FDA approves new drug to protect against RSV in infants

July 18 2023, by Dennis Thompson

Parents now have a new long-acting drug to protect their children against

respiratory syncytial virus (RSV), a common germ that hospitalizes as many as 3% of children under the age of 1 in the United States each year.

The U.S. Food and Drug Administration on Monday approved Beyfortus (nirsevimab-alip) for the prevention of RSV in newborns and infants born during or entering their first RSV season.

The drug also is approved in children up to 2 years old who remain vulnerable to severe RSV disease through their second RSV season.

"RSV can cause serious disease in infants and some children and results in a large number of emergency department and physician office visits each year," Dr. John Farley, director of the Office of Infectious Diseases in the FDA's Center for Drug Evaluation and Research, said in an agency news release. "Today's approval addresses the great need for products to help reduce the impact of RSV disease on children, families and the health care system."

RSV causes respiratory infections in people across all age groups, and 2 out of 3 infants are infected with RSV during their first year of life, according to Sanofi, the pharmaceutical company that will market the drug in the United States.

Last year, a surge of RSV cases flooded U.S. hospitals, caused by the lifting of social distancing restrictions that had prevented younger children from catching RSV during the pandemic.

Most infants and young children experience mild, cold-like symptoms, but some infections can evolve into severe cases of pneumonia and bronchiolitis (swelling of the small airway passages in the lungs).

RSV is the leading cause of hospitalization in infants younger than 1,

averaging 16 times higher than the annual rate for influenza, Sanofi said. About 3 out of 4 infants hospitalized for RSV are born healthy and at term.

Premature infants or newborns with chronic lung disease of prematurity or significant congenital heart disease are at highest risk for severe RSV disease, according to the FDA.

In most parts of the United States, RSV circulation is seasonal, typically starting during the fall and peaking in the winter. It is transmitted from person to person through close contact with someone who is infected.

Beyfortus is a monoclonal antibody—a laboratory-made protein that mimics immune system antibodies that target and fight RSV.

A single injection of Beyfortus administered before or during RSV season can provide protection during the season, the FDA said.

The FDA cited three clinical trials that supported the safety and efficacy of Beyfortus in reducing the risk of RSV cases serious enough to require medical treatment.

One trial included 1,453 preemies born during or entering their first RSV season. About 2.6% of infants treated with Beyfortus needed medical treatment for RSV, versus 9.5% who received a placebo—a risk reduction of about 70%.

The second trial included 1,490 term and late preterm infants, and showed a similar 75% risk reduction for Beyfortus compared to placebo.

The third trial focused on children up to 24 months of age who remained vulnerable to severe RSV disease through their second RSV season because they had either chronic lung disease of prematurity or congenital

heart disease. Again, the data supported the drug's use in children.

The FDA granted its approval to AstraZeneca, the company that developed the drug.

"Beyfortus represents an opportunity for a paradigm-shift in preventing serious respiratory disease due to RSV across a broad infant population in the U.S.," Iskra Reic, executive vice president for vaccines and immune therapies at AstraZeneca, said in a company news release.

The FDA in May approved the first RSV vaccine for use in adults 60 and older. It is expected to roll out later this year, with the approach of the annual RSV season.

More information: The U.S. Centers for Disease Control and Prevention has more about RSV.