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Sumitomo Pharma

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The Kitasato Institute
Sumitomo Pharma Co., Ltd.

Joint Research between The Kitasato Institute and Sumitomo Pharma:Drug Combination of Meropenem and KSP-1007 for Treatment of Carbapenem-Resistant Bacteria Infections Designated as Qualified Infectious Disease Product (QIDP)/Fast Track

The Kitasato Institute (Headquarters: Minato-ku, Tokyo; Chairperson: Hirosuke Kobayashi; hereinafter referred to as “Kitasato Institute”) and Sumitomo Pharma Co., Ltd. (Head Office: Osaka; Representative Director, President and CEO: Hiroshi Nomura; hereinafter referred to as “Sumitomo Pharma”) announced today that the combination of meropenem and KSP-1007 (development code) (the two hereinafter shall be referred to as “the compound”), which was discovered through a collaboration between the two parties and is being developed by Sumitomo Pharma for the treatment of carbapenem-resistant bacteria infections in the United States (in a Phase 1 study), has been granted Qualified Infectious Disease Product (QIDP) status and Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of complicated urinary tract infections, complicated intra-abdominal infections, hospital-acquired bacterial pneumonia, and ventilator-associated bacterial pneumonia.

The QIDP designation under the Generating Antibiotic Incentives Act makes the compound's development program eligible for priority review for development in the United States. If eventually approved by the FDA, the exclusivity period (data protection period) under the U.S. pharmaceutical regulations will be extended for an additional five years. Fast Track designation also allows for closer collaboration with the FDA and the sequential review of applications for approval.

Sumitomo Pharma plans to initially proceed with the development of the compound for the proposed indications of complicated urinary tract infections and complicated intra-abdominal infections.

Please see the press release dated January 13, 2022, regarding the start of the phase 1 study of the compound.
https://www.sumitomo-pharma.com/ir/news/2022/20220113.html

The joint research project between Kitasato Institute and Sumitomo Pharma began in October 2017 and is scheduled to continue10 years. For more details on the project, please see the 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, and the explanatory materials for the press conference.
https://www.sumitomo-pharma.com/ir/news/pdf/ene20171024.pdf (Press release)

(Reference)
About KSP-1007
KSP-1007 was discovered through a joint research and development initiative selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical

Empowerment (CiCLE) program for collaboration among industry, academia, and government. It can broadly and strongly inhibit β-lactamases, enzymes produced by bacteria that can degrade carbapenem antibiotics. In addition, KSP-1007 is expected to become an effective treatment option against carbapenem-resistant bacterial infections as a combination drug with meropenem hydrate, a carbapenem antibiotic in general use worldwide. (The name of Sumitomo Pharma's product for the Japanese market: MEROPEN®.)

About carbapenem-resistant bacteria infections

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

About complicated urinary tract infections, complicated intra-abdominal infections, hospital-acquired bacterial pneumonia, and ventilator-associated bacterial pneumonia

Complicated urinary tract infections are considered to be chronic or recurrent urinary tract infections due to functional or structural abnormalities of the genitourinary system, 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, the source of infection, to the normally sterile area of the abdomen, such as the peritoneal cavity and mesentery, and cause abscesses or peritonitis.

Hospital-acquired bacterial pneumonia is defined as pneumonia that occurs 48 hours or more after hospital admission. Ventilator-associated bacterial pneumonia develops after more than 48 hours from the initiation of mechanical ventilation and is the most common infection acquired in the ICU.

About Cyclic Innovation for Clinical Empowerment (CiCLE)

CiCLE 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 the development of open innovation in medical research and development by bringing together Japan's collective strengths through industry-academia-government collaborations.

The "Drug discovery research aiming at developing agents against infections from bacteria with antimicrobial resistance (AMR)" joint initiative between Kitasato Institute and Sumitomo Pharma (Representative organization: Sumitomo 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 that began with Dr. Shibasaburo Kitasato, its founder, and is now being continued by Dr. Satoshi Omura, 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).

About Sumitomo Pharma Co., Ltd.

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

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