

Paris, 24 July 2019

Press release

Results from the NAMSAL study confirm that dolutegravir is a good alternative treatment of HIV infection in low-income countries

The NAMSAL (New Antiretroviral and Monitoring Strategies in HIV-infected Adults in Low-income countries) study, co-funded by Unitaid and ANRS, is the first of its kind to compare in real-life conditions two treatments of HIV infection, one dolutegravir-based and the other based on efavirenz 400 mg. Until now, there has been no direct comparison of the action of these two drugs in countries with limited resources. Coordinated by Eric Delaporte (Université de Montpellier, Inserm, IRD) and Charles Kouanfack (Hôpital Central Yaoundé, Faculté de médecine, Université de Dschang), NAMSAL shows that dolutegravir is not inferior to efavirenz in real-life conditions, confirming the latest World Health Organization guidelines. The results are published today in [The New England Journal of Medicine](#).

The [latest World Health Organization \(WHO\) guidelines updated in December 2018](#) recommend first-line treatment of HIV infection based on dolutegravir¹ (DTG), as an alternative to efavirenz 400 mg-based treatment (EFV 400)². This recommendation was based on study findings showing that DTG was superior to EFV 600 in terms of both efficacy and safety. Alternatively, the safety of EFV 400 was good for an efficacy comparable to that of EFV 600. However, these results were recorded following studies in high-income countries in populations not comparable to those living in countries with limited resources. In particular, the results were recorded in women whose viral load was generally higher at the start of antiretroviral treatment and who were infected by HIV-1 strains different from those in developed countries.

NAMSAL is the first study to compare two treatments (EFV 400 and DTG) in combination with tenofovir and lamivudine in a country of limited resources. This phase 3, randomized, open study was conducted in Yaoundé in Cameroon between 2016 and 2018 in 613 people living with HIV

¹ With a note of caution regarding the use of DTG during periconception and in women and teenage girls of childbearing age, because of the potential risk of malformation of the neural tube when DTG is used during the first trimester of pregnancy.

² EFV 400 is better tolerated than the usually prescribed EFV 600 and is available in fixed-dose combination tablets.

who had never taken antiretroviral treatment. Coordinated by Eric Delaporte (Université de Montpellier, Inserm, IRD) and Charles Kouanfack (Hôpital Central Yaoundé, Faculté de médecine, Université de Dschang), the results published today not only show that DTG was not inferior to EFV 400 after 48 weeks of treatment, but also that the risk of development of resistance to treatment was lower with DTG.

That said, irrespective of the drug used, the results obtained are not as good as those recorded in higher-income countries, mainly because of the high viral load in people at initiation of treatment. This emphasizes the importance of screening to enable early treatment and the need to conduct such studies in countries with limited resources. Furthermore, the study confirms that weight gain and the risk of obesity are greater with DTG than with EFV 400.

According to Unitaïd Deputy Executive Director Dr Philippe Duneton, "*This trial is the first of its kind to supply comparative data on the use of dolutegravir in people living with HIV in low-income countries such as Cameroon. Unitaïd values the great importance of the partnership with ARNS and WHO, because it will accelerate access to better HIV treatment.*"

📌 For more information

Dolutegravir or Low Dose of Efavirenz-based regimen for the Initial Treatment of HIV-1 Infection

The NAMSAL study group

Charles Kouanfack, MD, PhD; Mireille Mpoudi-Etame, MD, MPH; Pierrette Omgba Bassega, MD; Sabrina Eymard-Duvernay, MSc; Sandrine Leroy, MD, PhD; Sylvie Boyer, PhD; Martine Peeters, PhD; Alexandra Calmy, MD, PhD; Eric Delaporte, MD, PhD
University of Dshangand Central Hospital of Yaoundé, Cameroon (C.K.);
Military Hospital of Yaoundé, Cameroon (M.M.N.);
Cité Verte Hospital, Yaoundé, Cameroon (P.O.B.);
TransVIHMI, University of Montpellier-IRD-INSERM, Montpellier, France (S.E.D., S.L., M.P., E.D.);
SessTim, Université Aix Marseille-IRD-INSERM (S.B)
Geneva University Hospitals, Geneva, Switzerland (A.C.)

The New England Journal of Medicine, n° , pp,

D.O.I. : doi.org/10.1056/NEJMoa1904340

📌 Research contact

Professor Eric Delaporte

eric.delaporte@umontpellier.fr

[Tel 06 80 43 52 40](tel:+33477123456)

Dr Charles Kouanfack

Faculté de Médecine et des Sciences Pharmaceutiques, Université de Dschang

Chef de service Hôpital de Jour Hôpital Central de Yaoundé

charleskouanfack@yahoo.fr

Tel : +237 699 95 07 43

📌 ANRS press contacts:

Séverine Ciancia 01 53 94 60 30 - **Marc Fournet** 01 53 94 80 63 information@anrs.fr

📌 IRD press contact:

Cristelle Duos / 04 91 99 94 87 / presse@ird.fr

About ANRS:

The ANRS is a funding body that coordinates research on HIV/AIDS and hepatitis. The ANRS runs, evaluates, coordinates, and finances research programs, whatever the scientific field concerned (basic, clinical, public health, or vaccine research). The ANRS brings together in France and abroad researchers from all disciplines. Its annual budget of around 50 million euros is principally provided by the French Ministry for Higher Education, Research, and Innovation and by the French Ministry of Health. The ANRS has been an autonomous agency of Inserm since 2012. www.anrs.fr | @agenceANRS

About IRD:

The IRD is a French public establishment operating under the joint authority of the French Ministry for Higher Education, Research, and Innovation and the French Ministry for Europe and Foreign Affairs. Via its network and presence in fifty or so countries, it takes an original approach to research, expertise, training, and knowledge-sharing to the benefit of countries and regions that make science and innovation key drivers in their development. The IRD priorities are part of efforts to implement the sustainable development goals (SDGs) adopted in September 2015 by the United Nations and to perform critical analyses. The aim of the SDGs is to orient development policies and tackle the challenges related to overarching environment, economic, social, and cultural changes that affect the whole planet. www.ird.fr

About Unitaid:

Unitaid brings the power of new medical discoveries to the people who most need them and sets the stage for their large-scale introduction by governments and partners such as PEPFAR, the Global Fund, and WHO. Unitaid invests in innovations to prevent, diagnose, and treat HIV/AIDS, hepatitis C, tuberculosis, and malaria more quickly, affordably, and effectively. A growing number of our projects address more than one disease, thus maximizing the effectiveness of health systems as a whole. www.unitaid.org