Trials Prove Experimental Diarrhea Medication Is Effective

November 5, 2010

A twice-daily dose of a new type of anti-diarrhea medication called crofelemer is significantly more effective than a placebo at treating chronic diarrhea in people with HIV. These data, announced November 4 by the drug's maker, Napo Pharmaceuticals, mean that the drug could be approved by 2012.

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.

According to Napo, however, 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 getting 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 study that was reported, called ADVENT, 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 states 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.

Napo says that it will be meeting with the U.S. Food and Drug Administration in the early part of 2011 to discuss how to move toward approval of the drug, which was granted "fast-track" review status by the agency. Napo is also studying the drug for other conditions that cause diarrhea, including irritable bowel disease, pediatric diarrhea and infectious diseases such as cholera.

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