

Oct. 26, 2010

Dear Napo Shareholders:

Several of you have pinged or called me over the last couple of days, asking about the cholera outbreak in Haiti, and if there is any way crofelemer could be useful in that devastating situation. I'd like to share with you (a) the status of the crofelemer approval process; (b) crofelemer's clinical performance in treating cholera, and how in the future we can deliver the drug to disaster areas like Haiti; and (c) Napo's role in assisting the current emergency, and how you can help.



### **Nearing the final stages of approval for crofelemer**

This past August, patient enrollment was completed in the final Phase 3 study of crofelemer in the US for chronic diarrhea in people living with HIV/AIDS. We expect to announce top-line data by mid-November, and a New Drug Application filing to support U.S. regulatory approval is targeted by the end of Q1/beginning of Q2 of 2011. Assuming success in the HIV indication, our licensing and development partner in the US, Salix Pharmaceuticals, has expressed interest in investigating the product for broader and larger indications. Its peak sales projections for the HIV indication are \$150 to 200 million annually in the United States.

### **Crofelemer's success in treating cholera, and getting the drug to the disaster in Haiti**

In September 2008, Napo released data on crofelemer's treatment of cholera in a proof-of-concept study conducted at the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B). The study targeted a reduction in the life-threatening fluid loss characteristic of cholera infection. All patients were admitted to the hospital with severe watery diarrhea resulting from cholera infection. In addition to receiving crofelemer, they received a single oral dose of azithromycin and rehydration therapy. The principal investigator, Dr. Pradip Bardhan, a scientist and Head of the Special Care Unit at ICDDR, B, commented in our disclosure: "Crofelemer produces an impressive reduction in stool volume output within the first 12-hour period. There is a clear need for new agents to produce reduction in stool volume output in the first 12 to 18 hours, which is the period where the patients are at maximum risk for dehydration. Both doses of crofelemer were well tolerated and no drug-related adverse events were observed in the cholera patients in this study. As a novel anti-secretory agent, crofelemer represents a complementary mechanism to existing standard-of-care treatment of cholera, which consists of administering rehydration therapy and antibiotics, with the inherent risk of resistance generation."

Also in September 2008, Napo allied with Santa Barbara, Calif.-based nonprofit humanitarian medical relief organization Direct Relief International to form the Crofelemer Access Program, a novel for-profit/not-for-profit alliance focusing resources on the acceleration of development of crofelemer for pediatric populations in disaster situations and resource-constrained geographies.

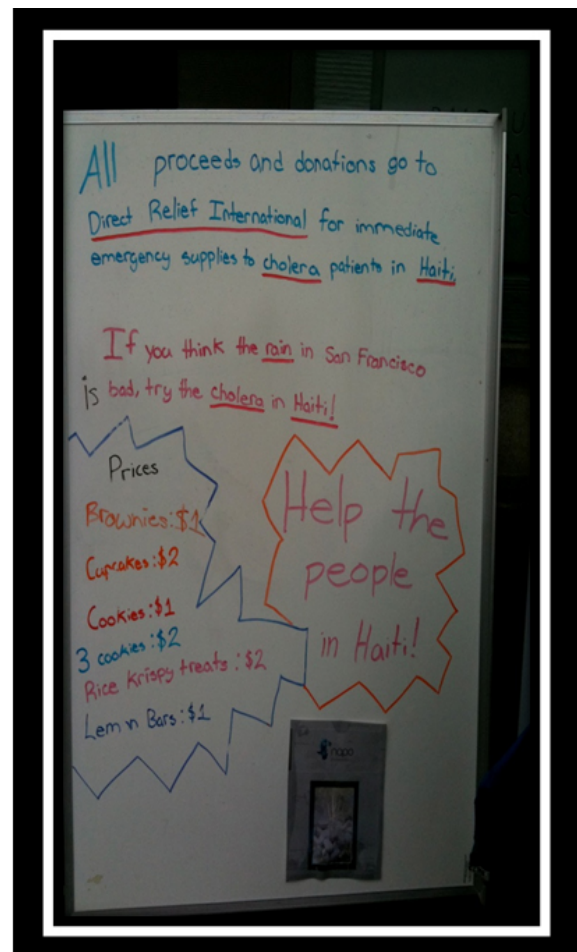
Napo has engaged global key opinion leaders and experts in pediatric diarrhea to advise and participate in the development, awareness building, and ultimate access to crofelemer to private and public markets as well. You can view Napo's participation in the Bay Area Global Health Summit held on Oct. 13, 2010: [http://www.livestream.com/2010bayareaglobalhealth/video?clipId=pla\\_8233f6c3-48e2-4f33-a3cd-f1155ed29ab6&utm\\_source=library&utm\\_medium=ui-thumb](http://www.livestream.com/2010bayareaglobalhealth/video?clipId=pla_8233f6c3-48e2-4f33-a3cd-f1155ed29ab6&utm_source=library&utm_medium=ui-thumb)

### **What Napo is doing to aid the cholera emergency and how you can help**

On October 24, Napo initiated a fund-raising and awareness-building effort for the cholera outbreak. It began with my two teenage daughters and a friend of theirs baking a variety of cookies and cakes, then selling their baked goods along the Embarcadero near the historic Ferry Building in San Francisco to raise money for Direct Relief's assistance to Haiti. In one afternoon, they raised ~\$500—almost one dollar at a time—and provided information about the need for a rapid response to cholera. Separately, Napo provided resources for the local round-up of pediatric rehydration supplies to supplement readiness inventories to be sent to Haiti this week. At last count, the outbreak had claimed the lives of more than 350 Haitians, mostly children.

Several Napo shareholders have asked how they can contribute. You can send donations to Direct Relief at: [www.directrelief.org/SupportUs.aspx](http://www.directrelief.org/SupportUs.aspx), by calling 1-800-676-1638, or by mailing a check to:

Direct Relief International  
27 S. La Patera Lane  
Santa Barbara, CA 93117



Please reference Napo when making your donation, and your funds will be directly applied to readiness resources for the cholera outbreak.\* Also, the little philanthropists (the girls who held the bake sale) will soon have a Facebook page, so next time you can order your baked goods virtually.

I very much look forward to my next communication with you about crofelemer: top-line Phase 3 results for chronic diarrhea in people living with HIV/AIDS.

All the best,

Lisa Conte

Chief Executive Officer and Founder, Napo Pharmaceuticals

\*On September 25, Direct Relief sent a 15-ton emergency airlift of medical supplies to St. Marc, Haiti, in response to the cholera outbreak concentrated there. The supplies were specifically requested by partner groups working to treat affected patients and prevent further infection, including Partners in Health and Hospital Albert Schweitzer. Direct Relief plans to send subsequent shipments in the coming weeks.