FDA approves first vaccine for RSV, a moment six decades in the making

By Brenda Goodman, CNN

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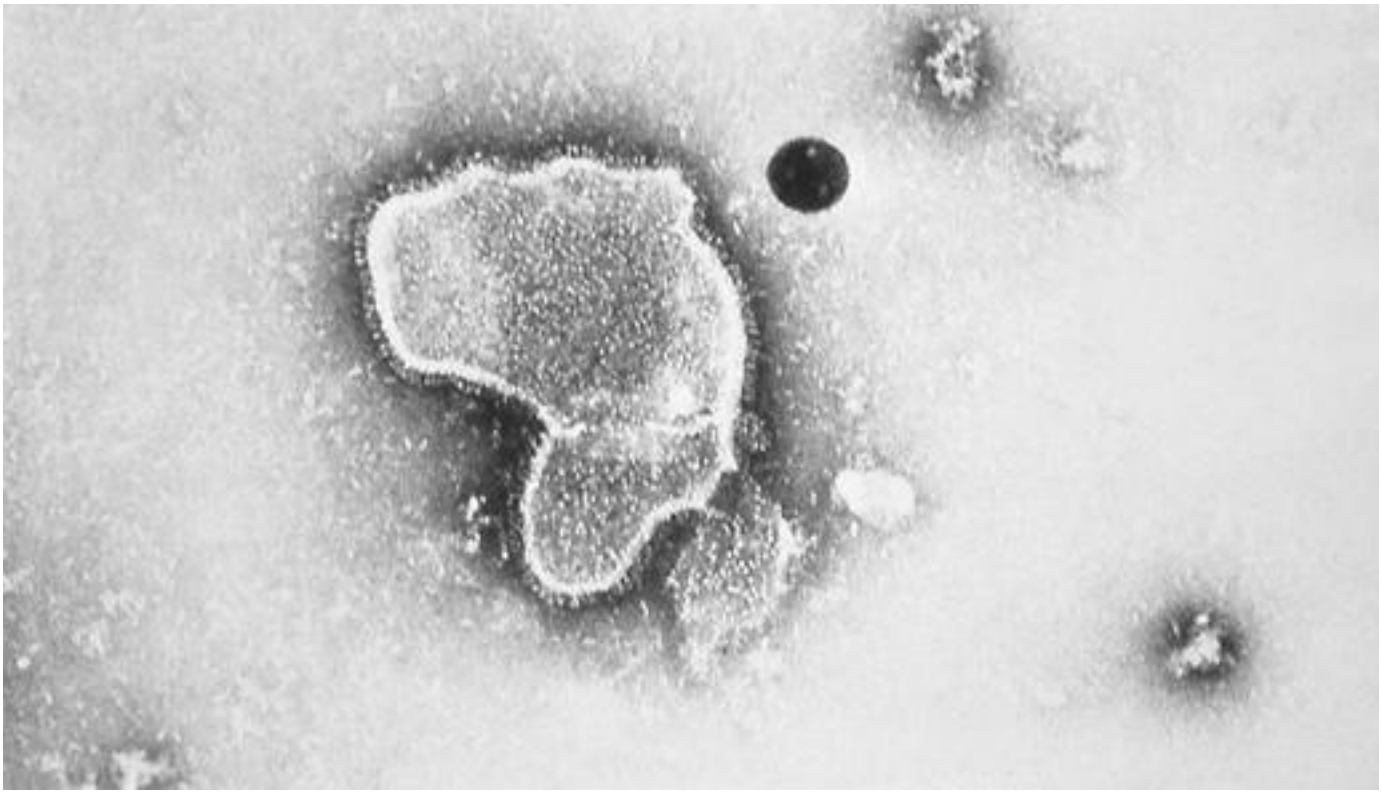
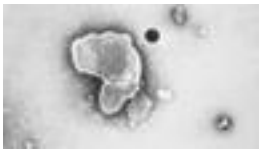


Erskin. L. Palmer/CDC

The US Food and Drug Administration approved the first vaccine against respiratory syncytial virus, known as RSV, and vaccines are in the works.

(CNN) — After a 60-year scientific quest, the world has its first vaccine to protect against respiratory syncytial virus, or RSV – and more are on the way.

On Wednesday, the US Food and Drug Administration approved Arexvy, made by GSK, which is designed to be given as a single shot to adults 60 and older.



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It could be available for seniors as soon as this fall, pending a recommendation for its use from the US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, which next meets in June.

"Older adults, in particular those with underlying health conditions, such as heart or lung disease or weakened immune systems, are at high risk for severe disease caused by RSV," said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, in a statement. "Today's approval of the first RSV vaccine is an important public health achievement to prevent a disease which can be life-threatening and reflects the FDA's continued commitment to facilitating the development of safe and effective vaccines for use in the United States."

Although RSV is a disease that's often associated with babies and young children, it can also be dangerous for seniors. In the US, an estimated 159,000 adults 65 and older are hospitalized each year with RSV, and an estimated 10,000 to 13,000 die as a result of their infection.

"RSV certainly is an important disease in the elderly. In some years, the burden of RSV disease comes close to the burden of flu in the elderly. And this is really a wonderful development," said Dr. Ruth Karron, a professor of international health at Johns Hopkins Bloomberg School of Public Health, who was not involved in the development of the vaccine.

A pivotal discovery paves the way

In a clinical trial of nearly 25,000 older adults, the results of which were published in the New England Journal of Medicine, the GSK vaccine was 83% effective at preventing lower respiratory tract disease caused by the virus.

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Lower respiratory tract disease was defined in the study as a positive test and two more symptoms for at least a day, including new or worsening cough, wheezing, shortness of breath, an elevated respiratory rate, lowered blood oxygen or crackles in the lungs, which a doctor would pick up with a stethoscope.

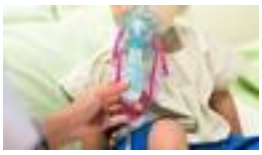
The vaccine was 94% effective at preventing severe disease in seniors. People were considered to have severe disease if they needed supplemental oxygen or needed mechanical help to breathe, like a ventilator.

GSK's RSV vaccine works by using a small piece of the virus: a protein that sticks out on its surface called the fusion, or F, protein, which helps the virus glom onto and infect cells in the body's upper airways. The protein pieces in the vaccine are made in a lab, using cells specially programmed to manufacture them.

The vaccine builds on a pivotal discovery made a decade ago by researchers at the National Institutes of Health, including some of the same scientists who helped make the Covid-19 vaccines.

Normally, the F protein is wiggly, flipping back and forth, changing shapes after it fuses with a cell.

The NIH researchers figured out how to freeze the protein in the shape it takes before it fuses onto a cell. In this shape, the body can develop strong antibodies against it.



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The GSK vaccine uses this potent pre-fusion form of the protein, along with an ingredient called an adjuvant, which boosts immune activity.

When researchers looked specifically at how well the vaccine worked in the most vulnerable seniors – those with underlying health conditions like COPD, heart failure or heart disease – they found that it was 94% effective at preventing lower respiratory tract infections.

"That's really exceptional information, because that's the type of disease we want to prevent. We want to prevent people from ending up in the hospital with RSV," said Dr. Len Friedland, director of scientific affairs and public health at GSK.

The most common side effects reported by people in the clinical trial included pain at the injection site and fatigue. Those usually resolved within a day or two.

There were a small number of serious adverse events in the study. Friedland said they were balanced between the group that got the vaccine and the group that got the

placebo. He says the researchers will continue to monitor for safety signals as the vaccine rolls out to a wider population.

The FDA said it is requiring GSK to continue to monitor for signs of Guillain-Barré syndrome, a nerve disorder that can cause paralysis or weakness that rarely follows viral infections and vaccination. It is also requiring the company to study the risk of a condition called acute disseminated encephalomyelitis, a rare type of inflammation that affects the brain and spinal cord. The FDA says two people in the clinical trials for the vaccine developed the condition after getting that shot along with an influenza vaccine.

It's unclear exactly how durable the protection from the vaccine will be, Friedland said. The researchers are following study participants for three years and will continue to evaluate vaccine efficacy over time. So far, protection appears to hold up well for about a year.

More RSV vaccines on the way

Three other RSV vaccines for older adults are also in the final phases of testing.

The FDA is expected to make a decision on Pfizer's RSV vaccine for older adults by the end of May. The agency is also reviewing Pfizer's maternal vaccine to protect infants and is expected to make a call on that one by the end of August.

Moderna is finishing its Phase 3 trial of an mRNA vaccine for RSV in older adults and expects to submit the results to the FDA for approval within the next few months.

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Bavarian Nordic, maker of the Jynneos mpox vaccine, says it will report results from a Phase 3 trial of its RSV vaccine for older adults this year.

Paul Chaplin, president and CEO of Bavarian Nordic, says there's a saying in Britain that you'll wait a long time for a bus, and then four will show up at once. The race to the finish line for an RSV vaccine is a little bit like that, he says.

"We've been waiting decades for a safe effective RSV vaccine, and there's been numerous attempts that have failed," Chaplin said.

“And I know GSK will likely get the first approval, but there are others coming through, including us. And I just think it’s fantastic, because RSV is a huge unmet medical need that a lot of people underestimate the importance of, and we will hopefully now have a number of effective vaccines that will help protect people.”

Scientific triumph after tragedy

The hunt for an effective vaccine for RSV is a story of scientific triumph over tragedy.

In the 1960s, two children died and many others were hospitalized with severe RSV when the experimental vaccines they had been given turned out to enhance the infection rather than defend against it.

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That study tested a vaccine made with an RSV virus that had been chemically treated to render it inert and mixed with an ingredient called alum, to wake up the immune system and help it respond.

It was tested at clinical trial sites in the US between 1966 and 1968.

At first, everything looked good. The vaccine was tested in animals, who tolerated it well, and then given to children, who also appeared to respond well.

Unfortunately, when RSV season started that fall, many of the children who were vaccinated required hospitalization and got more severe RSV disease than what would have normally occurred.

A study on the trial found that 80% of the vaccinated children who caught RSV later required hospitalization, compared with only 5% of children who got a placebo. Two of the young trial participants died.

The outcomes were a seismic shock to vaccine science. Efforts to develop vaccines and treatments against RSV halted as researchers tried to untangle what went so wrong.

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Many of the guardrails currently in place around clinical trials of vaccines grew out of the failures of the RSV vaccine.

The scientific breakthrough that allowed scientists to freeze the virus's F protein into place also allowed NIH scientists Drs. Jason McLellan and Barney Graham to stabilize the spike protein of the coronavirus, speeding the development of a Covid-19 vaccine.

"RSV has been one that's taken us a while to be able to unlock its mysteries and secrets," said Dr. Steven Varga, dean of the Graduate School of Biomedical Sciences at St. Jude Children's Research Hospital who has spent his career studying the virus and has designed a nanoparticle vaccine against it.

"It's a really exciting time. It's been a long time coming," he said.

Graham, now a professor at the Morehouse School of Medicine, agreed that the news is exciting but says there's more work to do.

"You can imagine that after a lifetime of work on RSV, it is exciting and gratifying to reach this milestone. However, there is still a lot more to do. Success with vaccines for the elderly and maternal immunization and monoclonal antibody treatment for young infants, still leaves children from 6 months to 5 years of age in need of protection," he wrote in an email.

Courtesy Elle Waldoch

Adam Kaseman died in September after a bout with RSV that landed him in the hospital.

Minnesota resident Tania Richter wishes the vaccine had been available for her grandfather Adam Kaseman, a retired school bus driver who died after a bout of severe RSV last summer. He was 95 but otherwise in good health and in assisted living in Jamestown, North Dakota, when RSV tore through the facility.

He was hospitalized and later recovered enough to be discharged into a nursing home, but Richter said it was the beginning of the end for him. He died a few weeks later.

"He was a great-grandpa. I didn't get to see him too much the last couple of years, just

with Covid, trying to keep everybody safe, kept that from happening," she said.

"I really wish it had been around before this happened because the vaccines give us a fighting chance," she said. "Hopefully, it will save someone else's grandpa."