National Institute of Biomedical Innovation
Aeras
Create Vaccine Company, Ltd.
Dainippon Sumitomo Pharma Co., Ltd.
Japan BCG Laboratory

# A Basic Agreement Reached for Joint Development of New TB Vaccines

National Institute of Biomedical Innovation, an independent administrative corporation (Headquarters: Ibaraki, Osaka; Director General: Yoshihiro Yoneda) ("NIBIO"), Aeras, a nonprofit biotech organization (Headquarters: Maryland, USA; President and CEO: Thomas G. Evans), Create Vaccine Company, Ltd. (Headquarters: Osaka: President: Koichi Kozuki) ("Create Vaccine"), Dainippon Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Osaka; President: Masayo Tada) ("DSP") and Japan BCG Laboratory (Head Office: Bunkyo-ku, Tokyo; President: Noboru Hagiwara) ("Japan BCG") jointly announce that a basic agreement has been reached among NIBIO, Aeras and Create Vaccine for joint development of new TB vaccines based on the human parainfluenza type-2 vector technology. The three parties intend to enter into a formal joint development agreement by the end of December this year. Create Vaccine is a joint venture company established on July 31, 2013 by DSP and Japan BCG for the promotion of new TB vaccine businesses.

Tuberculosis is one of the world's Big Three infectious diseases. Some 8.6 million people around the world become infected every year, while some 1.3 million patients are fatally victimized. It is widespread, particularly in Asia and Africa. In Japan every year, over 20,000 people contract the disease and over 2,000 die from it. Even though conventional vaccines are highly effective in infants and toddlers, they are much less effective against adult tuberculosis. Development of new TB vaccines is an impending challenge. Under the agreement, the three parties will work on the development of mucosal vaccines, incorporating clinical application of the human parainfluenza type-2 vector technology owned by NIBIO. If successfully developed, the mucosal vaccine will be the world's first TB vaccine of its kind.

Vaccine is a new business area which DSP is pursuing to enter into in line with its Third Mid-Term Business Plan. DSP hopes this joint development program will pave the way for consolidation of its business base for enhanced activities in this area. Japan BCG has accumulated abundant experiences in TB vaccines through the production, marketing and export of BCG vaccine. Aeras is engaged in the development of six TB vaccine candidates working globally in collaboration with academic, pharmaceutical and biotech industry partners and brings expertise in preclinical and clinical development, immunology and vaccine manufacturing. NIBIO has identified the "research and development of next-generation vaccines" as a priority area in its Second Medium-Term Plan.

Accordingly, it is promoting the development of next-generation vaccines and their adjuvant as well as the administration routes.

With this collaboration, NIBIO, Aeras and Create Vaccine look forward to successful outcomes from the program that will provide significant contribution of the prevention of tuberculosis.

## [Reference information]

**About NIBIO** NIBIO is the only independent administrative corporation specialized in the promotion and support of new drug discovery. By playing three major functions, namely "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.

#### **About Aeras**

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 is based in Rockville, Maryland, Cape Town, South Africa, and Beijing, China.

### **About Create Vaccine**

Create Vaccine is a joint venture company created by DSP and Japan BCG for the purposes of developing TB vaccines jointly with NIBIO and Aeras and marketing the developed products.

#### **About DSP**

DSP defines its corporate mission as "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 in order to realize our corporate mission.

# **About Japan BCG**

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 contribution to the health of people all around the world through stable supply of high-quality products and development of innovative products.

## Contact:

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

Yasuhiro Yasutomi, Department Manager

TEL: +81-29-837-2054

Email:yasutomi@nibio.go.jp

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