Novel HIV-Associated Diarrhea Drug Crofelemer Goes to FDA for Approval Review

December 15, 2011

Raleigh, North Carolina-based Salix Pharmaceuticals announced on Tuesday, December 14, that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting approved for Crofelemer, a novel therapy for HIV-associated diarrhea.

Modern antiretroviral (ARV) medication has dramatically improved the lives and health of people with HIV. Not only are the rates of diseases that cause chronic diarrhea a fraction of what they once were, but most medications that once caused or worsened diarrhea are no longer commonly used.

However, according to Salix and the drug's primary developer, Napo Pharmaceuticals, thousands of HIV-positive people in the United States and millions of people in other parts of the globe still struggle with chronic diarrhea. What's more, the condition can be more than merely unpleasant—it can have serious health consequences, including dehydration and the loss of life-sustaining nutrients from the body. Unfortunately, current remedies for diarrhea can have side effects and none of the meds were meant to be taken constantly for weeks or months at a time.

Crofelemer—which is based on a plant native to South America and is being sustainably harvested by growers there—acts by a different mechanism than current anti-diarrheal medications. Rather than being taken up systemically into the whole body, it acts locally in the gut and helps regulate the amount of water in the intestines. It also doesn't interact with other medications.

The NDA filed by Salix includes data from a Phase III clinical trial dubbed the ADVENT study. The trial first pitted three doses of Crofelemer against a placebo for four weeks in 50 people with chronic watery diarrhea. Once data from the first round were collected, 180 additional people were randomized to receive either the selected dose (125 milligrams twice daily) or a placebo.

Though the full data have not yet been presented, Napo reported in November 2010 that the selected dose reduced diarrhea to less than two watery stools for two weeks of a four-week period—a significant reduction compared with the placebo.

By regulation, the FDA has 60 days from the date of the NDA submission to conduct a filing review

to determine if the application is sufficiently complete to permit a substantive review.

If the drug is ultimately approved, Salix, after entering into a collaboration agreement with Napo, has an exclusive license to the HIV-associated diarrhea indication for Crofelemer and the additional indications of pediatric diarrhea and acute infectious diarrhea in North America, several Europe countries and Japan. Salix also has a worldwide license to all other possible human indications, including irritable bowel syndrome, for Crofelemer.

Napo has purported to terminate the license due to Salix's alleged failure to develop Crofelemer and other alleged breaches of the collaboration agreement. According to Salix, however, Napo's purported termination of the license is groundless and without merit.

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