



News Release

Access to Health

The Institute of Medical Science the University of Tokyo
Astellas Pharma Inc.

The Institute of Medical Science, the University of Tokyo and Astellas Enter into a New Collaborative Development Agreement for Rice-Based Oral Vaccine

Tokyo, June 23, 2016 - the Institute of Medical Science, the University of Tokyo (Tokyo, Dean: Yoshinori Murakami, “IMSUT”) and Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced that they have signed a new collaborative development agreement on the rice-based oral vaccine “MucoRice-CTB” (“MucoRice”) against cholera^{*1} and enterotoxigenic *Escherichia coli* (*E coli*)^{*2} caused diarrheal diseases.

MucoRice is a rice-based oral vaccine expressing cholera toxin B subunit (CTB)^{*3} in the intrinsic storage protein of rice using genetic engineering, which was developed by Prof. Hiroshi Kiyono, Project researcher Yoshikazu Yuki and their colleagues at International Research Development Center for Mucosal Vaccines (IMSUT).

In developing countries, diarrhea caused by pathogenic bacteria such as *Vibrio cholerae* and enterotoxigenic *E coli*, is one of the major causes of death among infants. At present, the challenges of the cholera vaccines used in developing countries are the need for the cold chain^{*4} and the ineffectiveness against enterotoxigenic *E coli*. MucoRice is stable at room temperature and easily produced, therefore it is expected to meet the unmet medical needs of existing cholera vaccines. Under the MEXT (Ministry of Education, Culture, Sports, Science and Technology) and the AMED (Japan Agency for Medical Research and Development) Translational Research Network Program, an investigator-initiated phase 1 trial of this vaccine is nearing completion at IMSUT hospital (Principal investigator, Assoc. Prof. Osamu Hosono) in Japan. Data from this trial is now being analyzed.

Under the contract, IMSUT provides clinical trial materials and trial data, etc. which are necessary for the phase 1 and phase 2 trials of MucoRice for cholera and enterotoxigenic *E coli.*, and Astellas is responsible for conducting and managing the clinical trials.

Through the collaborative development, IMSUT and Astellas will develop vaccines against infectious diseases affecting developing countries and hope we can address Access to Health issues.

***¹Cholera:**

Cholera is an acute gastroenteritis by *Vibrio cholera* which produce cholera toxin causing severe diarrhea. It is spread through contaminated food or water, therefore it is more common in developing countries.

***²Enterotoxigenic *Escherichia coli*:**

Enterotoxigenic *E coli* is the *E coli* which produces a toxin that causes diarrhea and abdominal pain in humans. Severe diarrhea is caused by ingesting food or water contaminated by it. It is common in areas that lacks an adequate environmental sanitation, responsible for diarrhea in infants, and is also known to be a major cause of diarrhea in tourists who visit these areas.

***³Cholera toxin B subunit (CTB):**

Cholera toxin consists of 2 types of subunits, CTA (chorea toxin A subunit) is toxic, and CTB pentamer adheres to epithelial cells and delivers CTA into the cell.

***⁴The cold chain:**

The cold chain is a system to store and transport vaccine at a constant low temperature to maintain its effect.

About Access to Health issues:

There are many people with insufficient access to healthcare they need due to the lack of available treatments, poverty, challenges in healthcare systems and limited healthcare information. Astellas recognizes this problem as “Access to Health” issue and works to improve “Access to Health” by engaging in various initiatives.

About the Institute of Medical Science, the University of Tokyo

The Institute of Medical science, the University of Tokyo (IMSUT) was founded by Prof. Shibasaburo Kitasato in 1892 as “The Institute of Infectious Disease”. IMSUT with its own affiliated hospital is Japan's foremost university-associated research institute for medical and life science. Focusing on infectious disease, cancer and immunological diseases, our mission is to translate basic research findings directly to novel medical therapies. Thus, research environment of IMSUT is represented by the "bed to bench and bench to bed" inheriting the Kitasato's DNA of

“Wisdom and Practice” for medical science leading to the next generation of Genome-based medicine, Antibody-drugs, Mucosal Vaccines, Gene-therapy and Regenerative medicine.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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