

April 7, 2014



# **Xenetic Biosciences Announces Positive Phase 1 Clinical Data for PulmoXen(TM) for Treatment of Cystic Fibrosis**

LEXINGTON, Mass., April 7, 2014 (GLOBE NEWSWIRE) -- Xenetic Biosciences, Inc. (OTCBB:XBIO), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, today announced the positive results from its Phase I clinical trial of PulmoXen<sup>TM</sup> for the treatment of cystic fibrosis. The single center, open-label trial was conducted in Russia by Xenetic's partner, OJSC Pharmsynthez. In this First-in-Human study, PulmoXen was administered to 12 healthy volunteers via inhalation daily for seven days, in two doses of 2500IU and 5000IU, and was found to be safe and well tolerated. PulmoXen is a novel, modified form of recombinant human DNase I (rhDNase I) designed to be a next-generation version of Pulmozyme.

"The positive data on this next-generation molecule targeting cystic fibrosis, a debilitating Orphan Disease, will allow Xenetic to pursue an Investigational New Drug (IND) filing with the U.S. Food and Drug Administration (FDA), in order to advance toward FDA-sanctioned Phase 1 clinical development," said Scott Maguire, CEO of Xenetic Biosciences. "These Phase 1 results demonstrate the success and effectiveness of our business strategy to pursue initial development of our clinical pipeline through human trials with our Russian partners, providing Xenetic a potential pipeline of therapies while mitigating drug development risk. We look forward to working with the FDA to further advance the clinical development of PulmoXen."

The natural enzymatic function of DNase I is to digest DNA. When delivered to the lungs, it can thereby reduce the viscosity of infected lung secretions, which contain significant amounts of extracellular DNA, as well as reduce bacterial biofilm formation in the lungs of cystic fibrosis patients. These effects of DNase I can facilitate clearance of sputum, and improve lung function in cystic fibrosis patients.

PulmoXen is a polysialic acid - conjugated form of rhDNase I that is being developed using Xenetic's patented PolyXen<sup>®</sup> delivery technology, with the intent to reduce the required dosage frequency by enhancing the stability and pharmacodynamic profile of the enzyme in sputum. A comparative evaluation of PulmoXen versus Pulmozyme, using *ex vivo* models of cystic fibrosis sputum, confirmed superiority of PulmoXen with respect to stability and enzymatic activity when digesting DNA in sputum from cystic fibrosis patients.

## **About Xenetic Biosciences**

Xenetic Biosciences is a biopharmaceutical company developing next-generation biologic drugs and novel oncology therapeutics. Xenetic's proprietary drug technology platforms include PolyXen<sup>®</sup> for creating next generation biologic drugs by extending the efficacy,

safety and half-life of biologic drugs and OncoHist<sup>®</sup> for the development of novel oncology drugs focused on orphan indications. Xenetic's lead product candidates include ErepoXen<sup>®</sup>, an improved, polysialylated form of erythropoietin (EPO) for the treatment of anemia in pre-dialysis patients with chronic kidney disease and OncoHist<sup>®</sup>, a recombinant human histone H1.3 molecule which Xenetic is developing for the treatment of refractory Acute Myeloid Leukemia (AML). Xenetic is developing a novel series of polysialylated blood coagulation factors through its license agreement with Baxter International Inc. Xenetic is also developing a broad pipeline of clinical candidates for next generation biologics and novel oncology therapeutics in a number of orphan disease indications. For more information, please visit the company's website at [www.xeneticbio.com](http://www.xeneticbio.com).

## Forward-Looking Statements

*Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Xenetic's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Xenetic does not undertake an obligation to update or revise any forward-looking statement. The information set forth herein speaks only as of the date hereof.*

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Source: Xenetic Biosciences, Inc.