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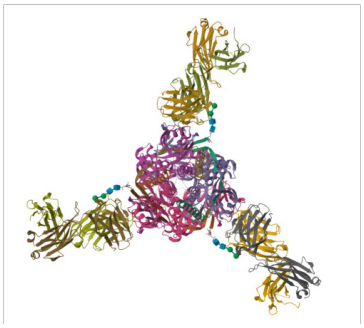


Clesrovimab

Developer(s)

Merck

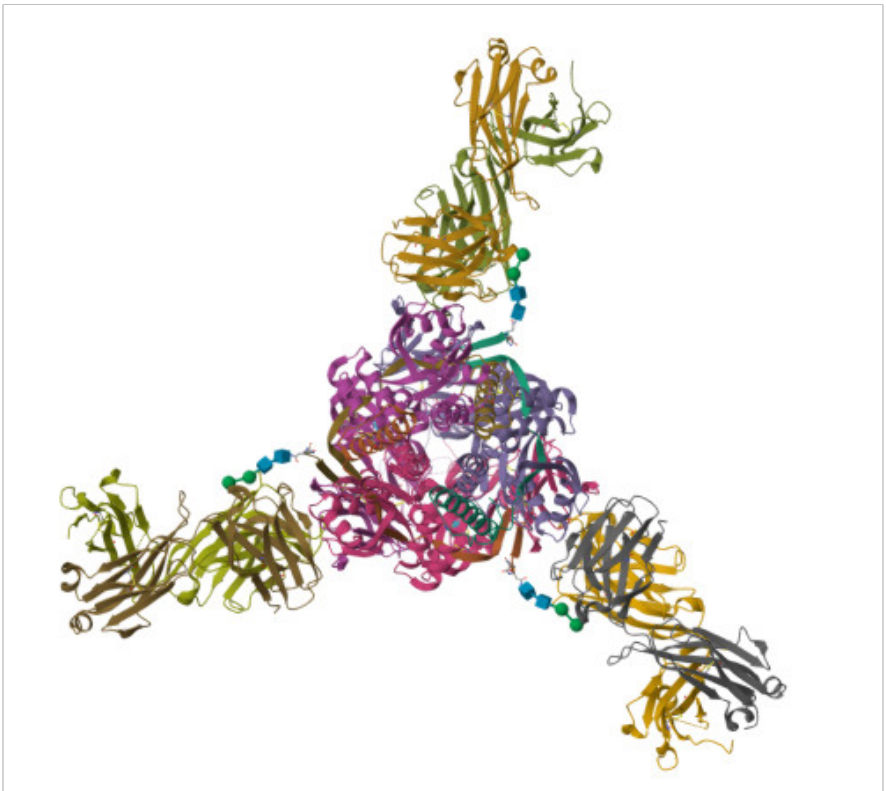
Originator

https://www.merck.com/

United States

Merck & Co., Inc. is an American multinational pharmaceutical company known as Merck Sharp & Drone (MSD) in territories outside of the USA and Canada. Merck was originally established in 1891, and is headquartered in Rahway, New Jersey. The company is particularly well known for developing and manufacturing biologic therapies, vaccines, medicines and animal health products.

Drug structure



Interaction of the parental antibody to MK-1654 (RB1) with the RSV pre-F trimer.

https://doi.org/10.2210/pdb6OUS/pdb

Drug information

Associated long-acting platforms

Monoclonal antibodies and antibody drug conjugates

Administration route

Intramuscular

Therapeutic area(s)

Respiratory syncytial virus (RSV)

Use case(s)

Prevention

Use of drug

Ease of administration

Administered by a nurse
Administered by a specialty health worker
Administered by a community health worker

Frequency of administration

Once

User acceptance

Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies

Dosage

Available dose and strength

100 mg in 0.5 mL

Maximum dose

105 mg

Recommended dosing regimen

105 mg prefilled injection is administered as a single intramuscular (IM) injection for neonates and infants born during or entering their first RSV season. For infants born outside the RSV season, administer ENFLONSIA once prior to the start of their first RSV season, considering the duration of protection provided by ENFLONSIA

Additional comments

105 mg/0.7 mL prefilled syringe

Dosage link(s)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761432s000lbl.pdf

Drug information

Drug's link(s)

https://go.drugbank.com/drugs/DB18877

Generic name

Clesrovimab

Brand name

ENFLONSIA

Compound type

Biotherapeutic

Drug class/category

Not provided

Summary

Clesrovimab-cfor is a respiratory syncytial virus F protein-directed fusion inhibitor. Clesrovimab (MK-1654) is a human IgG1 monoclonal antibody (mAb) indicated for the prevention of Respiratory syncytial virus (RSV). It is being studied as protection against mild, moderate, and severe RSV in preterm, full-term, and at-risk infants during their first RSV season. Clesrovimab is designed to be administered at the same single dose irrespective of birth weight and exhibits potent in vitro neutralization of RSV-A and RSV-B clinical isolates via high-affinity binding to the RSV fusion (F) protein antigenic

site IV. Engineered YTE substitution mutations in the mAb fragment crystallizable (Fc) domain result in an extended half-life through enhanced neonatal.

Approval status

Clesrovimab has received regulatory approval in 34 countries, including the United States of America (under Biologics License Application (BLA 761432)), member states of the European Union and European Economic Area (EU/EEA), as well as the United Arab Emirates. Clesrovimab has been approved for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season

Regulatory authorities

ENFLONSIA™ (Clesrovimab) 105 mg/0.7 mL prefilled syringe has been granted regulatory approval by the United States Food and Drug Administration (USFDA), the European Medicines Agency (EMA), and the Department of Health (DoH) of the United Arab Emirates.

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

General manufacturing requirements and production scale-up for therapeutic monoclonal antibody (mAb) products is primarily focused on pharmacokinetic suitability, formulation stability and the overall maintenance of product quality. Industrial bioprocessing steps can also potentially introduce additional challenges regarding mAb formulation viscosity and aggregation propensity.

Tentative equipment list for manufacturing

Industrial bioreactor vessel with a production volume capacity of between 5-25kL. Continuous disc stack centrifuges for bioreactor harvesting with subsequent membrane and depth filtration for supernatant clarification. Recombinant protein-A chromatography or other suitable affinity capture apparatus followed by two chromatographic polishing steps such as cation- and anion-exchange. Ultrafiltration membrane system to concentrate and formulate the final product.

Manufacturing

MAbs are highly dependent on their structural, chemical and conformational stability for biological activity. Chemical degradation of mAbs during manufacture can lead to the generation of product variants and complex impurity profiles resulting from a wide range of processes, including: N-linked glycosylation, isomerisation, fragmentation, deamidation, oxidation and C-terminal lysine clipping. Additionally prior to packaging, the final product requires close monitoring for the presence of residual contaminants such as endotoxins and pro-inflammatory peptidoglycans.

Specific analytical instrument required for characterization of formulation

Formulation characterisation steps for therapeutic mAb products include (but are not limited to): (1) Identification of post-translational modifications using ion-exchange chromatography and capillary isoelectric focusing, (2) Measurement of concentration dependent aggregation rates via thermal differential scanning calorimetry, sub-visible particle quantitation and size-exclusion chromatography, and (3) Antibody clipping and fragmentation detection by capillary electrophoresis.

Clinical trials

CLEVER (MK-1654-004)

Identifier

NCT04767373

Link

https://clinicaltrials.gov/study/NCT04767373

Phase

Phase II/III

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The primary objectives of this phase 2b/3 double-blind, randomized, placebo-controlled study are to evaluate the efficacy and safety of clesrovimab in healthy pre-term and full-term infants. It is hypothesized that clesrovimab will reduce the incidence of respiratory syncytial virus (RSV)-associated medically attended lower respiratory infection (MALRI) from Days 1 through 150 postdose compared to placebo.

Purpose

Efficacy and Safety of Clesrovimab (MK-1654) in Infants (MK-1654-004)

Interventions

Intervention 1
Biological: Clesrovimab
Dosage: Participants receive a single intramuscular (IM) administration of clesrovimab on Day 1.

Intervention 2
Drug: Placebo
Dosage: Placebo (0.9% sodium chloride [NaCL]) solution

Countries

Argentina
Belgium
Canada
Chile
China
Colombia
Denmark
Finland
France
Israel
Italy
Japan
Korea, Republic of
Malaysia
Mexico
Peru
Philippines

Poland

Romania

South Africa

Thailand

Türkiye

United Kingdom

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-04-07

Anticipated Date of Last Follow-up

2025-05-02

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2024-07-09

Actual Completion Date

2024-07-09

Studied populations

Age Cohort

- Children

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Key Inclusion Criteria: * Is a healthy male or female who is an early or moderate pre-term infant (≥29 to 34 weeks and 6 days gestational age) or a late pre-term or full-term infant (≥35 weeks gestational age). * For the phase 2b cohort only: Has a chronological age \>2 weeks of age up to 1 year and is entering their first RSV season at the time of obtaining documented informed consent. * For the phase 3 cohort only: Has a chronological age from birth up to 1 year and is entering their first RSV season at the time of obtaining documented informed consent. * For participants in South Korea only: Weighs ≥2 kg

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

3632

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Double (Participant, Investigator)

Frequency of administration

Other/Variable/Unknown : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key resources

Not provided

MK-1654-002

Identifier

NCT03524118

Link

https://clinicaltrials.gov/study/NCT03524118

Phase

Phase I/II

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, and incidence of anti-drug antibodies (ADAs) of single ascending doses of clesrovimab in healthy pre-term (born at 29 to 35 weeks gestational age) and full-term (born at >35 weeks gestational age) infants. Participants will be randomized into 1 of 4 dose escalation panels (Panels A to D); an additional panel (Panel E) of full-term infants will receive the same dose as Panel D. Key safety and tolerability variables will be reviewed after each dose panel prior to administering the next-highest dose.

Purpose

Safety, Tolerability, and Pharmacokinetics of Clesrovimab (MK-1654) in Infants (MK-1654-002)

Interventions

Intervention 1

Drug: Clesrovimab

Dosage: Single ascending doses of clesrovimab will be administered via IM injection.

Intervention 2

Drug: Placebo

Dosage: Placebo (0.9% sodium chloride [NaCl]) will be administered via IM injection.

Countries

Chile

Colombia

Korea, Republic of

South Africa

Spain

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2018-09-20

Anticipated Date of Last Follow-up

2025-01-06

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2022-09-14

Actual Completion Date

2022-09-14

Studied populations

Age Cohort

- Children

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Is healthy, based on screening safety laboratory, medical history, and physical examination results. * Is a pre-term infant (born at 29 weeks to 35 weeks gestational age [inclusive]) or a full-term infant (born at over 35 weeks gestational age), as confirmed in medical records. * Weighs ≥2 kg at screening.

Health status

Negative to : HIV, HBV, HCV
Other health status: Participants must not have had prior known or documented RSV infection.

Study type

Interventional (clinical trial)

Enrollment

183

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Triple (Participant, Care Provider, Investigator)

Frequency of administration

Other/Variable/Unknown : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key resources

Type	Title	Content	Link
Link	A Phase 1b/2a Single Ascending Dose Study of a Half-life Extended RSV Neutralizing Antibody, Clesrovimab, in Healthy Preterm and Full-term Infants		https://doi.org/10.1093/infdi

Type	Title	Content	Link
Link	Development of High-Titer Antidrug Antibodies in a Phase 1b/2a Infant Clesrovimab Trial Are Associated With RSV Exposure Beyond Day 150		https://doi.org/10.1093/infdi

SMART

Identifier

NCT04938830

Link

https://clinicaltrials.gov/study/NCT04938830

Phase

Phase III

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

This study aims to evaluate the safety and tolerability of clesrovimab compared to palivizumab as assessed by the proportion of participants experiencing adverse events (AEs).

Purpose

Clesrovimab (MK-1654) in Infants and Children at Increased Risk for Severe Respiratory Syncytial Virus (RSV) Disease (MK-1654-007)

Interventions

Intervention 1

Biological: Clesrovimab IM injection

Intervention 2

Biological: Palivizumab IM injection

Intervention 3

Biological: Placebo IM injection

Countries

Australia
Canada
Chile
Colombia
Czechia
Finland
France
Germany
Greece
Hong Kong
Hungary
Italy
Japan
Malaysia
Mexico
New Zealand
Norway
Peru
Puerto Rico
Singapore
South Africa
Spain

Taiwan, Province of China

Thailand

Türkiye

United Kingdom

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-11-30

Anticipated Date of Last Follow-up

2025-08-12

Estimated Primary Completion Date

2025-04-29

Estimated Completion Date

2025-08-13

Actual Primary Completion Date

2025-04-28

Actual Completion Date

2025-08-01

Studied populations

Age Cohort

Children

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Participants at increased risk for severe RSV infection recommended to receive palivizumab in accordance with national or local guidelines or professional society recommendations. * Is available to complete the follow-up period. Exclusion Criteria: * Requires mechanical ventilation at time of enrollment. * Has a life expectancy <6 months. * Has known hepatic or renal dysfunction, or chronic seizure disorder. * Is hospitalized at the time of randomization unless discharge is expected within 7 days after randomization. * Has severe immunodeficiency or is severely immunocompromised. * Has known hypersensitivity to any component of clesrovimab or palivizumab.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

1003

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Triple (Participant, Care Provider, Investigator)

Frequency of administration

Other/Variable/Unknown : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key resources

Not provided

MK-1654-005

Identifier

NCT04086472

Link

https://clinicaltrials.gov/study/NCT04086472

Phase

Phase II

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The primary objective of this study is to determine if a single intravenous (IV) dose of clesrovimab when administered at 1 of 4 dose levels results in a reduction in viral load after intranasal inoculation (with RSV A Memphis 37b) compared to IV placebo. It is hypothesized that at least 1 of the 4 dose levels of clesrovimab given prior to inoculation will reduce the area under the viral load-time curve (VL-AUC) from Day 2 through Day 11 (inclusive) after viral inoculation (Study Day 31 through Day 40) compared to placebo.

Purpose

Phase 2a Respiratory Syncytial Virus (RSV) Human Challenge Study of Clesrovimab (MK-1654) in Healthy Participants (MK-1654-005)

Interventions

Intervention 1

Biological: Clesrovimab

Dosage: 100 mg, 200 mg, 300 mg or 900 mg

Intervention 2

Placebo Comparator: Placebo

Countries

United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-10-28

Anticipated Date of Last Follow-up

2022-08-29

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2020-03-22

Actual Completion Date

2020-08-14

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Is a male or female 18 to 55 years of age in good health with no history of major medical conditions that will interfere with participant safety, as defined by medical history, physical examination (including vital signs), electrocardiogram (ECG), and routine laboratory tests and determined by the Investigator at a screening evaluation. * Has a total body weight ≥ 50 kg and Body Mass Index (BMI) ≥ 18 kg/m\^2 and ≤ 30kg/m\^2. * If male, agrees to study contraceptive requirements at dosing and continuing until 90 days after dosing or 28

days after viral inoculation (whichever is later) and to not donate sperm until 90 days after dosing. * If female, has a negative pregnancy test at screening and prior to dosing and agrees to use one form of effective contraception.

Health status

Negative to : HIV, HCV, HBV

Study type

Interventional (clinical trial)

Enrollment

80

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Triple (Participant, Investigator, Outcomes Assessor)

Frequency of administration

Other/Variable/Unknown : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intravenous

Use case

Prevention

Key resources

Type	Title	Content	Link
Link	Forward and reverse translational approaches to predict efficacy of neutralizing respiratory syncytial virus (RSV) antibody prophylaxis		https://doi.org/10.1016/j.ebi

Excipients

Proprietary excipients used

No proprietary excipient used

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

1. Arginine hydrochloride (10.33 mg) 2. Histidine (0.55 mg) 3. L-histidine monohydrochloride monohydrate (0.74 mg), 4. Polysorbate 80 (0.14 mg) 5. Sucrose (35 mg) 4. Water for injection (USP) None of the listed excipients is novel, nor do they exceed the maximum concentrations listed in the FDA IID for the injectable route.

Residual solvents used

No residual solvent used

Patent info

Formulation patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Anti-RSV antibodies (e.g. clesrovimab) formulation for Intramuscular administration Expiry date: 2039-10-14 The present invention relates to stable formulations comprising antibodies or antigen-binding fragments thereof that bind to respiratory syncytial virus (RSV). Also provided are methods of preventing and/or treating RSV-related diseases with the formulations of the invention.	WO2020081408	Composition	Merck Sharp & Dohme Corp	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted		Japan, Russian Federation
Filed	China, Albania, Serbia, Türkiye, Moldova, Republic of, North Macedonia, Mexico, Malaysia, Viet Nam	Canada, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Singapore, United States of America

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Morocco, Tunisia, Bosnia and Herzegovina, Cambodia, Montenegro	World Intellectual Property Organization (WIPO), Korea, Republic of

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Clesrovimab Expiry date: 2036-10-27 The present invention relates to monoclonal antibodies which have high anti-RSV neutralizing titers. The invention further provides for isolated nucleic acids encoding the antibodies of the invention and host cells transformed therewith. The invention yet further provides for diagnostic, prophylactic and therapeutic methods employing the antibodies and nucleic acids of the invention, particularly as a passive immunotherapy agent in infants and the elderly.	WO2017075124	Compound	Merck Sharp & Dohme Corp	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, China, Jordan, Mexico, Ukraine, South Africa, India, Namibia, Ghana, Botswana, Kenya, Colombia, Dominican Republic, Indonesia, Mongolia, Nigeria	Australia, Chile, Japan, Korea, Republic of, United States of America, Costa Rica, New Zealand, Panama, Seychelles

Patent status/countries	Low, Low- middle and upper-middle	High income
Filed	Argentina, Tajikistan, Belarus, Azerbaijan, Turkmenistan, Armenia, Kyrgyzstan, Kazakhstan, Ecuador, Morocco, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, Moldova, Republic of, North Macedonia, Georgia, Jordan, Malaysia, Nicaragua, Peru, Philippines, El Salvador, Tunisia, Egypt, Guatemala, Honduras, Iran (Islamic Republic of), Jamaica, Lebanon, Sri Lanka, Thailand, Pakistan	Canada, Russian Federation, Liechtenstein, Italy, Norway, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Hong Kong, Israel, Singapore, Taiwan, Province of China, Brunei Darussalam, Kuwait, United Arab Emirates, Bahrain, Saudi Arabia, Oman, Qatar, New Zealand, Trinidad and Tobago
Not in force	World Intellectual Property Organization (WIPO), Sierra Leone, Eswatini, Liberia, Sao Tome and Principe, Mozambique, Uganda, Zambia, Zimbabwe, Tanzania, United Republic of, Malawi, Rwanda, Sudan, Lesotho, Gambia (the)	World Intellectual Property Organization (WIPO), Australia

Supporting material

Publications

Phuah JY, Maas BM, Tang A, Zhang Y, Caro L, Railkar RA, Swanson MD, Cao Y, Li H, Roadcap B, Catchpole AP, Aliprantis AO, Vora KA. Quantification of clesrovimab, an investigational, half-life extended, anti-respiratory syncytial virus protein F human monoclonal antibody in the nasal epithelial lining fluid of healthy adults. Biomed Pharmacother. 2023 Dec 31;169:115851. DOI: 10.1016/j.biopha.2023.115851. Epub 2023 Nov 14. PMID: 37976891.

Background: Clesrovimab (MK-1654) is an investigational, half-life extended human monoclonal antibody (mAb) against RSV F glycoprotein in clinical trials as a prophylactic agent against RSV infection for infants.

Methods: This adult study measured clesrovimab concentrations in the serum and nasal epithelial lining fluid (ELF) to establish the partitioning of the antibody after dosing. Clesrovimab concentrations in the nasal ELF were normalized for sampling dilution using urea concentrations from ELF and serum. Furthermore, in vitro RSV neutralization of human nasal ELF following dosing was also measured to examine the activity of clesrovimab in the nasal compartment.

Findings: mAbs with YTE mutations are reported in literature to partition ~1-2 % of serum antibodies into nasal mucosa. Nasal: serum ratios of 1:69-1:30 were observed for clesrovimab in two separate adult human trials after urea normalization, translating to 1.4-3.3 % of serum concentrations. The nasal PK and estimates of peripheral volume of distribution correlated with higher extravascular distribution of clesrovimab. These higher concentration of the antibody in the nasal ELF corroborated with the nasal sample's ability to neutralize RSV ex vivo. An overall trend of decreased viral plaque AUC was also noted with increasing availability of clesrovimab in the nasal ELF from a human RSV challenge study.

Interpretation: Along with its extended half-life, the higher penetration of clesrovimab into the nasal epithelial lining fluid and the associated local increase in RSV neutralization activity could offer infants better protection against RSV infection.

Keywords: Monoclonal antibody; Nasal epithelial lining fluid; RSV; Respiratory syncytial virus; Urea normalization.

Additional documents

No documents were uploaded

Useful links

- Clesrovimab (MK-1654): Pediatric Clinical Program
- Merck’s Clesrovimab (MK-1654), an Investigational Respiratory Syncytial Virus (RSV) Preventative
- A Phase 1b/2a Single Ascending Dose Study of a Half-life Extended RSV Neutralizing Antibody, Clesrovimab, in Healthy Preterm and Full-term Infants
- Development of High-Titer Antidrug Antibodies in a Phase 1b/2a Infant Clesrovimab Trial Are Associated With RSV Exposure Beyond Day 150
- Forward and reverse translational approaches to predict efficacy of neutralizing respiratory syncytial virus (RSV) antibody prophylaxis

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Clesrovimab is a priority for licensing by the Medicines Patent Pool. Clesrovimab is backed by data from the Phase IIb/III CLEVER study, a pivotal, double-blind and placebo-controlled study that enrolled more than 3,600 infants up to 1 year of age who were entering their first RSV season. Results published in October 2024 showed that a single dose of clesrovimab could cut RSV-associated medically attended lower respiratory infection by 60.4% at 150 days versus placebo. At this same time point, clesrovimab lowered RSV-associated hospitalizations by 84.2% and hospitalizations linked to lower respiratory infections in RSV by 90.9%.