



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

First medicine for HIV pre-exposure prophylaxis recommended for approval in the EU

Truvada to enhance existing HIV prevention strategies

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Truvada (emtricitabine / tenofovir disoproxil) for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually-acquired human immunodeficiency virus type 1 (HIV-1) infection in adults at high risk. PrEP is a way for people who do not have HIV but who are at high risk of infection with HIV to lower their chances of becoming infected should they be exposed to the virus.

Truvada is the first medicine recommended to reduce the risk of HIV infection in the EU. It is to be used as part of an overall HIV infection prevention strategy, notably including condom use, that can not only prevent HIV infection but also other sexually transmitted infections.

While this approval for PrEP is new, Truvada is not a new medicine. It was first authorised in the EU in 2005 in combination with at least one other antiviral medicine to treat adults infected with HIV-1.

The main interventions currently used to prevent HIV-1 transmission in the EU are voluntary testing to allow people to learn about their HIV status, risk counselling and the promotion of condom use. However, in view of the increasing number of new HIV infections worldwide, the current range of prevention with screening, counselling and condom use needs further intensification.

Truvada contains two active substances, emtricitabine and tenofovir disoproxil, which is a 'prodrug' of tenofovir. This means that it is converted into tenofovir in the body. Emtricitabine and tenofovir work in similar ways by blocking the activity of viral reverse transcriptase, which is necessary for the virus to multiply.

The Committee for Medicinal Products for Human Use (CHMP) based its decision on two main studies which showed substantial reductions in the risk of HIV-1 infection when Truvada was used as PrEP.

In one of these, the iPrEx study, Truvada reduced the risk of HIV infection by 42% in HIV-negative men or transgender women who have sex with men and who were considered at high risk of HIV infection. The study compared Truvada with placebo (a dummy treatment) in 2,499 people who showed high-risk behaviour such as inconsistent or no condom use during sex.



In the second study (Partners PrEP trial) Truvada reduced the risk of becoming infected by 75% in the heterosexual partners of HIV-positive men and women. This study involved 4,758 heterosexual couples where one partner was HIV-positive and the other was not (serodiscordant couples), and evaluated the efficacy and safety of Truvada or tenofovir alone versus placebo.

Both studies showed that the better the adherence to daily treatment with Truvada the better the protection against HIV-1 infection.

The adverse events reported during the clinical trials of Truvada for PrEP were similar to those seen with Truvada used for the treatment of HIV-1 infection, including diarrhoea, nausea, tiredness, headache and dizziness.

CHMP noted that not all studies conducted in the EU on Truvada as PrEP were submitted as part of this application.

The opinion adopted by the CHMP at its July 2016 meeting is an intermediary step on Truvada's access to patients. The CHMP opinion will now be sent to the European Commission for the adoption of a decision to change the marketing authorisation. Once the extension of indication has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Truvada is Gilead Sciences International Ltd.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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