

# Napo Pharmaceuticals, Inc.

## ***NEWS***

### **For Immediate Release**

## **Napo Terminates Salix for Breach of Agreement For Failure to Commercially Develop Crofelemer**

**November 10, 2011...San Francisco, CA** – Napo Pharmaceuticals, Inc. (“Napo”) announced today that, on November 4, 2011, it terminated its Collaboration Agreement with Salix Pharmaceuticals, Inc. (“Salix”) dated December 9, 2008 (the “Collaboration Agreement”) to commercially develop its first in class novel drug compound, crofelemer. The compound is a treatment for diarrhea, a life-threatening ailment that impacts millions of people across the world.

Effective November 4, the termination is based on Salix’s breaches of the Collaboration Agreement. In recognition of the importance of the compound and based on an unmet medical need, the U.S. Food and Drug Administration (“FDA”) designated crofelemer for fast track status for the indications of chronic diarrhea in people living with HIV/AIDS (“CRO-HIV”) and diarrhea-predominant irritable bowel syndrome (“CRO-IBS”). Despite positive Phase 3 results announced on November 4, 2010, Salix has not filed a new drug application (“NDA”) with the FDA.

“Napo believes Salix has materially breached the Collaboration Agreement by unnecessarily stalling the advancement of this compound,” says William A. Brewer III, partner at Bickel & Brewer and counsel for Napo. “Most notably, Salix has failed to file an NDA one year after a highly successful Phase 3 clinical trial or to prepare for commercial manufacture of the drug – critical tasks that were fundamental to its responsibilities.”

On September 16, 2011, in accordance with the Collaboration Agreement, Napo sent Salix a notice of default. Napo terminated the agreement based on Salix’s failure to cure its breaches in a timely manner.

The termination of the Collaboration Agreement paves the way for Napo to pursue an NDA, enter into new licensing agreements if it chooses, and press forward with commercialization plans for crofelemer. The compound has received widespread support in the medical community. An estimated 40% percent of HIV/AIDS patients in the United States suffer from diarrhea. Every year, almost two million children die from dehydration associated with diarrhea, with millions more suffering measurable morbidity.

Napo has invested tens of millions of dollars in the development of crofelemer.

“Our company is committed to the advancement of crofelemer and the many ways in which it can benefit millions of people, both patients and our suppliers who sustainably harvest the raw plant material in rain forests,” says Lisa A. Conte, CEO of Napo. “We are anxious to move forward without the constraints placed upon us by Salix, and optimistic about realizing our vision to bring new drugs to the global marketplace as quickly as possible.”

**Napo Pharmaceuticals, Inc.**

Napo focuses on the development and commercialization of proprietary pharmaceuticals for the global marketplace. The company's business model merges traditional high-value markets in the West with the higher volume business models of emerging and developing economies. Napo's discovery process leverages the knowledge of traditional healers, or shamans, working in rain forest areas and provides benefit sharing to the communities with which it works. Visit Napo at [www.napopharma.com](http://www.napopharma.com)

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