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Merck Unveils New RSV Shot for Babies, as Moderna Trials mRNA RSV Vaccine for Infants and Toddlers

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Merck last week announced "positive" results from a Phase 2/3 clinical trial for a monoclonal antibody drug the pharmaceutical giant is developing to protect infants against respiratory syncytial virus (RSV) disease.

The drug, clesrovimab, met its safety and efficacy endpoints, the company said in a press release, reducing the need for medical attention for infants who took the drug through 150 days. Clesrovimab targets infants in their first RSV season.

The press release offered no other details of the study. The company said it will present the clinical trial results at an unnamed "upcoming scientific congress" and file them with global regulators for approval.

If approved, clesrovimab will be the third monoclonal antibody to treat RSV-related illness that is available for babies. Palivizumab, sold under the brand name Synagis, a short-acting monoclonal that must be administered monthly, was approved by the U.S. Food and Drug Administration (FDA) in 1998 and is typically used only for high-risk infants.

The FDA in July 2023 approved AstraZeneca and Sanofi's nirsevimab, under the brand name Beyfortus, for all infants under 8 months or high-risk infants up to 24 months of age. The drug went on the market in the fall of 2023 in the U.S. and Europe.

Merck said it assessed clesrovimab for any injection-related adverse events, adverse events of special interest, solicited systemic adverse events, or serious adverse events. The drugmaker said clesrovimab met its safety endpoints, although it didn't say what those endpoints were.

Nirsevimab/Beyfortus also reportedly met its safety endpoints, although 12 infants died during the trials. An FDA spokesperson told CNBC when the drug was approved that "none of the deaths appeared to be related to nirsevimab."

An investigation by The Defender found that at least two infant deaths reported to the Vaccine Adverse Event Reporting System, or VAERS, were linked to Beyfortus.

And French scientist Hélène Banoun, Ph.D., identified a significant increase in mortality among newborns between 2 and 6 days old in France following the start of the nirsevimab vaccination campaign there. The babies were injected before leaving the hospital.

The Centers for Disease Control and Prevention (CDC) added the monoclonal antibodies to its 2024 childhood immunization schedule, even though they are not vaccines.

Vaccines stimulate the immune system to trigger an immune response. Monoclonal antibodies are lab-cloned proteins injected into the body that act like antibodies, seeking out antigens in the body to destroy.

The CDC had to change the name of its vaccine schedule to "vaccines and other immunizing agents" before adding the RSV monoclonal antibodies to the list.

RSV is a common respiratory virus that usually causes mild cold-like symptoms but can lead to hospitalization and, in rare cases, death in infants and the elderly. By age 2, 97% of all babies have been infected with the RSV virus, which confers partial immunity, making any subsequent episodes less severe.

The protection conferred by the monoclonal antibodies lasts weeks after injection and then wanes over time, according to the CDC. And the antibodies carry risks, including the risk of making RSV illness worse in some children, according to Banoun's research.

> "It is crazy to give newborns monoclonal antibodies — a potentially dangerous product for symptoms they probably won't get," Dr. Meryl Nass told The Defender. "Give them vitamin D and breastfeed them and the problem will disappear for almost all babies."

Dr. Paul Thomas, pediatrician and author of the forthcoming book, "Vax Facts: What to Consider Before Vaccinating at All Ages & Stages of Life," told The Defender:

> "Monoclonal antibodies are a very new technology, and this is an area of medicine where I would urge caution and avoid becoming an early adopter of this technology. There will likely be serious side effects and unexpected negative outcomes."

Growing Market for 'Blockbuster' Drug

Merck's clesrovimab is gearing up to compete with Beyfortus, the only comparable product, in a market that is growing rapidly, helped along by the national vaccination campaigns launched in the U.S. and several European countries.

"We are encouraged by these findings and look forward to working with regulators to provide a new option to help address the impact of RSV on infants and their families," Dr. Paula Annunziato, senior vice president of infectious diseases and vaccines in Global Clinical Development at Merck Research Laboratories, said in the press release.

Beyfortus shots cost $495 in 2023 and increased to $519.75 in 2024.

The drug netted about $592 million during its first year on the market. Sanofi said it expects that number to roughly double this year, breaching "blockbuster" status — $1 billion in sales — Fierce Pharma reported.

Beyfortus' uptake in the U.S. has surpassed previous childhood immunization benchmarks, such as those for rotavirus and pneumococcal disease, Sanofi told Fierce Pharma. About 20% of eligible infants in the U.S. and over 80% in France, Spain and Luxembourg — the other countries with 2023-2024 nirsevimab vaccination campaigns — have received the drug.

Sales were constrained only by shortages of the drug last year. Top Biden administration

health officials have been meeting with the companies to support them in ramping up production, hoping to double the number of doses available this year.

‘Perfectly Healthy Baby Now Enters the Unknown of Pharmaceutical Trials’

Merck in 2020 was also developing an mRNA RSV vaccine for older adults in conjunction with Moderna but gave those rights back to Moderna so it could pursue monoclonal antibody development for infants.

Moderna continued developing that RSV vaccine. The FDA approved Moderna’s adult mRNA RSV shot for adults over 60 in May — Moderna’s second-ever product to be approved for the market, NBC reported.

The company is now running a clinical trial for an RSV mRNA vaccine for children and teens ages 2-17. Children and teens in that age group are not typically considered to be at risk of severe or life-threatening RSV infections.

Moderna also is conducting an mRNA vaccine trial called the Rhyme Trial for an RSV and a human metapneumovirus (hMPV) vaccine for infants ages 5-24 months. According to Moderna, the mRNA drug offers better protection than the “passive protection” from monoclonal antibodies, because the mRNA shot will stimulate the child’s immune system to create its own protection.

One of the clinics hosting the Rhyme Trial in the United Kingdom posted a photograph on Instagram, celebrating the first baby — “six-month-old Robyn” — to get a shot and calling for other participants in the trial.

Thomas said it was “horrifying” that Moderna, which before its RSV vaccines had only brought one dangerous product, the COVID-19 vaccine, to market, was now conducting experiments on babies for another product.

Thomas said:

> “The image that went viral shows a bunch of adult researchers smiling holding one of their victims who seems a bit perplexed. Perhaps this baby is wondering why they are so happy. This baby just got an experimental treatment. A perfectly healthy baby now enters the unknown of pharmaceutical trials!”

The Oxford Vaccine Group at the University of Oxford is running the Phase 1 study, which is meant to test the new mRNA vaccines on about 200 infants for their safety, tolerability and how well they prevent infections from the viruses.

The trial is testing two vaccines at once. Some babies will receive mRNA-1345, its RSV vaccine approved for adults, and others will receive mRNA-1365, designed to protect against RSV and hMPV. Others will receive a placebo, although the study notes that the placebo may be Nimenrix — a meningococcal vaccine — rather than a true placebo.

According to the CDC, hMPV is a virus that causes common cold symptoms and circulates every winter. Most people, including children, develop no serious complications from the cold, although it can cause bronchiolitis and pneumonia, particularly in older vulnerable people.

The virus caused about 11,300 deaths globally in 2018, according to the trial information sheet. It is less likely than RSV to cause severe disease in children.

Thomas said that in his clinical experience, hMPV was an illness "we simply do not need to worry about." If there is any use for a shot, he said, it should be reserved for high-risk individuals. "It would not make any sense to have this product unleashed on all healthy children, as they simply are not at risk of anything serious happening."

Children in the trial will receive three doses of the vaccine or placebo over four months and follow-up will happen through in-person visits and phone calls. Parents will also keep an electronic diary to track side effects and illness.

The parent information sheet warns that side effects could include myocarditis or pericarditis, for which parents should seek immediate medical attention. "Most of the time, people recover with treatment and rest" from those conditions, it says.

During follow-up visits, clinicians will take blood samples and nasal swabs from children. The samples will be maintained for 25 years and used for future research as well.

Previous attempts to develop an RSV vaccine failed after vaccine-induced antibody-dependent enhancement (ADE) resulted in infant deaths.

ADE occurs when antibodies bind to a pathogen but can't prevent infection. Instead, the antibodies do the opposite of what was intended — they act as a "trojan horse," facilitating the pathogen's entry into cells and exacerbating the immune response.

Recent research has shown this may be a problem with the current monoclonal antibody treatments as well.

The Rhyme Trial parent information sheet acknowledges that this happened with the previous attempt to develop an RSV vaccine for children but states, "That vaccine was made by a very different method than the RSV vaccines in this Study," and "Experts believe that there is very little risk of this happening with the mRNA-1345 or mRNA-1365 vaccines in this Study."

They will be monitoring children closely to see if such a reaction occurs, they note.

Parents won't be compensated for participation, although they can be reimbursed up to 43 pounds for travel and meal costs.

Moderna's trial also will be carried out in the U.S., although most locations listed for the study on the clinical trials government website are listed as "not yet recruiting" subjects.

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