FDA Approves RSV Monoclonal Antibody for Infants and Young Children

Nirsevimab-alip, marketed as Beyfortus by AstraZeneca, has received US Food and Drug Administration authorization for preventing respiratory syncytial virus (RSV) lower respiratory tract disease in infants and children up to 2 years old.

Approval of the drug, a single-dose monoclonal antibody, is based on results from clinical trials involving preterm infants and term infants that showed nirsevimab-alip reduced the risk of severe RSV lower respiratory tract infection by 70% to 75% compared with placebo. A third trial that included children aged 2 years or younger demonstrated the drug’s safety.

Nirsevimab-alip’s adverse effects include rash and reactions at the injection site. Similar to other monoclonal antibodies, the drug also comes with warnings about the risk of serious hypersensitivity reactions such as anaphylaxis. – Emily Harris

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Note: Source references are available through embedded hyperlinks in the article text online.