



## **Xcellerex Initiates Phase I Clinical Trial of Novel Yellow Fever Vaccine**

### ***Trial to Evaluate Safety and Immunogenicity of Inactivated Vaccine Candidate***

**Marlborough, MA, January 12, 2010** – Xcellerex, Inc. today announced that it has initiated a Phase I clinical trial of XRX-001, a novel, prophylactic vaccine against yellow fever, a tropical virus disease that is often fatal. The company is developing the vaccine to prevent yellow fever in persons traveling to tropical countries where yellow fever is endemic. The only currently available yellow fever vaccine is an attenuated, live vaccine with rare but potentially serious adverse effects. XRX-001 is an inactivated virus vaccine adsorbed to alum adjuvant. Because it is inactivated and non-replicating, it is anticipated to significantly reduce the risks of serious and fatal adverse events that are sometimes associated with the live yellow fever vaccine. In addition, the absence of foreign proteins derived from hens' eggs should also reduce the risk of allergic reactions and eliminate the need to exclude egg-allergic people from vaccination. In addition, Xcellerex believes that the XRX-001 vaccine should not be subject to the precautions and contraindications of the currently marketed live vaccine. These precautions and contraindications, which are all related to potential serious outcomes of replicating live virus infection, include age <9 months or >65 years, immune suppression due to thymectomy, HIV/AIDS, cancer, treatment with immunosuppressive medications or radiation, and pregnancy.

The double-blind, controlled Phase I trial will enroll 60 healthy subjects divided into three groups. Two groups of volunteers will receive two different dose levels of XRX-001 and the third will receive placebo. The primary objective of the trial is to evaluate the safety and tolerability of XRX-001 vaccine, and secondary objectives will assess the neutralizing antibody response--an accepted correlate of protective immunity to yellow fever. In a second parallel trial, the Company will compare the antibody response in those receiving XRX-001 to travelers receiving the currently-marketed vaccine.

"The introduction of a non-replicating vaccine against yellow fever into clinical development is important because there are increasing constraints on the use of the live vaccine," said Dr. Thomas Monath, Acting Chief Medical Officer for Xcellerex. "Approximately one million people travel annually from the U.S. to yellow fever endemic areas and would benefit from vaccination."

"The initiation of the Phase I clinical trial is a significant milestone for Xcellerex and is further validation of both our disposable manufacturing technology and business

model." stated Joseph Zakrzewski, President and CEO of Xcellerex. "We have manufactured XRX-001 using our proprietary, disposable technology and believe that XRX-001, if approved, will offer patients a safer alternative than the existing live virus vaccine currently on the market. The XRX-001 pre-clinical data are very encouraging and we are excited about the opportunity to bring our first proprietary product into the clinic."

### **About Yellow Fever**

Yellow fever is a hemorrhagic fever caused by a virus spread by mosquitoes. It occurs in tropical areas of Africa and South America, affecting travelers to and residents of those areas. The incubation period (time from infection to illness) is usually 3-6 days. Approximately 15% of yellow fever infections cause severe damage to liver, heart and kidney, bleeding and shock. Twenty to 50 percent of people with the more severe form of yellow fever die of the disease. There is no specific treatment for the disease, but contracting yellow fever is preventable through vaccination. The currently available live, attenuated vaccine (17D vaccine) was developed in 1936 and approximately 30 million people traveling to or living in endemic regions are vaccinated annually. The safety of this vaccine has only been questioned since 2001 when serious adverse events resembling yellow fever disease were first reported.

### **About Xcellerex, Inc.**

Xcellerex is revolutionizing the way biomolecules are developed, manufactured and commercialized. The company's unique single-use component technology platform transforms biomanufacturing economics and enables the development of biotherapeutics and vaccines, thereby dramatically improving the ability of Xcellerex and its partners to deploy manufacturing capacity. Xcellerex leverages its technology and services platform by: 1) commercializing its FlexFactories® (complete, turnkey, modular production trains) and XDR™ single-use bioreactor systems; 2) building a portfolio of proprietary biotherapeutics and vaccines through creative alliances and in-licensing; and 3) creatively structuring transactions around FlexFactories, XDRs and its pipeline. Learn more at [www.xcellerex.com](http://www.xcellerex.com)

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