

## PRESS RELEASE

### **Global Collaboration Forms to Advance Japanese TB Vaccine Technology**

**January 27, 2014 – Osaka, Japan and Rockville, MD, USA** - Japan's National Institute of Biomedical Innovation ("NIBIO"), Aeras and Create Vaccine Company, Ltd ("CREATE") announce today that they signed a collaboration agreement on December 26, 2013, on the preclinical and clinical development of new mucosal tuberculosis (TB) vaccines based on NIBIO's human parainfluenza type-2 (rhPIV2) vector technology.

"These will be important candidates; designed to target mucous membranes to keep TB from entering the lungs," said Tom Evans, MD, President and CEO of Aeras, a nonprofit biotech advancing TB vaccines globally. "This type of collaboration among global experts is exactly the approach needed to find an effective vaccine that will end tuberculosis in Japan and around the world."

The collaboration is supported through a generous grant from the Global Health Innovative Technology Fund (GHIT), a new partnership formed to facilitate international partnerships that enable Japanese technology, innovations, and insights to play a more direct role in reducing disparities in health between the rich and the poor of the world.

The vaccine platform was created by Tsukuba Primate Research Center at NIBIO. "Based on the promising results of early research and the improved safety profile of candidates using this rhPIV2 platform, we believe that this platform has great possibility," said Dr. Yasuhiro Yasutomi (Director of Tsukuba Primate Research Center, NIBIO). "Further studies contribute to the ultimate goal of establishing a new vaccine strategy that can definitely prevent TB."

CREATE is a joint venture company created by Dainippon Sumitomo Pharma and Japan BCG Laboratory to develop and market TB vaccines developed in partnership with NIBIO and Aeras.

The collaboration announced today will advance vaccine candidates based on the rhPIV2 technology through preclinical stages with a goal to advance to safety and immunogenicity testing in clinical trials. The partners will collaborate jointly to establish development criteria and assess progress through agreed upon development milestones. This will include the characterization of new vaccine constructs with a variety of antigens, the conduct of immunology studies to identify the most promising novel vaccines and the establishment of current good manufacturing practices (cGMP).

"Development of TB vaccines is a new challenge," said Koichi Kozuki, President of CREATE. "The exciting partnership among NIBIO, Aeras and CREATE will accelerate development efforts for clinical application of new TB vaccines to the patients who need it."

TB is one of the deadliest and most disabling diseases in the world today. Each year, more than 8.6 million people become sick with TB and 1.3 million people die of the disease. Although its burden is spread across all age groups, it exacts its greatest toll on individuals during their most productive years, from ages 15 to 44. The global emergence and spread of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), now found in all countries surveyed worldwide, are confounding efforts to halt the spread of TB and are imposing enormous personal costs and a significant economic burden on national health systems. The cost of treating MDR-TB can be 200 times greater than for drug-susceptible TB. In Japan every year, more than 20,000 people contract TB and more than 2,000 die from the disease.

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**About Aeras** (Headquarters: Maryland, USA; President and CEO: Thomas G. Evans)

Aeras is a global nonprofit biotech advancing TB vaccines for the world. In collaboration with global partners in Africa, Asia, North America and Europe, Aeras is supporting the clinical testing of six experimental vaccines as well as a robust portfolio of earlier stage candidates. Aeras receives funding from Australian AID, the Bill & Melinda Gates Foundation, the Global Health Innovative Technology Fund (GHIT), the UK Department for International Development, the Netherlands' Ministry of Foreign Affairs, and a range of other governments. Aeras is based in Rockville, Maryland, Cape Town, South Africa, and Beijing, China. [www.aeras.org](http://www.aeras.org)

**About CREATE** (Headquarters: Osaka; President: Koichi Kozuki)

Create Vaccine Company, Ltd, established July 31, 2013, is a joint venture company created by Dainippon Sumitomo Pharma and Japan BCG for the purposes of developing TB vaccines jointly with NIBIO and Aeras and to market the developed products.

**About Dainippon Sumitomo Pharma**

Dainippon Sumitomo Pharma (DSP) defines its corporate mission to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives for people worldwide. By pouring all efforts into the research and development of new drugs, DSP aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world.

<http://www.ds-pharma.com/>

**About Japan BCG Laboratory**

Capitalizing on its profound knowledge and technical expertise gained in the course of many years of vaccine production and research, Japan BCG strives to make a contribution to the health of people all around the world through the development and stable supply of high-quality, innovative products. <http://www.bcg.gr.jp/english/>

**About NIBIO** (Headquarters: Ibaraki, Osaka; Director General: Yoshihiro Yoneda)

Japan's National Institute of Biomedical Innovation is the only independent administrative corporation in Japan specialized in the promotion and support of new drug discovery. By playing three major functions: research on basic technology of pharmaceuticals; research on biological resources; and research and development promotion of pharmaceuticals, NIBIO supports the research of private companies, universities and the like directed toward the development of new pharmaceuticals and medical devices.

<http://www.nibio.go.jp/english/index.html>

**Contact:**

National Institute of Biomedical Innovation: (Tsukuba Primate Research Center):

TEL: +81-29-837-2054

Aeras: +1 240-599-3018

Dainippon Sumitomo Pharma (Corporate Communications):

TEL: +81-6-6203-1407 (Osaka) +81-3-5159-3300 (Tokyo)

Japan BCG Laboratory (Planning and Development Department):

TEL: +81-3-5395-5592