

RSV vaccine for older adults is 84% effective, Moderna says

It's another positive sign for mRNA vaccines and the fight against RSV.

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Moderna's mRNA-based vaccine against RSV (respiratory syncytial (sin-SISH-uhl) virus) was effective at preventing disease in older adults, according to preliminary, top-line results of an ongoing phase III clinical trial the company announced Tuesday. Moderna said it will now seek regulatory approval for the vaccine in the first half of this year.

According to the company, the vaccine was 83.7 percent effective at preventing RSV-associated lower respiratory tract disease (RSV-LRTD) involving two or more symptoms in adults age 60 and over. It was 82.4 percent effective at preventing RSV-LRTD with three or more symptoms in the same group. No safety concerns were identified.

The findings are another positive sign for mRNA vaccine platforms generally, which Moderna and other pharmaceutical companies have quickly shifted to for fighting various other infections and diseases given the global success of mRNA-based COVID-19 vaccines. mRNA-based vaccines are now in development for everything from seasonal flu to HIV and certain cancers.

RSV has been among the top priorities for vaccine development. The seasonal respiratory virus is potentially lethal to young children, as well as the elderly. This was particularly noticeable last year, as RSV and other seasonal viruses caused unusually large off-season waves of infection in the wake of SARS-CoV-2's disruptive spread. Typically, RSV sends around 3.6 million children worldwide to the hospital each year and kills over 100,000 children under 5. Just in the US, RSV sends an estimated 58,000 to 80,000 children under 5 to the hospital each year, killing between 100 to 300, according to the Centers for Disease Control and Prevention. For older adults in the US, the virus sends about 60,000 to 120,000 to the hospital, killing 6,000 to 10,000.

Researchers have been working on an RSV vaccine for decades. In the 1960s, tragedy struck an early vaccine trial, virtually halting progress. It was only in the last decade or so that researchers could fully understand and overcome the failure.

Now, with decades of foundational research, Moderna's mRNA-based candidate is just one of several in the works. In August, Pfizer announced that its protein-based RSV vaccine was about 86 percent effective in older adults. Two months later, the company announced its vaccine was 82 percent effective at preventing severe RSV in the first three months of an infant's life after vaccinating pregnant trial participants. And in October, GSK announced that its protein-based RSV vaccine was about 83 percent effective against disease in older adults.

For Moderna's trial, the company enrolled approximately 37,000 adults 60 years or older in 22 countries. The interim analysis was based on 64 cases of RSV-LRTD with two or more symptoms, of which 55 occurred in the placebo group, the company reported. There were 20 cases of RSV-LRTD with three or more symptoms, of which 17 cases were observed in the placebo group.

"Today's results represent an important step forward in preventing lower respiratory disease due to RSV in adults 60 years of age and older," Moderna CEO Stéphane Bancel said in the press release. "These data are encouraging, and represent the second demonstration of positive phase 3 trial results from our mRNA infectious disease vaccine platform after Spikevax, our COVID-19 vaccine." Bancel went on to say that the company will be focusing on preventing respiratory viruses, in particular, with its platform. In addition to the RSV vaccine candidate, "we are committed to developing a portfolio of respiratory mRNA vaccines to target the most significant viruses causing respiratory disease, including COVID-19, influenza, and human metapneumovirus."



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