Clinical Trial of Diarrhea Drug Continues

August 5, 2009

The first of a two-stage clinical trial of crofelemer for the treatment of chronic diarrhea in people living with HIV on antiretroviral (ARV) therapy has been completed, according to a press release from its developer, Napo Pharmaceuticals Inc. With the selection of a dose, based on the Stage I results of the ADVENT trial, the Stage II exploration of the drug's safety and effectiveness will commence.

Crofelemer is a product extracted from the bark of Croton lechleri—also known as sangre de grado, or dragon's blood, because of its blood-like ooze when chopped—a tree found in many regions of South America. The purified product acts as an anti-secretory agent, acting locally in the gastrointestinal tract.

The ADVENT trial is a randomized and blinded study, consisting of two stages. Stage I consisted of 28 days of treatment for three dose groups (125 mg, 250 mg and 500 mg orally twice daily) and a placebo group, totaling close to 200 patients, with about 50 patients in each group. To select a dose for Stage II, an independent review board conducted an interim analysis of the safety and efficacy of each dose.

Though the press release did not specify the dose selected, Napo says the trial will now move into Stage II with the addition of 150 patients, 75 of whom will be randomized to crofelemer, and the other 75 to placebo. These 150 Stage II patients will be combined, respectively, with the 50 subjects from Stage I who were on the dose selected for Stage II and the 50 who were on the placebo, for a final Stage II patient population of 250 (125 in each group). All patients in the trial will be treated in a five-month extension phase after their 28-day treatment.

According to Napo's press release, up to 30 percent of the 1 million people living with HIV in the United States are managing diarrhea chronically.