

Paris, 23 July 2019

## Press release

# On-demand or daily PrEP: ANRS Prévenir study confirms that these two biomedical prevention strategies are very effective and safe

The ANRS Prévenir study offers prevention based on daily or on-demand PrEP (preexposure prophylaxis) to seronegative volunteers at high risk of HIV infection in and around Paris, France. ANRS Prévenir reached its recruitment target of 3000 participants 2 years after its May 2017 inception. Data analysis on 13 June 2019 confirmed the excellent efficacy of PrEP, with only two cases of HIV infection in participants who had discontinued PrEP several weeks before. These results are presented today by Jean-Michel Molina (Hôpital Saint-Louis, AP-HP and Université de Paris) at the [10th IAS Conference on HIV Science \(Mexico City, 21-24 July 2019\)](#).

The ANRS Prévenir study started in May 2017 and is a follow-up study of the ANRS Ipergay trial, which showed that on-demand PrEP (preexposure prophylaxis), also called event-driven PrEP was effective in French and Canadian seronegative volunteers at high risk of HIV infection (99% of whom were men who have sex with men [MSM]).

On-demand PrEP uses a short 4 pill dosing strategy before and after a sex event as an alternative to routinely taking a daily pill to achieve protection against sexual exposure to HIV. The so-called “2+1+1” approach involves a double dose of 2 pills taken between two and 24 hours before sex, then, a third pill 24 hours after the first two pills, and a fourth pill 48 hours after the first two pills.

ANRS Prévenir is seeking to improve the availability of PrEP in and around Paris, France, and to assess the impact of this preventive strategy on the HIV/AIDS epidemic in this region. The study is led by Jean-Michel Molina, Dominique Costagliola (Institut Pierre Louis d'Epidémiologie et de Santé Publique, Inserm, Sorbonne Université, Paris, France), Jade Ghosn (Hôpital Bichat, APHP, Inserm, Université de Paris), and Daniela Rojas Castro (AIDES- Coalition PLUS), and the study co-investigators, in partnership with the nonprofit organization AIDES, and is supported by Sidaction and Gilead.

Of the 3057 volunteers included, 56% were already using PrEP. In the study, 49% of the volunteers used on-demand PrEP. Those volunteers who used daily PrEP had more partners and used condoms less often. However, 20% of sexual intercourses are protected by condoms (provided at quarterly follow-up visits).

After a follow-up of over 2000 person-years, the incidence of HIV was very low—0.09 new infections for 100 person-years of follow-up—which corresponds to about 143 infections avoided based on the incidence of HIV observed in the placebo group of the Ipergay trial. In all, only 2 people to date have been infected by HIV during the follow-up of the ANRS Prévenir study. They had been using PrEP for more than 2 years, but interrupted it completely 7 to 10 weeks before the infection occurred. This underscores the importance of adherence to the dosing schedule chosen, either daily or on-demand PrEP for protection against HIV infection and of resumption of condom use if PrEP is stopped. The safety of daily or on-demand PrEP was high, as during the study only 3 people had to interrupt PrEP because of gastrointestinal side effects (nausea, diarrhea, vomiting).

In view of these encouraging results in real-life conditions in a large number of participants, the authors conclude that PrEP, daily or on-demand at the time of sexual relations, is highly effective in protecting against HIV infection.

The findings from the ANRS Ipergay and ANRS Prévenir studies provided evidence for the World Health Organization to update its recommendation for oral PrEP to include an option of event-driven/on-demand dosing for men who have sex with men. A technical brief detailing the evidence and considerations for event-driven PrEP implementation is being released by WHO during the 10<sup>th</sup> IAS conference in Mexico City (available at: [www.who.int/hiv/pub/prep/211/](http://www.who.int/hiv/pub/prep/211/) ). Dr. Rachel Baggaley, WHO Coordinator for Key Populations and Innovative HIV Prevention stated *“WHO is pleased to see these exciting results. Building on this evidence we are releasing a new technical brief to provide guidance to countries on an event-driven PrEP option for men who have sex with men, allowing people greater choice, flexibility and convenience for HIV prevention.”*

New studies will soon be put in place in the ANRS Prévenir research program, the aim being to shed light on the mechanism of action of PrEP and on PrEP use by 18- to 25-year-olds, and also to prevent the risk of hepatitis C virus infection and of sexually transmitted bacterial infections.

### **ANRS Prévenir study**

ANRS Prévenir is designed to assess the public health impact of the roll-out of PrEP in the Paris area. The aim is to reduce the number of new infections by 15% in three years, principally among MSM, who are the most exposed to HIV. The study is also assessing the impact of personalized support offered by community stakeholders and coordinated by the nonprofit organization AIDES, and of the prevention and management of other sexually transmitted infections, with a view to improving the sexual health of vulnerable people.

**For whom? How?** PrEP consists of the administration in a single tablet of two antiretrovirals, which are generally prescribed for the treatment of HIV infection and which can also be used in prevention of HIV infection in seronegative people who are at high risk of HIV infection because of insufficient use of condoms. The study volunteers can choose to take one PrEP tablet every day or to take a tablet whenever they anticipate having sexual intercourse (a tablet must be taken at least 2 h before sex and again on each of the next 2 days). PrEP is available in France as generic medication.

**ANRS Prévenir recruitment** In addition to hospital centers, volunteers are recruited at centers offering free information, screening, and diagnosis (CeGIDD), and in community health centers like Le 190 and CheckPoint-Paris.

➤ **For more information**

<http://programme.ias2019.org/Abstract/Abstract/1057>

[www.prevenir.anrs.fr](http://www.prevenir.anrs.fr)

**NB. TIME DIFFERENCE:**

**Paris time minus 7 hours = Mexico City time  
(When it's 14.00 in Paris, it's 7.00 in Mexico City)**

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