

Nirsevimab: Adis Evaluation

Key Points

- A long-acting recombinant neutralising human IgG1k mAb to the prefusion conformation of the RSV F protein being jointly developed by AstraZeneca and Sanofi for the prevention of RSV disease
- Received its first approval on 3 November 2022 in the EU
- Approved for use in the prevention of RSV LRT disease in neonates and infants during their first RSV season

Summary

Nirsevimab (Beyfortus®), a long-acting intramuscular recombinant neutralising human IgG1k monoclonal antibody (mAb) to the prefusion conformation of the respiratory syncytial virus (RSV) F protein that has been modified with a triple amino acid substitution (YTE) 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 (LRT) disease in neonates and infants during their first RSV season.

This summary represents the opinions of the [author/authors]. For a full list of declarations, including funding and author disclosure statements, and copyright information, please see the full text online. © Springer Nature Switzerland AG 2022.