

Paris, 25 July 2017

Press release

On-demand PrEP and infrequent sexual intercourse

The ANRS IPERGAY trial, directed by Prof Jean-Michel Molina from Hôpital Saint Louis, AP-HP, and University of Paris Diderot, demonstrated in its randomized phase, the efficacy of on-demand pre-exposure prophylaxis (PrEP) in men who have sex with men and who reported high-risk behavior to prevent HIV acquisition. Now, a substudy of ANRS IPERGAY reveals that on-demand PrEP is also effective in participants who have infrequent sexual intercourse and take fewer tablets of PrEP. Dr Guillemette Antoni will present these results on 25 July 2017 in an oral communication, during the 9th Conference on HIV Science (IAS 2017), organized by the International AIDS Society and the ANRS in Paris from July 23rd to 26th 2017.

In addition, the results of the open-label extension of the ANRS IPERGAY trial, which followed the randomized phase from November 2014 to June 2016, are published in *The Lancet HIV* online on July 24, 2017. They show that on-demand PrEP remains well tolerated and reduces by 97 % the incidence of HIV infection among men who have sex with men and report high-risk behavior. Also, there was no significant increase in the rate of other sexually transmitted infections.

Pre-exposure prophylaxis, or PrEP, is a preventive antiretroviral treatment of HIV infection administered orally as tablets of TDF-FTC Truvada®. PrEP has been the subject of several studies, including the ANRS IPERGAY trial coordinated by Prof Jean Michel Molina, the head of the Infectious Diseases Department at the Hôpital Saint Louis, AP-HP, in collaboration with his colleagues and the NGO AIDES (see below). The aim was to assess the efficacy of on-demand treatment: 2 tablets before intercourse, 1 tablet 24 hours after the first dose, and 1 tablet 48 hours after the first dose. ANRS IPERGAY was conducted in seronegative men who have sex with men (MSM) and who report high-risk behavior for HIV transmission. The results¹ of the first, randomized (volunteers divided into two groups: one on Truvada®, the other on a placebo) phase of this study showed that on-demand PrEP was 86 % effective.

ANRS IPERGAY was conducted in close collaboration with the NGO AIDES, which provided support to the volunteers throughout the trial and participated actively in developing community-based research and in recruitment of participants. The trial was performed in Paris (AP-HP), at the Hôpital Saint-Louis and the Hôpital Tenon, in Lyon, Nice, Tourcoing, and Nantes, and also in Montreal (CHUM) in partnership with the nonprofit organization Rezo. INSERM SC10 coordinated the trial.

On-demand PrEP when sexual intercourse is infrequent

In the randomized phase of ANRS IPERGAY, the participants took a median of 15 tablets/month and had a median of sexual intercourse 10 times a month. The researchers wondered, therefore, whether on-demand PrEP would also be effective in MSM who have less frequent sexual intercourse and therefore take fewer tablets. They analyzed therefore the trial periods when participants were taking fewer than 15 tablets/month, but at each sexual intercourse, which corresponded to a median intake of 9.5 tablets/month and to a median of 5 sexual intercourses per month. In this analysis, 6 HIV infections occurred, all in the placebo arm. In other words, no infection was seen among participants whose on-demand intake of Truvada®, which was adapted to their sexual activity, was low. These results support the efficacy of on-demand PrEP in participants with less frequent sexual intercourse. Dr Guillemette Antoni (Inserm, SC10-

US19) will present these results on 25 July 2017 in an oral communication, during the 9th IAS Conference on HIV Science, organized by the International Aids Society and the ANRS in Paris from 23 to 26 July 2017.

PrEP efficacy: another step forward

Following the results of the randomized phase of the ANRS IPERGAY trial, an open label extension was implemented in November 2014 (all participants received on-demand Truvada®) to assess whether the clinical benefits observed in the blind phase were maintained, and also to assess long-term safety, effect on sexual behavior, and the incidence of other sexually transmitted infections (STIs). The results presented last year at the 21st International AIDS Conference in Durban, will be published in *The Lancet HIV* online on July 24, 2017, during the IAS 2017 in Paris. During this 18-month open label extension phase of the trial among 362 volunteers, only one participant (who discontinued PrEP) acquired HIV infection and there was no increase in the incidence of other STIs. These data confirm that on-demand PrEP is well tolerated and highly effective (97 %) in reducing the incidence of HIV infection in this high risk population.

“All together, these data support the high efficacy of on-demand PrEP to prevent HIV infection among MSM with high risk behaviors” concludes Jean-Michel Molina.

¹ Molina et al. New England Journal of Medicine Dec 3, 2015

Press release : <http://www.anrs.fr/en/presse/communiqués-de-presse/327/treatment-taken-time-sexual-relations-reduces-risk-hiv-infection>

Sources:

Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. The Lancet HIV, 24 July 2017: [http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(17\)30089-9/fulltext?elsca1=tlxpr](http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(17)30089-9/fulltext?elsca1=tlxpr).

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On-Demand PrEP with TDF/FTC remains highly effective among MSM with infrequent sexual intercourse: A sub-study of the ANRS IPERGAY trial. Presented at the IAS Conference, Paris July 25 2017.

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