Respiratory syncytial virus (RSV) strain surveillance study (MK-1654-010)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001082

Study ID

1000001082

DARWIN EU® study

No

Study countries

United States

Study description

Clesrovimab (also known as MK-1654 or ENFLONSIA) is a fully human IgG1 monoclonal antibody (mAb) that targets the respiratory syncytial virus (RSV) fusion (F) protein to prevent RSV entry into host cells. Clesrovimab received

FDA approval in June 2025 for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.
RSV sequences can drift over time, resulting in a possibility of emergence of viral resistance to any monoclonal antibody (mAb). By regularly monitoring the genetic sequences of circulating RSV strains, researchers can track changes in the virus and identify new strains that may be resistant to treatment. The primary objective is to evaluate the presence of sequence variations affecting the RSV genome over a 5-year period, with a particular focus on the region of the F protein where clesrovimab binds (known as Site IV).

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Last updated: 08/07/2025

Institution | Pharmaceutical company

Contact details

Study institution contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2024

Study start date

Planned: 01/09/2027

Data analysis start date

Planned: 01/06/2033

Date of final study report

Planned: 31/07/2034

Sources of funding

- Pharmaceutical company and other private sector

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:

Other

Study topic, other:

Virologic surveillance of the RSV virus

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Virologic surveillance

Data collection methods:

Primary data collection

Study design:

Global, multicenter, non-interventional RSV surveillance study collecting RSV-positive respiratory specimens from children <5 years over 5 years from a minimum of 4 North American sites and at least 2 sites from other global regions (e.g. Europe, South America, Asia Pacific region).

Main study objective:

The primary objective of this study is to evaluate genetic variation in circulating respiratory syncytial virus (RSV) strains over a 5-year period, with a particular focus on changes occurring within Site IV of the RSV fusion (F) protein, the region where clesrovimab binds. Other objectives of the study include estimating the seasonal prevalence of RSV F protein sequence variations and evaluating the phenotype of select RSV variants.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Global RSV strain surveillance study

Population studied

Short description of the study population

Children under 5 years of age who seek medical attention due to a respiratory illness in one of the participating sites and test positive to RSV by Reverse Transcription Polymerase Chain Reaction (RT-PCR).

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

Estimated number of subjects

2000

Study design details

Setting

Children under 5 years of age who seek medical attention due to a respiratory illness in one of the participating sites and test positive to RSV by RT PCR.

Outcomes

The study will provide a comprehensive assessment of genetic variation in circulating RSV strains collected from children under 5 years of age across multiple global regions. The primary endpoint is to evaluate the presence of sequence variations affecting the RSV genome over a 5-year period with a special focus on the clesrovimab binding epitope within Site IV of the F protein. Additional outcomes include assessing the total number of RSV-A and RSV-B

subtypes and the association of these subtypes with patient characteristics; Evaluating the total number of RSV variants with polymorphisms in the clesrovimab binding epitope of the RSV F protein; Assessing sequence variations affecting the RSV F protein with special attention to Site IV of the RSV F protein predicted to decrease sensitivity to clesrovimab; Estimation of the seasonal and geographic prevalence of RSV F protein sequence variation; And evaluating the phenotype (viral fitness, sensitivity to mAb) of select RSV variants of interest.

Data analysis plan

RSV F protein gene sequences obtained from collected specimens will be compared with contemporary RSV-A and RSV-B reference strains to identify nucleotide changes and amino acid substitutions. Sequence alignments will be used to characterize genetic diversity in circulating RSV strains, with particular focus on Site IV of the RSV F protein, the clesrovimab binding epitope. A 10% variant allele frequency (VAF) threshold will be applied for variant reporting. Descriptive analyses will summarize the number and proportion of RSV samples containing amino acid substitutions in the F protein.

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)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Non-interventional study

Vaccination registry

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

Not applicable