

Meiji Seika Pharma Co., Ltd.

September 19, 2025

Meiji Seika Pharma to Present Global Phase III Results for OP0595, a Novel β -Lactamase Inhibitor Combating AMR, at IDWeek 2025

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Toshiaki Nagasato) today announced that the results of the double-blind comparative trial (Integral-1 trial) of the novel β -lactamase inhibitor OP0595 (INN: nacubactam) for patients with complicated urinary tract infections or acute uncomplicated pyelonephritis will be orally presented at IDWeek 2025 (October 19–25, 2025, in Atlanta, Georgia, USA).

The Integral-1 trial is an international, multi-center, randomized, double-blind Phase III study (jRCT2031230075) that evaluated the efficacy and safety of OP0595 in combination with cefepime or aztreonam versus imipenem/cilastatin (a carbapenem) in patients with complicated urinary tract infections or acute uncomplicated pyelonephritis caused by Gram-negative bacteria sensitive to carbapenems. The trial has already announced that the primary objective was achieved (March 14, 2025, press release), and detailed results of the study are planned to be presented at IDWeek 2025.

Additionally, OP0595 is currently under investigation in an international, multi-center, randomized, single-blind Phase III clinical trial (Integral-2 study: [jRCT2031230076](#)) in patients with carbapenem-resistant Enterobacterales (CRE) infections.

OP0595 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, thereby contributing to the fight against antimicrobial resistance (AMR), which is a global issue known as a "silent pandemic."

Date, Venue	October 20, 2025, 8:00 a.m. (EST), Room B302–B304, Georgia World Congress Center
Symposium	New Antimicrobials in the Pipeline
Title	Nacubactam (OP0595): A Novel Triple-Action Diazabicyclooctane in Combination with Cefepime or Aztreonam

[About OP0595]

OP0595 (nacubactam) is a novel β -lactamase inhibitor developed by Meiji Seika Pharma. When used in combination with approved β -lactam antibiotics, it is expected to be effective against carbapenemase-producing Enterobacterales (CRE). This mechanism restores the antimicrobial activities of β -lactam antibiotics to the CRE. Additionally, OP0595 inhibits penicillin-binding protein (PBP) 2, an enzyme involved in the biosynthesis of peptidoglycan, a key component of bacterial cell walls. This additional mechanism enhances the antimicrobial activities of β -lactam antibiotics to the CRE. This mechanism is the differentiation from existing β -lactamase inhibitors. Currently, bacteria resistant to carbapenems, which are considered the last line of defense for treating severe infections, pose a global threat. In response to this threat, there are medical needs for the effective medicines against multidrug-resistant Gram-negative bacteria, including CRE.