Resolution n°6-2020-e

Cost Extension for three ARV Clinical Trial Projects (“TRIO”)

Recalling three Unitaid Board Resolutions in which the Executive Board approved the commitment of funds for three separate projects to support clinical trials aimed at generating important information on optimal antiretrovirals (the “ARV Clinical Trial Projects”), as listed below:

- R14-2016-e approving the commitment of up to US$ 8,981,030 to University of Liverpool for the “DolPHIN2: Dolutegravir in Pregnant HIV Mothers and Neonates” project;
- R16-2016-e approving the commitment of up to US$ 13,203,856 to Wits Health Consortium (Pty) Ltd on behalf of Wits RHI (now Ezintsha) for the “Safer, More Robust and Less Expensive Antiretroviral First-Line Therapy (ADVANCE Trial)” project; and
- R3-2016-e approving the commitment of up to US$ 2,622,755 to Institut Bouisson Bertrand (IBB) for the “Enabling access to a robust and well-tolerated new-generation first-line antiretroviral treatment in low-income countries (ANRS 12313 - NAMSAL Trial)” project;

Taking into account the Secretariat’s recommendations and acknowledging the need to investigate emergent safety signals in relation to dolutegravir, including recently observed clinical obesity, the Executive Board authorises, subject to availability of funds, the Executive Director to commit additional funding and extend the duration of each of the ARV Clinical Trial Projects as follows:

- Additional funding of up to US$ 1,943,782 to University of Liverpool and an extension to project duration of 9 months for the DolPHIN2 Trial;
- Additional funding of up to US$ 6,900,381 to Wits Health Consortium (Pty) Ltd on behalf of Ezintsha and an extension to project duration of 2 years and 5 months for the ADVANCE Trial; and
- Additional funding of up to US$ 638,557 to IBB and an extension to project duration of 7 months for the NAMSAL Trial.

The additional funding and extension to the duration of each of the grants is conditional upon signature of amendments to the legal agreements between Unitaid and each of the three lead grantees.

Marisol Touraine
Chair of the Unitaid Executive Board

Date: 27 May 2020