Post-Marketing Study to Assess the Effectiveness and Safety of RECARBRIO in Chinese Adult Patients With Limited or No Alternative Treatment Options for Susceptible Gram-Negative Bacterial Infections (MK-7655A-035)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001027

Study ID

1000001027

DARWIN EU® study

No

Study countries

China

Study description

This study is being conducted to better understand how well the antibiotic RECARBRIO works and how safe it is when used in everyday medical practice in China. Serious infections caused by Gram-negative bacteria are becoming harder to treat because many antibiotics are no longer effective. Patients with these infections may have very limited or no other treatment options, creating an urgent need for effective and safe therapies. Although RECARBRIO has already been approved for use in China based on clinical trials, there is limited information on how it performs in real-world settings, especially in Chinese patients. The main objective of the study is to evaluate how well RECARBRIO works by determining how many patients show improvement or complete recovery from their infection after treatment. The study will also assess safety by tracking whether patients experience side effects or adverse reactions during treatment and in the period shortly after treatment ends. This study will describe the real-world effectiveness of RECARBRIO in Chinese adult patients with limited or no alternative treatment options for susceptible Gram negative bacterial infections.

Study status

Planned

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
ClinicalTrialsDisclosure@msd.com

Study contact

ClinicalTrialsDisclosure@msd.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/06/2026

Study start date
Planned: 30/10/2026

Data analysis start date
Planned: 30/04/2028

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

MK-7655A-035-00-v1-Protocol_final-redaction.pdf (1.38 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a multicenter, non-interventional cohort study with a hybrid design incorporating both retrospective and prospective data collection. Data will be obtained primarily through chart review at participating sites using a standardized Case Report Form (CRF).

Main study objective:

To evaluate the real-world effectiveness of RECARBRIO (imipenem/cilastatin/relebactam) in Chinese adult patients with limited or no alternative treatment options for susceptible Gram-negative bacterial infections—including hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), complicated urinary tract infections (cUTI, including pyelonephritis), and complicated intra-abdominal infections (cIAI)—by estimating separately the proportion of patients achieving a favorable clinical response at the test of cure (TOC) and end of treatment (EOT) visits.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

RECARBRIO

Study drug International non-proprietary name (INN) or common name

IMIPENEM

CILASTATIN SODIUM

RELEBACTAM

Anatomical Therapeutic Chemical (ATC) code

(J01DH56) imipenem, cilastatin and relebactam

imipenem, cilastatin and relebactam

Additional medical condition(s)

Hospital-Acquired Bacterial Pneumonia and Ventilator- Associated Bacterial Pneumonia; Complicated Urinary Tract Infection; Complicated Intra-Abdominal Infection

Population studied

Short description of the study population

Chinese patients aged 18 years or older who have received at least one dose of RECARBRIO for Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP), Complicated Intra-Abdominal Infection (cIAI), or Complicated Urinary Tract Infection (cUTI) (including pyelonephritis) with limited or no alternative treatment options and meet all study inclusion and exclusion criteria.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

140

Study design details

Setting

Chinese adult patients with limited or no alternative treatment options for susceptible Gram-negative bacterial infections—including HABP/VABP, cUTI including pyelonephritis and cIAI.

Comparators

A non-comparative, single-arm framework will be employed, with no external comparator group included in the study. Comparisons are limited to within-cohort outcome assessments across specified evaluation timepoints with all analyses conducted descriptively in this real-world population.

Outcomes

The primary outcomes are favorable clinical response (clinical cure) to RECARBRIO for the index infection, assessed separately at the TOC and EOT visits, in the overall study population who have received at least 3 days of RECARBRIO for the treatment of cIAI or cUTI (including pyelonephritis) with limited or no alternative treatment options. Clinical cure is defined as the complete resolution or significant improvement of signs and symptoms of the index infection.

Data analysis plan

Descriptive statistical methods will be used to summarize study data, and no formal hypothesis testing will be performed. Patient attrition, patient characteristics, treatment patterns, and effectiveness outcomes of interest will be described using frequency and percentage distributions for categorical variables, and mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum for continuous variables.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Drug prescriptions

Electronic healthcare records (EHR)

Laboratory tests and analyses

Non-interventional study

Other

Data sources (types), other

Medical records (paper), microbiology reports, medication records related to RECARBRIO and concomitant systemic antibiotic therapy, and other relevant clinical documents.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No