Tenofovir HIV Prevention Gel to Be Fast-Tracked for FDA Approval

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Conrad, a nonprofit scientific organization based in Arlington, Virginia, and dedicated to reproductive health, has announced that the U.S. Food and Drug Administration (FDA) has granted "fast track" approval to the group's tenofovir-based HIV microbicide. This facilitates the development and expedites the review of the organization's vaginal gel, which has shown promise in preventing HIV transmission.

On July 20, researchers at the XVIII International AIDS Conference (IAC) in Vienna reported that a 1 percent tenofovir vaginal gel—a drug that is also being tested orally to prevent infection and that is currently approved as an oral medication to treat the disease in those already infected—cut male-to-female HIV transmission by 39 percent, and herpes infections by 51 percent. These results sparked widespread enthusiasm about the gel and reinvigorated a field that had suffered one failure after another in recent years.

The researchers who reported these promising results from the CAPRISA 004 study cautioned that further trials would be needed to confirm the gel's efficacy and to better understand how to use it. Nevertheless, the biggest question on the minds of advocates and scientists was how quickly the gel could become available if it were found to be efficacious.

To help answer that question, Conrad, along with other key stakeholders, met with the FDA on October 20 for an "end of Phase II" meeting to chart the course for the ultimate approval of the gel. During the meeting, the FDA confirmed that a currently ongoing trial, called VOICES, would be sufficient—when combined with the CAPRISA 004 results—for Conrad to file a new drug application (NDA) for FDA approval.

The FDA further agreed to allow the company to speed up its data submission process, provided that Conrad conducts additional studies to chart the efficacy and safety of the gel in adolescent and post-menopausal women, as well as potential interactions with other vaginal products.

Rather than waiting for all of these studies to be complete before reviewing the application for approval, the FDA will conduct a "rolling review," thus allowing Conrad to submit new data as it becomes available. This process could significantly speed the approval process and potentially ensure that the gel is available by 2014.

Though FDA approval is not required to sell the gel in other countries, it is required for use by women in the United States. FDA approval would also likely be required if the U.S. Congress were to approve funding to purchase and distribute the product in resource-poor nations.

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