Gilead Seeks Approval of Truvada as PrEP in Europe

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Gilead Sciences has filed for approval of Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) against HIV with the European Medicines Agency (EMA). If validated by the EMA, PrEP will be approved for use along with safer sex practices in all 28 member states of the European Union.

“In Europe, 2014 saw the highest number of HIV diagnoses recorded in any given year—nearly 30,000—highlighting the substantial need for additional strategies to help address the epidemic,” Sheena McCormack, MSc, FRCP, a professor of clinical epidemiology at University College London and the chief investigator of the U.K. PROUD study of PrEP among MSM, said in a press release. “We are excited by the potential public health impact Truvada for PrEP may have, as part of a comprehensive HIV prevention strategy, in lowering transmission rates among at-risk populations across Europe.”

PrEP was approved in the United States in 2012. After a slow start, its use has risen dramatically over the past two years. In 2015, the HIV prevention method was approved in Kenya and South Africa, and was also given a temporary recommendation for use in France. Approval is pending in Australia, Brazil, Canada, Peru and Thailand.

The EMA application is based on the results of two large placebo-controlled trials of Truvada as PrEP, iPrEx and Partners PrEP.

“The EMA filing for Truvada for PrEP is timely given the growing body of evidence supporting its use in preventing HIV and the interest expressed by the medical and patient advocacy communities,” Norbert W. Bischofberger, PhD, Gilead’s executive vice president of research and development and chief scientific officer, said in the same press release. “Appropriate use of Truvada for PrEP is supported by European AIDS Clinical Society and World Health Organization guidelines, and Gilead believes it is an important HIV prevention tool that, when taken as directed and used in combination with other prevention strategies, has the potential to help reduce new HIV infections.”

The most commonly reported side effects of PrEP in all studies have included headache, stomach discomfort and weight loss.

To read the Gilead press release, click here.

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http://beta.docker.poz.com/article/Europe-PrEP-application-28330-3552