 to discuss the potential neural tube defect (NTD) safety signal in women taking dolutegravir (DTG) at conception and develop a joint position on behalf of women for access to optimal HIV treatment and prevention.

#### KEY OUTCOMES

##### Discussion

We deliberated on the potential safety signal data from the Botswana Tsepamo study and determined unanimously based on the data currently available that DTG's benefits – reduced side effects, improved efficacy, and a high barrier to resistance – outweigh its potential risks.

Although this decision was reached unanimously, DTG, like all ARVs, has associated risks of side effects, including adverse birth outcomes. For example, the rate of any adverse birth outcomes with use of efavirenz (EFVs) is 36 percent.<sup>1</sup> Furthermore, the risks associated with EFV use in settings with high rates of background EFV resistance must be recognized and factored into this evaluation of risks and benefits, just as the potential risk of adverse birth outcomes for women on DTG must be weighed against the benefits of DTG for the mother and unborn baby. However, the short and long-term side effects of EFV, and the associated impact on individuals and families, cannot be ignored simply because it has been in use longer than DTG. Meeting participants repeatedly expressed the severity of everyday challenges that they encounter using EFV, including fatigue, forgetfulness, depression, and even suicidality. These side effects discouraged them from continuing to use the drug, or negatively affect their ability to work and care for themselves and their families. As one meeting participant expressed:

1 Zash R. 9th IAS Conference Abstract MOAX0202LB

“On TLE, I felt dizzy, tired, couldn't work, and couldn't take care of my small kids properly. It's been one month since I started using it [DTG]. It's a big change. I'm active, my kids are happy because they have an active mother, and I can do my work without depending on anybody.”

As a result of these struggles, and the lack of conclusive evidence linking DTG to increased risk of NTDs, we, the women living with HIV at this meeting, concluded that blanket exclusions that deny women equitable access to this optimal HIV treatment are not warranted or justified.

The following are key takeaways and recommendations for policymakers:

##### Takeaways

We reviewed the existing data and believe the potential risk to be an exposure similar to the other ARV treatments that are currently available to women.

We strongly believe in our diversity – not all women seek to have children.

We believe in our ability to make decisions about our reproductive health, including when to have children and what medications are best for us.

We are disappointed at our lack of involvement in decision making in regards to our treatment access.

We believe that with correct information and contraceptive access and support we are able to make informed choices in using DTG and planning our pregnancy. When ARVs first became available years ago, some people said that Africans should not be allowed to access them because they did not have watches and could not tell time to know when to take their medicine. Those people were wrong then, and they are wrong today when they say that African women are incapable of making an informed choice.

We strongly believe that this is an opportunity for integrating the much-needed access to contraceptives within HIV treatment and care in order to achieve universal reproductive health care for all.

#### Recommendations

Policy makers and stakeholders must not deny us, women living with HIV, access to DTG regardless of our childbearing potential.

Global stakeholders and national programmes should strengthen HIV and SRH services to ensure access to DTG together with acceptable, available, affordable and accessible contraception to women and girls.

Global stakeholders and national programmes should better integrate HIV, sexual and reproductive health (SRH), and other treatment support services, such as viral load monitoring and resistance testing.

We, the women living with HIV, should not be forced or coerced to take a particular medication and should be provided adequate information to make informed choices.

Health care workers and ministries of health should clearly communicate the short and long-term side effects of ARVs to enable us to make informed decisions.

Key stakeholders and national programmes must involve us, the women living with HIV, in local, national, and global discussions and decisions regarding HIV treatment options.

Research studies must make deliberate effort to include women in clinical trials and studies.

National programmes must strengthen surveillance systems in order to detect any and all potential risk and harm due to use of ARVs.

#### Action Required

We strongly urge key stakeholders – especially national programmes and global partners – to respect the voices of those affected by HIV. The actual women living with HIV must be consulted in the guidance offered by global and national bodies, especially now in light of the potential early NTD signal with DTG. We are calling for TLD to be made available urgently across Africa, with everyone having access, regardless of gender or reproductive capability, and with integration of sexual and reproductive health services.

It is critical to not just view a pregnant mother, or any woman of childbearing potential, as a vessel for a baby, but as an individual in her own right, who deserves access to the very best, evidence-based treatment available and the right to be adequately informed to make a choice that she feels is best for her. As a result, women must not be forced to accept any one ARV regimen. All women should be able

to make an informed choice for their own treatment and we call on key stakeholders to join us and help us make access to TLD, and improved health services, a reality for everyone.

NOTHING FOR US WITHOUT US.

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