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News Release

FDA Approves Crofelemer as First-Ever Oral Botanical Drug

Amazon tree-derived medicine cleared for usage in HIV patients with diarrhea

(AUSTIN, Texas, January 2, 2013) On New Year's Eve of 2012, the US Food and Drug Administration (FDA) announced its approval of crofelemer (Fulyzaq™, Salix Pharmaceuticals, Ltd., Raleigh, North Carolina) — marking the second time a botanical, and the first time an *orally administered* botanical, has received drug approval from the Administration.¹ The first botanical drug to be approved in the United States was a topical green tea extract, Veregen®, in 2006.² Both botanical drugs meet all US pharmaceutical requirements and can be dispensed only by prescription.

Crofelemer is the first drug to be approved in the United States to treat HIV-associated diarrhea.¹ It is derived from the latex of the South American sangre de drago tree (dragon's blood, *Croton lechleri*).² A red, blood-resembling latex leaks from the tree when its bark is cut, and it is this substance that contains the novel polymolecular structure crofelemer, originally developed and standardized by Shaman Pharmaceuticals.

According to [FDA's press release](#) regarding the approval, "The safety and efficacy of Fulyzaq were established in a clinical trial of 374 HIV-positive patients on stable antiretroviral therapy [ART] with a history of diarrhea lasting one month or longer... Results showed that 17.6 percent of patients taking Fulyzaq experienced clinical response compared with 8 percent taking placebo. In some patients, a persistent anti-diarrheal effect was seen for 20 weeks."¹

The herbal medicine and pharmaceutical communities have been expressing satisfaction with FDA's decision, ushered out the door on the last day of the year — an action typical of FDA efforts to complete pending drug reviews before the end of each calendar year.³ Salix, which owns the license for crofelemer's development and submitted the product's New Drug Application (NDA) for review, called the approval a "significant step forward in addressing the unmet medical need of people with HIV/AIDS on ART who experience non-infectious diarrhea."⁴ According to a [Salix press release](#), the company expects Fulyzaq to be available to patients in early 2013. A Bloomberg analysis estimates crofelemer will bring the company sales of \$18 million in 2013 and \$26 million in 2014.⁵ Napo Pharmaceuticals (San Francisco, California), the company that owns the intellectual property rights of the drug, will issue comments in the coming days (S. King, email, January 2, 2013). Glenmark Pharmaceuticals, Ltd., the India-based manufacturer and supplier of crofelemer for the US market, experienced an increase in market shares of 3.4 percent following the announcement.⁶

The drug's approval marks an important event in the decades-long history of crofelemer. The original Investigational New Drug (IND) application was submitted by the now-defunct Shaman Pharmaceuticals (formerly in San Francisco, CA) in the early 1990s. In 2002, Shaman CEO Lisa Conte reorganized into Napo Pharmaceuticals, retaining

Shaman's original intellectual property.² In 2008, Salix obtained a license from Napo in order to continue to work toward crofelemer drug approval.

Salix filed the NDA for crofelemer in December 2011, which initiated the FDA review period. Due to the serious nature of the medical condition crofelemer treats, FDA assigned the NDA "priority review" status, which indicates that the Administration will aim to approve or reject the application in approximately six months.² Although FDA accepted the NDA for filing in February 2012, it delayed its decision twice, including the most recent delay in September 2012, which added to Napo's concerns regarding the length of time it was taking Salix to move the product forward. In May 2011, Napo filed a legal complaint for breach of contract against Salix before the New York State Supreme Court, claiming that Salix was "unnecessarily stalling the advancement of this compound." Salix has maintained that it has proceeded with the NDA expeditiously. Although the lawsuit is still pending at this time, a ruling is yet to be determined.

Updated and more extensive information on the crofelemer approval will be reported in the January issue of the American Botanical Council's monthly e-newsletter HerbalEGram, to be published online next week. Additional background on crofelemer is available in the following articles previously published by the American Botanical Council:

[FDA Delays Decision on Crofelemer for Second Time](#). HerbalEGram. Volume 9, Number 11, November 2012.

[Dragon's Blood Herb Profile](#). *HerbalGram* 92. Winter 2011. Pages 1-4.

[Blood of the Dragon: The Sustainable Harvest and Replanting of the *Croton lechleri* Tree](#). *HerbalGram* 84. Winter 2009. Pages 56-65.

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4. FDA approves Fulyzaq™ (crofelemer) 125 mg delayed-release tablets for the symptomatic relief of diarrhea in patients with HIV/AIDS on anti-retroviral therapy (ART) [press release]. Raleigh, NC: Salix Pharmaceuticals, Inc.; January 2, 2013. Available at: www.salix.com/news-media/news/index/fda-approves-fulyzaq-crofelemer-125-mg-delayed-release-tablets-for-the-symptomatic-relief-of-diarrhea-in-patients-with-hiv-aids-on-anti-retroviral-therapy-art. Accessed January 2, 2013.
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About the American Botanical Council

Founded in 1988, the American Botanical Council is a leading international nonprofit organization addressing research and educational issues regarding herbs, teas, medicinal plants, essential oils, and other beneficial plant-derived materials. ABC's members include academic researchers and educators; libraries; health professionals and medical institutions; government agencies; members of the herb, dietary supplement, cosmetic, and pharmaceutical industries; journalists; consumers; and others in over 81 countries. The organization occupies a historic 2.5-acre site in Austin, Texas, where it publishes the peer-reviewed quarterly journal *HerbalGram*, the monthly e-publication HerbalEGram, the weekly e-newsletter "Herbal News & Events," HerbClips (summaries of scientific and clinical publications), reference books, and other educational materials. ABC also hosts HerbMedPro, a powerful herbal database, covering scientific and clinical publications on more than 240 herbs. ABC also co-produces the "Herbal Insights" segment for *Healing Quest*, a television series on PBS.

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