

January 13, 2022

The Kitasato Institute  
Sumitomo Dainippon Pharma Co., Ltd.

**Kitasato Institute and Sumitomo Dainippon Pharma**  
**Start Phase 1 Study on New Drug Candidate Compound Discovered in Joint**  
**Research as Treatment for Carbapenem-resistant Bacterial Infections**

The Kitasato Institute (Headquarters: Minato-ku, Tokyo; Chairperson: Hirosuke Kobayashi; hereafter referred to as “Kitasato Institute”) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka; Representative Director, President and CEO: Hiroshi Nomura; hereafter referred to as “Sumitomo Dainippon Pharma”) announced today that Sumitomo Dainippon Pharma has started a phase 1 study in the United States on KSP-1007 (hereafter referred to as “the compound”), which was discovered through joint research by the two organizations aiming to find new treatments for carbapenem-resistant bacterial infections.

Going forward, Sumitomo Dainippon Pharma will proceed with the development of the compound for the proposed indications of complicated urinary tract infections and complicated intra-abdominal infections. The compound was discovered through a joint research and development initiative selected by Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) program for collaboration among industry, academia, and government.

The compound can broadly and strongly inhibit  $\beta$ -lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. It is expected to become an effective treatment option against carbapenem-resistant bacterial infections in a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide (name of Sumitomo Dainippon Pharma’s product for the domestic market: MEROPEN®).

The emergence and spread of antimicrobial resistant (AMR) bacteria, which are resistant to antibiotics, is a global problem and often referred to as a silent pandemic. AMR is having a major impact on our economies and medical systems. It is estimated that 700,000 people die of AMR bacterial infections every year, and urgent measures are being called for both at the national and global level under the leadership of the World Health Organization (WHO). With increased use of antibiotics associated with COVID-19, there is concern that antimicrobial resistant bacteria will further increase, and last year’s G7 summit reiterated that new antibiotic development was an urgent international issue.

We aim to make further contributions to global health through an innovative treatment for infectious diseases resulting from a fusion of the long tradition and track record of Kitasato Institute in research in the infectious diseases area and Sumitomo Dainippon Pharma’s accumulated knowledge in research and development in this area.

\* The joint research project between Kitasato Institute and Sumitomo Dainippon Pharma began in October 2017 and is scheduled to continue for a total of 10 years. For more details on the project, please see press release [“Kitasato Institute and Sumitomo Dainippon Pharma Sign a Joint Drug Discovery Research Agreement for Infections Caused by Bacteria with Antimicrobial Resistance \(AMR\)”](#) issued October 24, 2017.

<https://www.ds-pharma.com/ir/news/pdf/ene20171024.pdf> (Press release)

## Reference

### About carbapenem-resistant bacterial infections

Carbapenem-resistant bacterial infections is a general name for infections due to such bacteria as *Enterobacteriaceae*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* with resistance to meropenem and other carbapenem antibiotics, which are important for the treatment of severe bacterial infections. These infections are classified as Priority 1 (Critical) in “List of bacteria for which new antibiotics are urgently needed” published by the WHO.

### About complicated urinary tract infections and complicated intra-abdominal infections

Complicated urinary tract infections are considered to be chronic or recurrent urinary tract infections due to functional or structural abnormalities of the genitourinary tract, catheter or other medical device interventions, or the presence of underlying diseases. They are also broadly divided into cystitis, pyelonephritis, urosepsis, and catheter-related urinary tract infections.

Complicated intra-abdominal infections are severe infections that spread from the hollow viscus of origin to normally sterile area of the abdomen, such as the peritoneal cavity and mesentery, and cause abscess formation or peritonitis.

### About Cyclic Innovation for Clinical Empowerment (CiCLE)

Cyclic Innovation for Clinical Empowerment is a project of the Japan Agency for Medical Research and Development (AMED) that aims to formulate innovative infrastructure (including human resources) for accelerating research and development and the clinical application of drug discovery outcomes in ways that precisely match the needs of healthcare professionals as well as to create an environment that empowers development of open innovation in medical research and development by bringing together Japan’s collective strengths through industry-academia-government collaboration.

The “Drug discovery research aiming at developing agents against infections due to bacteria with antimicrobial resistance (AMR)” joint initiative between Kitasato Institute and Sumitomo Dainippon Pharma (Representative organization: Sumitomo Dainippon Pharma) was selected as a research and development project through an open invitation in the first round of CiCLE grant programs in 2017.

### About The Kitasato Institute

Kitasato Institute states its mission as “With profound respect for the sanctity of life, our purpose is to contribute to society by dedicating ourselves to the quest for truth through the application of practical science.” The institute has a long tradition and track record in infection control, which began with Dr. Shibasaburo Kitasato, its founder, and is now being continued by Dr. Satoshi Ōmura, a recipient of the Nobel Prize in Physiology or Medicine. In fulfilling its mission of contributing to society, Kitasato Institute focuses on education, research, and medical care. For more details, please visit Kitasato Institute website (<https://www.kitasato-u.ac.jp/en/index.html>).

### About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma 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 channeling our total efforts into research and development for new drugs, we aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also worldwide in order to realize our corporate mission. For more details, please visit Sumitomo Dainippon Pharma’s website (<https://www.ds-pharma.com/>).

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