

Meiji Seika Pharma Co., Ltd.

April 26, 2023

## **Meiji Seika Pharma Initiated the Global Phase III Clinical Trials of OP0595, a Novel $\beta$ -Lactamase Inhibitor for Combatting Antimicrobial Resistance (AMR)**

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi) today announced the initiation of the global phase III clinical trials of OP0595 (INN: nacubactam), a novel  $\beta$ -lactamase inhibitor for combatting antimicrobial resistance (AMR). OP0595 is being developed by Meiji Seika Pharma under the project entitled "Research and development of a novel  $\beta$ -lactamase inhibitor (OP0595) as a stand-alone drug using non-clinical PK/PD", as a part of the Cyclic Innovation for Clinical Empowerment (CiCLE) program supported by the Japan Agency for Medical Research and Development (AMED).

The global phase III clinical trials consist of "OP0595-5 study" (a phase III study in patients with complicated urinary tract infection/acute uncomplicated pyelonephritis) and "OP0595-6 study" (a phase III study in patients with carbapenem-resistant *Enterobacterales* (CRE) infection). These studies are to be conducted in Asia including Japan and China, Europe and the Middle East (in 17 countries planned in total for both studies). The studies to be conducted in China have been entrusted from Meiji to Fobeni Healthcom Pharmaceutical Jiangsu Co., Ltd (Headquarters: Taizhou City, Jiangsu Province, China, Chairman: Wen Deyong).

OP0595 is a novel  $\beta$ -lactamase inhibitor discovered by Meiji Seika Pharma, which is expected to be effective against CRE in combination with  $\beta$ -lactam antibiotics. Carbapenem antibiotics are regarded as the "last resort" in the treatment of severe infections, however, currently, increase of carbapenem-resistant bacteria are becoming a threat worldwide. Under the circumstances, there is a strong demand for the development and marketing of drugs that are effective against multidrug-resistant bacteria such as CRE.

Meiji Seika Pharma is developing OP0595 globally and will deliver it to those patients suffering from drug-resistant bacterial infections as soon as possible, and contributes to the fight against antimicrobial resistance (AMR) which has become a global issue as a "silent pandemic."