

Meiji Seika Pharma Co., Ltd.

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Positive Results of Global Phase III Clinical Trial of OP0595, a Novel β -Lactamase Inhibitor for Combating Antimicrobial Resistance (AMR), in Patients with Complicated Urinary Tract Infections or Acute Uncomplicated Pyelonephritis

— Cefepime/OP0595 Demonstrated Superiority and Aztreonam/OP0595 Demonstrated Non-Inferiority to Imipenem/Cilastatin

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi) today announced that it has achieved positive results in the global Phase III clinical trial of OP0595 (INN: nacubactam), a novel β -lactamase inhibitor for combating antimicrobial resistance (AMR), in patients with complicated urinary tract Infections or acute uncomplicated pyelonephritis. The clinical trial (Integral-1 study: [jRCT2031230075](#)) was conducted as a double-blind comparative study.

The Integral-1 trial was an international, multi-center, randomized, double-blind Phase III study comparing the efficacy and safety of cefepime or aztreonam in combination with OP0595 versus imipenem/cilastatin (a carbapenem antibiotic) in patients with complicated urinary tract infections or acute uncomplicated pyelonephritis. The primary efficacy endpoint was composite clinical and microbiological success at 7 days after the end of treatment. Cefepime/OP0595 met the primary endpoint of statistical non-inferiority to imipenem/cilastatin. Additionally, a prespecified superiority assessment followed by a declaration of noninferiority for the primary endpoint demonstrated the superiority of cefepime/OP0595 and the non-inferiority of aztreonam/OP0595 compared to imipenem/cilastatin. Regarding safety, the incidence of adverse events was similar between either cefepime/OP0595 or aztreonam/OP0595 and imipenem/cilastatin, and no major clinical safety concerns were found. Further details and data will be presented at scientific conferences and in publications.

OP0595 is currently under investigation in an international, multi-center, randomized, single-blind Phase III clinical trial (Integral-2 study: [JRCT2031230076](https://www.clinicaltrials.gov/ct2/show/study?term=JRCT2031230076)) in patients with carbapenem-resistant Enterobacterales (CRE) infections. It is being developed by Meiji Seika Pharma as part of the Cyclic Innovation for Clinical Empowerment (CiCLE) program supported by the Japan Agency for Medical Research and Development (AMED). This project is entitled "Research and development of a novel β -lactamase inhibitor (OP0595) as a stand-alone drug using non-clinical PK/PD analysis".

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