

Meiji Seika Pharma Co., Ltd.

July 17, 2026

Results from the Global Phase III Trial (Integral-2) of Nacubactam, a Novel β -Lactamase Inhibitor, Highlighted in *The Lancet Microbe*'s Coverage of ESCMID Global Congress 2026

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Toshiaki Nagasato) today announced that results from the global Phase III trial (Integral-2) of nacubactam (Development Code: OP0595), a novel β -lactamase inhibitor, were highlighted in [*The Lancet Microbe*'s coverage](#) of ESCMID Global Congress 2026 (held in Munich, Germany).

As highlighted in *The Lancet Microbe*'s coverage, the key findings presented by Meiji Seika Pharma at ESCMID Global Congress 2026 are as follows:

The Integral-2 study (jRCT2031230076) is a global Phase III clinical trial that enrolled patients with complicated urinary tract infections, acute uncomplicated pyelonephritis, hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, or complicated intra-abdominal infections caused by carbapenem-resistant Gram-negative bacteria (excluding *Acinetobacter* species). The study has achieved the prespecified study objectives. For the primary endpoint of overall treatment success at seven days after the end of treatment, cefepime/nacubactam and aztreonam/nacubactam showed success rates of 44.4% (12/27 patients) and 50.0% (12/24 patients), respectively; for reference, the success rate with Best Available Therapy (BAT) was 26.1% (6/23 patients). No major clinical safety concerns were observed.

For background, nacubactam is a β -lactamase inhibitor intended for use in combination with cefepime or aztreonam for infections caused by Gram-negative bacteria resistant to carbapenems. Based on the results of two Phase III global studies—the Integral-1 study (enrolling patients with complicated urinary tract infections and acute uncomplicated pyelonephritis; jRCT2031230075) and the Integral-2 study (enrolling patients with infections caused by carbapenem-resistant Enterobacterales [CRE]; jRCT2031230076)—Meiji Seika Pharma submitted a New Drug Application (NDA) in Japan in December 2025.

Meiji Seika Pharma is committed to contributing to the fight against antimicrobial resistance (AMR), a global issue known as the silent pandemic.

About Nacubactam (Development Code: 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 CRE. This mechanism restores the antimicrobial activity of β -lactam antibiotics against CRE. Additionally, OP0595 inhibits penicillin-binding protein 2 (PBP2), 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 against CRE. This dual mechanism differentiates it from existing β -lactamase inhibitors.

References:

[Venkatesan P. ESCMID Global Congress 2026. The Lancet Microbe. 2026:101476.](#)