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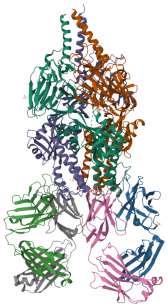


Nirsevimab

Developer(s)

AstraZeneca

Originator

https://www.astrazeneca.com/

United Kingdom

AstraZeneca plc (AZ), is a British-Swedish multinational biopharmaceutical company headquartered in Cambridge, UK. Their product portfolio targets a diverse array of pathologies, including oncology, cardiovascular diseases, gastrointestinal conditions, infectious agents and neurological disorders. Notably, they partnered with Oxford University to develop the ChAdOx1 nCoV-19 vaccine.

Sanofi

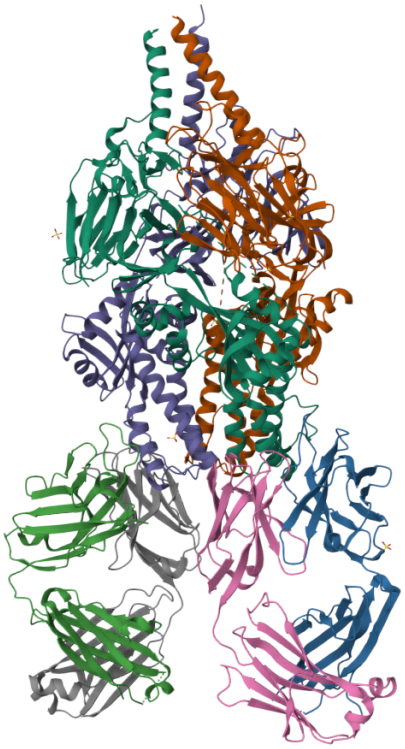
Originator

https://www.sanofi.com/en

France

Sanofi S.A. is a leading French multinational pharmaceutical and healthcare company headquartered in Paris, France. Established in 1973, Sanofi researches, develops, manufactures and markets of a broad portfolio of pharmaceutical products encompassing several therapeutic areas, including: diabetes, internal medicine, cardiovascular disease, neurology, oncology, thrombosis and vaccines.

Drug structure



Crystal Structure of Nirsevimab (MEDI8897) Bound to RSV F B9320

https://doi.org/10.2210/pdb5UDD/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

User acceptance

Not provided

Dosage

Available dose and strength

Solution for injection in pre-filled syringes with 50 mg in 0.5 ml and 100 mg in 1 ml (100 mg/ml)

Frequency of administration

Single dose. For toddlers who remain vulnerable to severe RSV disease after the first immunisation with Beyfortus, the paediatrician will recommend a further dose in the second RSV season.

Maximum dose

The recommended dose is a single dose of 200 mg, administered as two intramuscular injections (2 x 100 mg)

Recommended dosing regimen

The recommended dose for infants weighing less than 5 kg is a single dose of 50 mg. For infants weighing 5 kg or more, the recommended single dose is 100 ml

Additional comments

For toddlers who remain vulnerable to severe RSV disease after the first immunisation with Beyfortus, the paediatrician will recommend a further dose in the second RSV season. The recommended dose is

Dosage link(s)

https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/public-summary-swiss-par/public-summary-swiss-par-beyfortus.html
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf
https://www.ema.europa.eu/en/medicines/human/EPAR/beyfortus

Drug information

Drug's link(s)

Not provided

Generic name

Nirsevimab

Brand name

Beyfortus

Compound type

Biotherapeutic

Summary

Nirsevimab (MEDI8897) is a recombinant human IgG1 kappa monoclonal antibody used for the treatment of Respiratory Syncytial Virus (RSV), which is a major cause of acute lower respiratory infection and hospitalisation in young children and infants. Nirsevimab acts to block viral entry into the host cell by targeting the RSV fusion (F) protein and binding to a highly conserved epitope located within the F1 and F2 subunits. Nirsevimab neutralises RSV-A and -B strains with >50-fold greater efficacy than palivizumab and possesses an extended half-life (68.7±10.9 days) through the introduction of a triple amino acid substitution (YTE) in the Fc region. Given its favourable safety profile, nirsevimab may provide a cost-effective option for RSV prophylaxis that supports once-per-season IM dosing.

Approval status

Beyfortus (nirsevimab-alip) (100 mg/mL), available in 0.5 mL and 1 mL extended-release single-dose intramuscular injections, has been approved by several regulatory authorities for the prevention of lower respiratory tract disease caused by Respiratory

Syncytial Virus (RSV) in neonates and infants during their initial RSV season and for children up to 24 months of age. These approvals have been granted in multiple regions, including the United States, Australia, the European Union countries, Switzerland, the United Kingdom, Saudi Arabia, Qatar, China, and Japan. Real world data from countries such as the US, Spain and France have confirmed and even surpassed the outstanding efficacy data generated during the clinical development of this monoclonal antibody.

Regulatory authorities

Beyfortus has received Fast Track Designation from the USFDA and European Marketing Authorisation from EMA. It was first approved by EMA and the UK in the year 2022 followed by other countries. Beyfortus has now been launched in more than 20 countries. Many more countries are expected to implement all-infant protection in the future.

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

monoclonal antibodies 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

MUSIC

Identifier

NCT04484935

Link

https://clinicaltrials.gov/study/NCT04484935

Phase

Phase II

Status

Completed

Sponsor

AstraZeneca

More details

Study D5290C00008 is a Phase 2, open-label, uncontrolled, single-dose study to evaluate the safety and tolerability, pharmacokinetic(s) (PK), occurrence of antidrug antibody (ADA), and efficacy of nirsevimab in immunocompromised children who are ≤ 24 months of age at the time of dose administration. Approximately 100 subjects will be enrolled. Subjects will be followed for approximately 1 year after dose administration.

Purpose

Evaluate the Safety and Tolerability, for Nirsevimab in Immunocompromised Children

Interventions

Intervention 1

Nirsevimab

Countries

United States of America

Belgium

Japan

Poland

South Africa

Spain

Ukraine

United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2020-08-19

Anticipated Date of Last Follow-up

2023-10-25

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-02-17

Actual Completion Date

2023-02-17

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: - Neonate, infant, or young child ≤ 24 months of age at the time of dose administration who, per investigator judgement, are: (1) In their first year of life AND entering their first RSV season at the time of dose administration OR (2) In their second year of life AND entering their second RSV season at the time of dose administration. The subject must meet at least 1 of the following conditions at the time of informed consent: (1) Diagnosed with combined immunodeficiency; antibody deficiency; or other immunodeficiency OR (2) Diagnosed with human immunodeficiency virus infection OR (3) History of organ or bone marrow transplantation OR (4) Subject is receiving immunosuppressive (chemo) / therapy OR (5) Subject is receiving systemic high-dose corticosteroid therapy.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

100

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Open: no masking is used. All involved know the identity of the intervention assignment.

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

VAS00006

Identifier

NCT05437510

Link

https://clinicaltrials.gov/study/NCT05437510

Phase

Phase III

Status

Not provided

Sponsor

Sanofi Pasteur

More details

The purpose of this study is to determine the efficacy and safety of a single intramuscular (IM) dose of nirsevimab, compared to no intervention, for the prevention of hospitalizations due to lower respiratory tract infection (LRTI) caused by confirmed RSV infection (henceforth referred to as RSV LRTI hospitalizations) in all infants under 12 months of age who are not eligible to receive palivizumab. The visit frequency will be 1 in-person dosing/randomization visit, with monthly safety follow-up electronic contacts through the first 6 months post dosing/randomization for all participants. The study will also include a 12-month (Day 366) follow-up telephone call. The D366 follow-up telephone call will be the final follow-up telephone call for France, Germany and UK non-reconsented partici

Purpose

Study of a Single Intramuscular Dose of Nirsevimab in the Prevention of Hospitalizations Due to Respiratory Syncytial Virus (RSV) Infection in Healthy Term and Preterm Infants During the First Year of

Interventions

Intervention 1

Nirsevimab

Countries

France
Germany
United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-08-08

Anticipated Date of Last Follow-up

2025-02-20

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2025-02-27

Actual Primary Completion Date

2024-03-27

Actual Completion Date

Not provided

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: - Born at ≥ 29 weeks gestational age and aged 0 to 12 months (calendar age), who are entering their first RSV season on the day of inclusion in the study (D01). - Informed consent form has been signed and dated by the parent(s) or other LAR(s) (and by an independent witness if required by local regulations). - Participant and parent/LAR are able to attend the scheduled visit and to comply with all study procedures.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

8058

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

JUBILUS

Identifier

NCT06042049

Link

https://clinicaltrials.gov/study/NCT06042049

Phase

Phase III

Status

Not provided

Sponsor

AstraZeneca

More details

The purpose of this study is to measure the safety, PK, occurrence of ADA to nirsevimab, and anti-RSV neutralizing Ab in Japanese children with certain health conditions or pre-term infants aged ≤12 months. Study details include * The study duration is approximately 21 months with a 2-month enrollment period. * Study intervention is 2 doses administered 5- 6 months apart. * The study has 5 or 6 site visits and several telephone contacts with a 2 or 4 week interval

Purpose

A Study to Assess Safety, Pharmacokinetics Anti-Drug Antibody and Anti-RSV Antibody After 2 Doses of Nirsevimab

Interventions

Intervention 1

Nirsevimab

Countries

Japan

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-07-27

Anticipated Date of Last Follow-up

2025-01-27

Estimated Primary Completion Date

2024-09-09

Estimated Completion Date

2025-08-15

Actual Primary Completion Date

2024-09-10

Actual Completion Date

Not provided

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: (1) Written informed consent and any locally required authorization obtained from the participant's parent(s)/legally authorized representative(s) before performing any protocol-related procedures, including screening evaluations. (2) Japanese infants of ≤12 months of age eligible to receive palivizumab in accordance with national or local guidelines and those who must meet at least one of the following conditions at the time of informed consent. i. Immunodeficiency ii. Chronic Lung Disease iii. Congenital Heart Disease iv. Down syndrome v. Born pre-term ≤28 wks Gestation age and aged ≤12 months, or born pre-term \>28 wks and ≤35 wks Gestation age and aged ≤6 months. (3) The participant's parent(s) / legal guardian(s) can understand and comply.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

33

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

No masking is used. All involved know the identity of the intervention assignment.

Frequency of administration

Once every 6 months
Other : "Two doses administered 5- 6 months apart "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

PK/ADA

Identifier

NCT04840849

Link

https://clinicaltrials.gov/study/NCT04840849

Phase

Phase I

Status

Completed

Sponsor

AstraZeneca

More details

The purpose of this study is to evaluate the Pharmacokinetics, Safety, Tolerability of Nirsevimab in Healthy Chinese Adults.

Purpose

Evaluate the Pharmacokinetics, Safety, and Tolerability of Nirsevimab in Healthy Chinese Adults

Interventions

Intervention 1

Nirsevimab

Intervention 2

Placebo

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-06-22

Anticipated Date of Last Follow-up

2023-01-16

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2021-11-18

Actual Completion Date

2021-11-18

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: (1) Age 18 to 45 years. (2) Weight ≥ 45 kg and ≤ 110 kg and Body Mass Index of 19 to 26 kg/m2. (3) Healthy Chinese subjects (both male and female). (4) Normotensive. (5) Normal electrocardiogram (ECG) within 28 days prior to Day 1.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

24

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 : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

CHIMES

Identifier

NCT05110261

Link

https://clinicaltrials.gov/study/NCT05110261

Phase

Phase III

Status

Recruiting

Sponsor

AstraZeneca

More details

The purpose of this study is to evaluate the Safety and Efficacy of Nirsevimab, in Healthy Preterm and Term Infants in China.

Purpose

Evaluate the Safety and Efficacy of Nirsevimab in Healthy Preterm and Term Infants in China

Interventions

Intervention 1

Nirsevimab

Intervention 2

Placebo

Countries

China

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-11-24

Anticipated Date of Last Follow-up

2024-10-10

Estimated Primary Completion Date

2025-05-02

Estimated Completion Date

2025-11-28

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

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: 1. Healthy Chinese preterm and term infants in their first year of life and born ≥ 29 weeks 0 days GA (infants who have an underlying illness such as cystic fibrosis or Down syndrome with no other risk factors are eligible) 2. Infants who are entering their first RSV season at the time of screening 3. Written informed consent and any locally required authorization obtained from the subject's parent(s)/legal representative(s) prior to performing any protocol-related procedures, including screening evaluations 4. Subject's parent(s)/legal representative(s) able to understand and comply with the requirements of the protocol including follow-up visits as judged by the Investigator 5. Subject is available to complete the follow up period, which will be approximately 1 year.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

800

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor).

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

D5290C00001

Identifier

NCT02114268

Link

https://clinicaltrials.gov/study/NCT02114268

Phase

Phase I

Status

Completed

Sponsor

MedImmune LLC

More details

The purpose of this study was to evaluate the safety, tolerability and pharmacokinetics of an extended half-life anti-respiratory syncytial virus (RSV) monoclonal antibody compared to placebo when administered to healthy adult participants.

Purpose

A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI8897 in Healthy Adults

Interventions

Intervention 1

MEDI8897 Intravenous

Intervention 2

MEDI8897 Intramuscular

Intervention 3

Placebo

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-04-01

Anticipated Date of Last Follow-up

2016-10-05

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2015-06-01

Actual Completion Date

2015-06-01

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Key Inclusion Criteria: * Age 18 through 49 years and in good health by history, physical exam, and labs * Weight greater than or equal to (\>=) 45 kilogram (kg) and less than or equal to (\<=) 110 kg at Screening * Written informed consent prior to performing any protocol related procedures, including Screening evaluations * Ability to complete the Follow-up period of 360 days Key Exclusion Criteria: * Acute illness including fever \>= 99.5 Fahrenheit (°F) on day of dosing * Any drug therapy within 7 days prior to Day 1 (except contraceptives) * Receipt of any investigational drug therapy within 120 days prior to investigational product dosing through 360 days after investigational product dosing * Previous receipt of a monoclonal antibody (mAb) * Pregnant or nursing mother

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

342

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 : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular
Intravenous

Use case

Prevention

Key results

Type of key results	Title	Website link
Article	Safety, Tolerability, and Pharmacokinetics of MEDI8897, the Respiratory Syncytial Virus Prefusion F-Targeting Monoclonal Antibody with an Extended Half-Life, in Healthy Adults	https://doi.org/10.1128/aac.01714-16

MEDI8897 1b

Identifier

NCT02290340

Link

https://clinicaltrials.gov/study/NCT02290340

Phase

Phase I

Status

Completed

Sponsor

MedImmune LLC

More details

The purpose of this study is to evaluate the safety, tolerability and pharmacokinetics of an extended half-life anti-respiratory syncytial virus (RSV) monoclonal antibody compared to placebo when administered to healthy preterm infants.

Purpose

A Phase 1b/2a Randomized, Double-Blind, Placebo-controlled, Dose-escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI8897, a Monoclonal Antibody With an Extended Half-li

Interventions

Intervention 1

Placebo (intramuscular)

Intervention 2

MEDI8897 10 mg (intramuscular)

Intervention 3

MEDI8897 25 mg (intramuscular)

Intervention 4

MEDI8897 50 mg (intramuscular)

Countries

Chile

South Africa

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2015-01-13

Anticipated Date of Last Follow-up

2018-09-18

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2016-09-28

Actual Completion Date

2016-09-28

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: - Healthy infants born between 32 weeks 0 days and 34 weeks 6 days gestational age. - Infants who are entering their first RSV season at the time of screening. Key Exclusion Criteria: - Gestational age \< 32 weeks 0 days and \>34 weeks 6 days. - Meets AAP or other local criteria to receive commercial palivizumab. - Any fever (≥ 100.4°F \[≥ 38.0°C\], regardless of route) or lower respiratory illness within 7 days prior to randomization. - Acute illness (defined as the presence of moderate or severe signs and symptoms) at the time of randomization. - Active RSV infection or known prior history of RSV infection. - Receipt of palivizumab or any RSV vaccine, including maternal RSV vaccination.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

151

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor).

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

MEDI8897 Ph2b

Identifier

NCT02878330

Link

https://clinicaltrials.gov/study/NCT02878330

Phase

Phase II

Status

Completed

Sponsor

MedImmune LLC

More details

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics (PK), and antidrug antibody (ADA) response for MEDI8897 in healthy preterm infants who are between 29 and 35 weeks gestational age (GA) and entering their first Respiratory Syncytial Virus (RSV) season.

Purpose

A Study to Evaluate the Safety and Efficacy of MEDI8897 for the Prevention of Medically Attended RSV LRTI in Healthy Preterm Infants.

Interventions

Intervention 1

MEDI8897

Intervention 2

Placebo

Countries

Argentina
Australia
Belgium
Brazil
Bulgaria
Canada
Chile
Czechia
Estonia
Finland
France
Hungary
Italy
Latvia
Lithuania
New Zealand
Poland
South Africa
Spain
Sweden
Türkiye
United Kingdom
United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-11-03

Anticipated Date of Last Follow-up

2019-09-24

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-07-17

Actual Completion Date

2018-12-06

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: 1. Healthy infants born between 29 weeks 0 days and 34 weeks 6 days GA. 2. Infants who are entering their first full RSV season at the time of screening. Key Exclusion Criteria: 1. Meets American Academy of Pediatrics (AAP) or other local criteria to receive commercial palivizumab. 2. Any fever (\>= 100.4°F \[\>= 38.0°C\], regardless of route) or lower respiratory illness within 7 days prior to randomization. 3. Acute illness (defined as the presence of moderate or severe signs and symptoms) at the time of randomization. 4. Active RSV infection or known prior history of RSV infection. 5. Receipt of palivizumab or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

1453

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Type of key results	Title	Website link
Article	Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants	https://doi.org/10.1056/nejmoa1913556

MEDLEY

Identifier

NCT03959488

Link

https://clinicaltrials.gov/study/NCT03959488

Phase

Phase II/III

Status

Completed

Sponsor

AstraZeneca

More details

The purpose of this study is to evaluate the safety and tolerability of MEDI8897 compared to palivizumab when administered to preterm infants entering their first RSV season and children with chronic lung disease (CLD) and congenital heart disease (CHD) entering their first and second RSV season.

Purpose

A Study to Evaluate the Safety of MEDI8897 for the Prevention of Medically Attended Respiratory Syncytial Virus(RSV) Lower Respiratory Track Infection (LRTI) in High-risk Children

Interventions

Intervention 1

MEDI8897

Intervention 2

Palivizumab

Countries

Austria
Belgium
Bulgaria
Canada
Czechia
Estonia
Finland
France
Germany
Hungary
Italy
Japan
Korea, Republic of
Latvia
Lithuania
Mexico
New Zealand
Poland
Russian Federation
South Africa
Spain
Sweden
Türkiye
Ukraine
United Kingdom
United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-07-30

Anticipated Date of Last Follow-up

2023-09-20

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2021-05-03

Actual Completion Date

2023-01-20

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 For the preterm cohort: Preterm infants in their first year of life and born ≤ 35 weeks 0 days GA eligible to receive palivizumab in accordance with national or local guidelines, including those with: (i) Uncomplicated small atrial or ventricular septal defects or patent ductus arteriosus OR (ii) Aortic stenosis, pulmonic stenosis, or coarctation of the aorta alone. For the CLD/CHD cohort: (i) Subjects with CLD - infants in their first year of life and a diagnosis of CLD. (ii) Infants who are entering their first RSV season at the time of screening. (iii) Written informed consent and any locally required authorization. (iv) Subject's parent(s)/legal guardian(s) able to understand and comply with the requirements of the protocol.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

925

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant Care, Provider, Investigator, Outcomes Assessor).

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Type of key results	Title	Website link
Article	Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity	https://doi.org/10.1056/nejmc2112186

MELODY

Identifier

NCT03979313

Link

https://clinicaltrials.gov/study/NCT03979313

Phase

Phase III

Status

Completed

Sponsor

AstraZeneca

More details

The purpose of this study is to evaluate the efficacy, safety, pharmacokinetics (PK), and antidrug antibody (ADA) response for MEDI8897 in healthy late preterm and term infants who are 35 weeks or greater gestational age and entering their first RSV season.

Purpose

A Study to Evaluate the Safety and Efficacy of MEDI8897 for the Prevention of Medically Attended Lower Respiratory Tract Infection Due to Respiratory Syncytial Virus in Healthy Late Preterm and Term I

Interventions

Intervention 1

MEDI8897

Intervention 2

Placebo

Countries

Argentina
Australia
Austria
Belgium
Bulgaria
Canada
Chile
Colombia
Czechia
Estonia
Finland
France
Germany
Israel
Italy
Japan
Korea, Republic of
Latvia
Lithuania
Mexico
New Zealand
Panama
Poland
Russian Federation
South Africa
Spain
Sweden

Türkiye

Ukraine

United Kingdom

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-07-23

Anticipated Date of Last Follow-up

2024-02-05

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2021-03-11

Actual Completion Date

2023-03-21

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: - Healthy infants in their first year of life and born at or after 35 weeks 0 days GA. - Infants who are entering their first RSV season at the time of screening. Key Exclusion Criteria: - Meets national or other local criteria to receive commercial palivizumab. - Any fever (≥ 100.4°F \[≥ 38.0°C\], regardless of route) or acute illness within 7 days prior to randomization. - Active RSV infection (a child with signs/symptoms of respiratory infection must have negative RSV testing) or known prior history of RSV infection. - Receipt of palivizumab or other RSV monoclonal antibody or any RSV vaccine, including maternal RSV vaccination.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

3012

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor).

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Type of key results	Title	Website link
Article	Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants	https://doi.org/10.1056/nejmoa2110275

Type of key results	Title	Website link
Article	Respiratory syncytial virus: promising progress against a leading cause of pneumonia	https://doi.org/10.1016/s2214-109x(21)00455-1

RAENHoB

Identifier

NCT06856967

Link

https://clinicaltrials.gov/study/NCT06856967

Phase

Marketed

Status

Recruiting

Sponsor

Meyer Children's Hospital IRCCS

More details

This study aims to evaluate the impact of Nirsevimab, a monoclonal antibody used for RSV prophylaxis, on reducing RSV- related hospitalizations. It will be conducted at 8 pediatric departments in Tuscany, Italy. First, a matched case-control study investigates the real-world effectiveness of Nirsevimab in preventing RSV-related lower respiratory tract infection (LRTI) hospitalizations during the RSV epidemic season 2024-2025. Second, a descriptive study examines how the Nirsevimab immunization campaign affects RSV epidemiology, focusing on patients' age, comorbidities, infection severity, and clinical outcomes. The findings aim to optimize RSV prevention strategies and inform public health policies.

Purpose

Evaluation of the Effect of Nirsevimab on Hospitalizations Due to RSV Infection in

Infants Under One Year of Age.

Interventions

Intervention 1

Nirsevimab

Countries

Italy

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-12-04

Anticipated Date of Last Follow-up

2025-03-05

Estimated Primary Completion Date

2025-03-01

Estimated Completion Date

2025-04-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Neonates

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

No

Comments about the studied populations

Infants < 12 months during RSV 2024-2025 epidemic season *Case patients* -Age <12 months -Diagnosis of LRTI (i.e., bronchiolitis and/or pneumonia) at admission -Positive RSV PCR on nasopharyngeal swab *Control patients* -Age <12 months -Diagnosis of LRTI (i.e., bronchiolitis and/or pneumonia) at admission -Hospitalized for conditions other than respiratory infections *Exclusion Criteria* -Parental refusal -Previous immunization with Palivizumab -Previous maternal RSV vaccine immunization during pregnancy

Health status

Not provided

Study type

Observational studies (incl. patient registries)

Enrollment

138

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Observational Model : Case-Control Prospective design

Masking

Open label

Masking description

Not provided

Frequency of administration

Other : "Once "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

PrEP

Key results

Not provided

Abrysvo : Beyfortus

Identifier

NCT06551506

Link

https://clinicaltrials.gov/study/NCT06551506

Phase

Marketed

Status

Recruiting

Sponsor

National Institute of Allergy and Infectious Diseases (NIAID)

More details

Respiratory Syncytial Virus (RSV) is the leading cause of lower respiratory tract infections (LRTIs) in infants and young children. It is also a leading cause of mortality in children \<5 years of age worldwide. Until recently, no Food and Drug Administration (FDA)-approved vaccines were available to prevent RSV infection. The only prophylactic product for RSV prevention recommended for infants was the monoclonal antibody palivizumab, but administration was limited to those with extreme prematurity, chronic lung disease, or hemodynamically significant congenital heart disease. However, in 2023, the FDA approved two products designed to prevent RSV lower respiratory tract disease (LRTD) in all infants: an active RSV vaccine based on the prefusion F protein (RSVpreF, ABRYSVO, Pfizer) adminis

Purpose

The Immunology and Safety of Maternal RSV Vaccination (ABRYSVO), InfantNirsevimab (BEYFORTUS) Immunization, or Both Products

Interventions

Intervention 1

maternal RSVpreF (ABRYSVO)

Dosage: 120 mcg/0.5ml

Intervention 2

nirsevimab (BEYFORTUS)

Dosage: 50mg/0.5mL if body weight <5kg or 100mg/mL if body weight is >= 5kg at birth

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-09-19

Anticipated Date of Last Follow-up

2025-03-13

Estimated Primary Completion Date

2026-05-31

Estimated Completion Date

2026-05-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Neonates

Genders

- Female

Accepts pregnant individuals

Yes

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: 1. 18-45 years of age at time of enrollment with an uncomplicated singleton pregnancy who are at no known increased risk for complications per clinical judgement of the investigator 2. Understands and agrees to comply with all study procedures 3. Willing and able to provide consent for study participation for themselves and their infant prior to initiation of any study procedures 4. In good health, as determined by the medical history and clinical judgment of the investigator Note: Healthy volunteers with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. 5. Intention to deliver at a hospital or

birthing facility where study procedure

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

400

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

NIRSE-CL

Identifier

NCT06511687

Link

https://clinicaltrials.gov/study/NCT06511687

Phase

Marketed

Status

Recruiting

Sponsor

Instituto Sistemas Complejos de Ingeniería

More details

The Nirse-CL study is a collaborative effort between the Ministry of Health of Chile, Instituto Sistemas Complejos de Ingeniería (ISCI), and the Faculty of Medicine of the University of Chile. The primary aim is to determine the effectiveness of the monoclonal antibody nirsevimab in preventing RSV infection in infants based on the integrated analysis of several national databases before, during, and after the implementation of a universal immunization program. The impact of the program on RSV-related health outcomes will also be determined.

Purpose

Effectiveness And Impact Of Nirsevimab In Chile (NIRSE-CL)

Interventions

Intervention 1

Nirsevimab

Countries

Chile

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-04-01

Anticipated Date of Last Follow-up

2024-07-15

Estimated Primary Completion Date

2024-10-01

Estimated Completion Date

2024-10-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children

Neonates

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

Not provided

Health status

Not provided

Study type

Not provided

Enrollment

160000

Allocation

Not provided

Intervention model

Not provided

Intervention model description

Not provided

Masking

Not provided

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

NIRSE-GAL

Identifier

NCT06180993

Link

https://clinicaltrials.gov/study/NCT06180993

Phase

Marketed

Status

Recruiting

Sponsor

Federico Martinón Torres

More details

A longitudinal observational study based on routinely collected data on hospital and health care use for RSV infections will be undertaken. The Galician public health registries will be used for data collection including baseline information and follow-up data. Historical data will be retrieved for comparison purposes. The study aims to observe and analyze data from all the eligible children in Galicia for nirsevimab treatment. The number of eligible children is expected to be approximately 14,000 per each RSV season.

Purpose

Evaluation of the Effectiveness and Impact of Nirsevimab Administered as Routine Immunization

Interventions

Intervention 1

Nirsevimab

Countries

Spain

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-09-25

Anticipated Date of Last Follow-up

2023-12-21

Estimated Primary Completion Date

2026-03-31

Estimated Completion Date

2026-10-31

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

Unspecified

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

Yes

Comments about the studied populations

1 Day to 24 Months (Child)

Health status

Not provided

Study type

Observational studies (incl. patient registries)

Enrollment

42000

Allocation

Non-randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Not provided

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Type of key results	Title	Website link
Article	Assessment of effectiveness and impact of universal prophylaxis with nirsevimab for prevention of hospitalizations due to respiratory syncytial virus in infants. The NIRSE-GAL study protocol	https://pubmed.ncbi.nlm.nih.gov/38738
Article	Press Release: Beyfortus real-world evidence published in The Lancet shows 82% reduction in infant RSV hospitalizations	https://www.sanofi.com/en/media-room/press-releases/2024/2024-05-02-05-00-00-2873804

Real-World Effectiveness of Perinatal RSV Immunoprophylaxis

Identifier

NCT06172660

Link

https://clinicaltrials.gov/study/NCT06172660

Phase

Marketed

Status

Recruiting

Sponsor

Yale University

More details

The purpose of this study is to continue evaluating how well the RSV vaccines work as they are currently being used in routine clinical practice. Some of the questions that the investigators hope to answer with this study are: 1) What is the overall effectiveness of these vaccines? 2) How long does immunity last? 3) How effective are the vaccines against new strains? 3) Does the vaccine's effectiveness vary by age?

Purpose

Real-World Effectiveness of Perinatal RSV Immunoprophylaxis

Interventions

Intervention 1

Nirsevimab

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-10-01

Anticipated Date of Last Follow-up

2024-10-03

Estimated Primary Completion Date

2028-12-30

Estimated Completion Date

2028-12-30

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Children
- Neonates

Genders

All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: ≤ 12 months of age at the time of presentation for evaluation for an acute respiratory infection (ARI). Documentation of an ARI, which is defined as an acute onset (<10 days) illness that includes: At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, nausea or vomiting, diarrhea, fatigue, congestion OR any one of the following: cough, shortness of breath, difficulty breathing, olfactory disorder, taste disorder, confusion, persistent chest pain, pale, gray, hypoxia, clinical or radiographic evidence of pneumonia or respiratory distress syndrome. Exclusion Criteria: Illness duration of >10 days at the time of resp. specimen collection, measured from the date of the 1st symptom of the current acute illnes

Health status

Not provided

Study type

Not provided

Enrollment

3750

Allocation

Non-randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Intramuscular

Use case

Prevention

Key results

Not provided

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

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Patent info

Compound patent families

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Nirsevimab dosing regimens Expiry date: 2040-04-30 This disclosure describes methods of treating or preventing RSV infection in a patient in need thereof. The methods including dosing regiments for administering a composition including a fixed dose of an anti-RSV monoclonal antibody or an antigen binding fragment thereof. In another aspect, this disclosure describes pharmaceutical compositions for the treatment or prevention of RSV infection. In yet another aspect, this disclosure describes a pharmaceutical unit dose including nirsevimab.	WO2020223435	Use	Medimmune Limited	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Tajikistan, Belarus, Azerbaijan, Turkmenistan, Armenia, Kyrgyzstan, Kazakhstan	Russian Federation, United States of America
Filed	Brazil, China, Albania, Serbia, Türkiye, North Macedonia, Mexico, India, South Africa	Australia, 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, Israel, Korea, Republic of, Singapore, Taiwan, Province of China, United States of America, United Arab Emirates, Hong Kong, New Zealand

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

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Nirsevimab formulations Expiry date: 2038-02-28 The present invention provides a formulation comprising: (i) an anti-RSV monoclonal antibody; and (ii) an ionic excipient; wherein the monoclonal antibody is present at a concentration of about 50mg/ml or greater and the ionic excipient is present at a concentration of between 50 and 150 mM and the formulation has a pH of about 5.5 to about 7.5.	WO2018160722	Composition	Medimmune Limited	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	China, Colombia, Kazakhstan, Mexico, South Africa, Indonesia, Ukraine, Viet Nam	Australia, Chile, Russian Federation, United Kingdom, Japan, Korea, Republic of, Taiwan, Province of China, United States of America, Hong Kong, New Zealand
Filed	Argentina, China, Costa Rica, Ecuador, Morocco, Tunisia, Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, Moldova, Republic of, North Macedonia, Philippines, South Africa, India, Guatemala, Thailand	Australia, 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, Israel, Singapore, Taiwan, Province of China, United States of America, United Arab Emirates, Hong Kong, Kuwait, Bahrain, Saudi Arabia, Oman, Qatar

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Brazil, Tajikistan, Belarus, Azerbaijan, Turkmenistan, Armenia, Kyrgyzstan, Malaysia	World Intellectual Property Organization (WIPO)

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Nirsevimab and its use to prevent or treat an RSV infection Expiry date: 2035-01-14 This application provides antibodies and functional equivalents thereof which are capable of specifically binding RSV, as well as means and methods for producing them.	WO2015108967	Compound	Medimmune, Llc	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, Albania, Serbia, Türkiye, North Macedonia, Mexico	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, Japan, Korea, Republic of, Russian Federation, Taiwan, Province of China, United States of America
Filed	China, Albania, Serbia, Türkiye, North Macedonia	Australia, 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, Russian Federation

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), Albania, Serbia, Bosnia and Herzegovina, Montenegro, Türkiye, North Macedonia	World Intellectual Property Organization (WIPO), Australia, 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, Japan, United States of America

Patent informations

Patent description	Representative patent	Categories	Patent holder	Licence with MPP	Patent source
Nirsevimab and analogues (antibody D25) Expiry date: 2028-05-30 The invention provides antibodies and functional equivalents thereof which are capable of specifically binding RSV, and means and methods for producing them.	WO2008147196	Compound	Aimm Therapeutics B.V	No	

Patent status

Patent status/countries	Low, Low- middle and upper-middle	High income
Granted	Brazil, China, Türkiye, Mexico, South Africa, India	Australia, Canada, Liechtenstein, Italy, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Norway, Hong Kong, Israel, Japan, Korea, Republic of, New Zealand, Russian Federation, United States of America
Filed		Cyprus

Patent status/countries	Low, Low- middle and upper-middle	High income
Not in force	World Intellectual Property Organization (WIPO), China, Albania, Serbia, Bosnia and Herzegovina, Türkiye, North Macedonia, India	World Intellectual Property Organization (WIPO), Canada, Liechtenstein, Italy, Malta, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Bulgaria, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, Norway, Japan, New Zealand, United States of America

Supporting material

Publications

Keam SJ. Nirsevimab: First Approval. Drugs. 2023 Feb;83(2):181-187. doi: 10.1007/s40265-022-01829-6. PMID: 36577878.

Nirsevimab (Beyfortus®), a long-acting intramuscular recombinant neutralising human IgG1κ monoclonal antibody to the prefusion conformation of the respiratory syncytial virus (RSV) F protein that has been modified with a triple amino acid substitution in the Fc region to extend the serum half-life, is being jointly developed by AstraZeneca and Sanofi for the prevention of RSV disease. The extended serum half-life allows administration of nirsevimab as a single dose to cover the RSV season. Nirsevimab was approved in the EU on 3 November 2022 and in the UK on 7 November 2022 for the prevention of RSV lower respiratory tract disease in neonates and infants during their first RSV season. This article summarizes the milestones in the development of nirsevimab leading to this first approval for the prevention of RSV disease in all infants.

Moline HL, Tannis A, Toepfer AP, et al. Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus–Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season — New Vaccine Surveillance Network, October 2023–February 2024. MMWR Morb Mortal Wkly Rep 2024;73:209–214. DOI: http://dx.doi.org/10.15585/mmwr.mm7309a4

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among infants in the United States. In August 2023, CDC’s Advisory Committee on Immunization Practices recommended nirsevimab, a long-acting monoclonal antibody, for infants aged <8 months to protect against RSV-associated lower respiratory tract infection during their first RSV season and for children aged 8–19 months at increased risk for severe RSV disease. In phase 3 clinical trials, nirsevimab efficacy against RSV-associated lower respiratory tract infection with hospitalization was 81% (95% CI = 62%–90%) through 150 days after receipt; post-introduction effectiveness has not been assessed in the United States. In this analysis, the New Vaccine Surveillance Network evaluated nirsevimab effectiveness against RSV-associated hospitalization

among infants in their first RSV season during October 1, 2023–February 29, 2024. Among 699 infants hospitalized with acute respiratory illness, 59 (8%) received nirsevimab ≥7 days before symptom onset. Nirsevimab effectiveness was 90% (95% CI = 75%–96%) against RSV-associated hospitalization with a median time from receipt to symptom onset of 45 days (IQR = 19–76 days). The number of infants who received nirsevimab was too low to stratify by duration from receipt; however, nirsevimab effectiveness is expected to decrease with increasing time after receipt because of antibody decay. Although nirsevimab uptake and the interval from receipt of nirsevimab were limited in this analysis, this early estimate supports the current nirsevimab recommendation for the prevention of severe RSV disease in infants. Infants should be protected by maternal RSV vaccination or infant receipt of nirsevimab.

Additional documents

- WHO position paper on immunization to protect infants against respiratory syncytial virus disease

Useful links

- RSV: Jab for winter virus could cut baby hospitalisations by 80%, study says
- Nirsevimab significantly protected infants against RSV disease in Phase III MELODY trial
- Press Release: Beyfortus public health advantage bolstered by first real-world comparison of infant vs maternal RSV immunization programs
- AstraZeneca, Sanofi’s Beyfortus 90% Effective at Preventing RSV Hospitalizations: CDC
- Strategic Advisory Group of Experts on Immunization (SAGE) - September 2024 - with supporting meeting documents
- RSV vaccine and mAb snapshot - PATH - Feb 2025

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

Not provided