



Napo Pharmaceuticals Launches Mytesi (crofelemer) as the Only FDA-Approved Treatment for Relief of Noninfectious Diarrhea in HIV+ Patients

Launch Includes Copay Savings and Patient Assistance Programs to Ensure Affordable Access to Mytesi™, Formerly Marketed as Fulyzaq®

NEW YORK, NY – October 13, 2016 – Napo Pharmaceuticals, Inc., announced today the launch and general availability of Mytesi (crofelemer), the only antidiarrheal studied in and FDA-approved for the relief of diarrhea in HIV+ patients.¹ Previously marketed as Fulyzaq, the product launch under the Mytesi brand importantly includes the unveiling of the *Mytesi Copay Savings Program* and *NapoCares™ Patient Assistance Program* to provide people living with HIV/AIDS with broad, affordable access to the drug.

“Chronic, symptomatic diarrhea remains a significant, underreported consequence of HIV, whether due to the side effects of antiretroviral therapy (ART) or the direct effect of HIV on the gastrointestinal (GI) tract. This problem is only going to increase as the HIV+ population gets older; more than 40 percent of people currently living with HIV/AIDS in the United States are over the age of 50,” commented Lisa Conte, CEO and founder of Napo. “By launching Mytesi, not only are we making this important drug widely available, we are including two important patient assistance programs to ensure that patients can gain access to our drug, regardless of insurance or economic status. The launch of Mytesi also highlights Napo’s dedication to both superior patient care and corporate responsibility.”

“One of the major reasons diarrhea among HIV+ patients remains underrecognized is due to a disconnect between physicians and their patients: patients often do not report the true extent of their diarrhea, and physicians are not always fully aware of the negative impact of diarrhea on their patients’ lifestyles. In addition, both groups may not be aware that a specific treatment is available,” added Rodger D. MacArthur, MD, Professor of Medicine, Division of Infectious Diseases at the Medical College of Georgia, an HIV specialist who was an investigator in and is the author of the ADVENT Trial, the pivotal study that led to regulatory approval of crofelemer. “Some healthcare providers believe that diarrhea is only associated with ART and that newer antiretroviral medications cause less diarrhea.

¹ Mytesi™ is an anti-diarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.



However, HIV enteropathy, which is chronic diarrhea due to the direct or indirect effects of HIV on the GI tract, is a problem for many HIV+ patients, independent of their ART regimen.”

Many patients who are HIV+ are only aware of Imodium^{®2} and Lomotil^{®3} as treatments for diarrhea, but these agents have not been studied in patients who are HIV+, and the effect of these drugs on antiretroviral medications is not known. Also, Lomotil and Imodium are opioids that work by slowing movement through the GI tract, which can cause constipation. Mytesi is a prescription treatment for diarrhea that works to normalize the flow of water in the GI tract, and subgroup analyses in the pivotal clinical trial showed a more pronounced effect in HIV+ patients who had longstanding infection (≥12 years) or who tried other antidiarrheal medications.⁴

The *Mytesi Copay Savings Program* provides copay assistance to eligible patients who have private health insurance, with the intent to have patients pay no more than \$25 for a Mytesi prescription. The *NapoCares Patient Assistance Program* provides Mytesi free of charge to eligible patients who are not insured and may not be able to afford medication.

About Mytesi™

Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

² Imodium is a registered trademark of Johnson & Johnson.

³ Lomotil is a registered trademark of Pfizer Inc.

⁴ The efficacy of Mytesi 125-mg delayed-release tablets twice daily was evaluated in a randomized, double-blind, placebo-controlled (one month) and placebo-free (five month), multicenter study. The study enrolled 374 HIV+ patients on stable ART and who had a history of diarrhea for one month or more.



More information and complete Prescribing Information are available at Mytesi.com.

About Napo Pharmaceuticals, Inc.

San Francisco–based Napo Pharmaceuticals, Inc., focuses on the development and commercialization of proprietary pharmaceuticals from rainforest resources for the global marketplace in collaboration with local partners. Recently, Napo and Jaguar Animal Health, Inc. (NASDAQ: JAGX), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses, announced plans for a proposed merger of the two companies.

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