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FDA Approves World's First RSV Vaccine for Older Adults: Arexvy by GlaxoSmithKline

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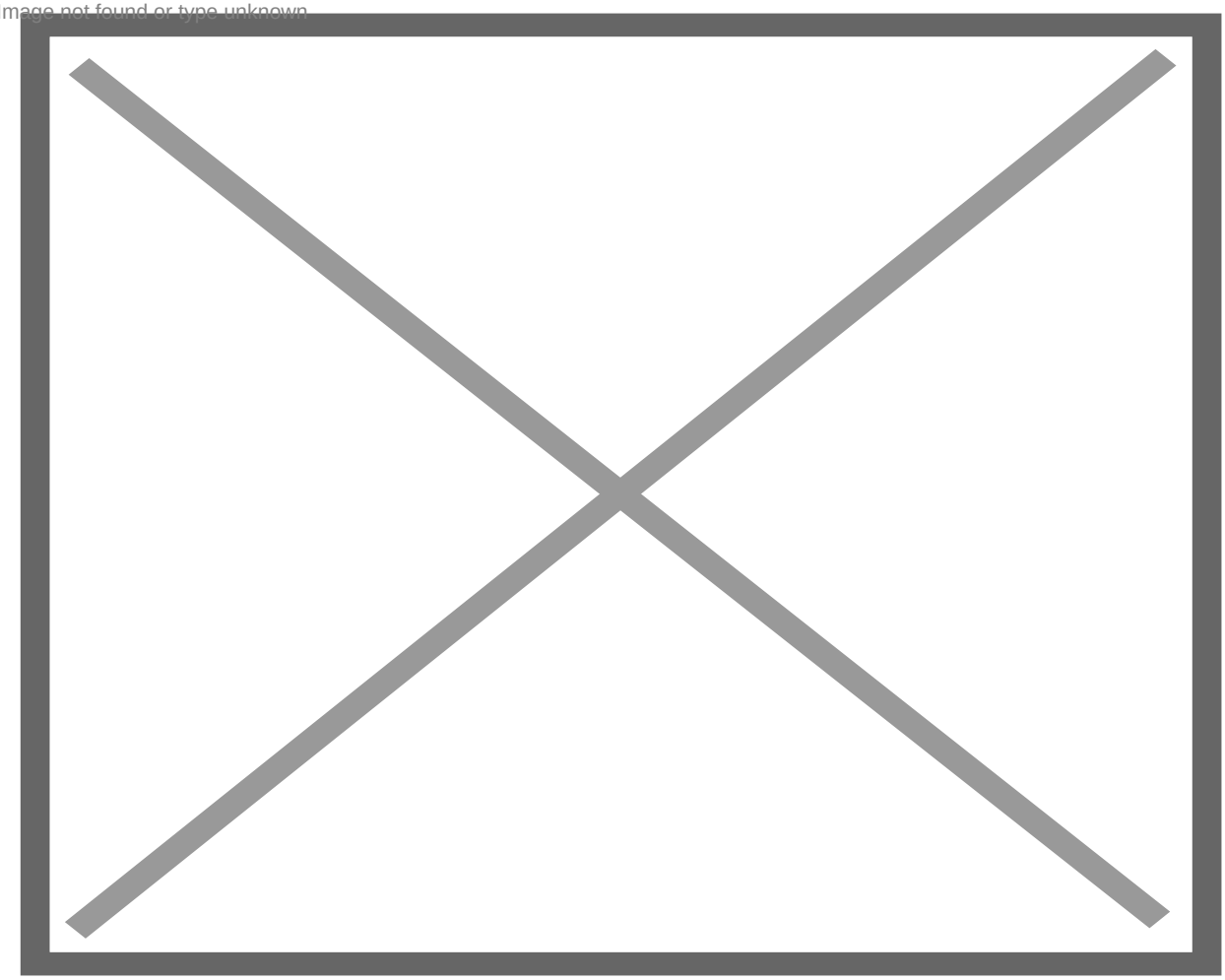

Respiratory Syncytial Virus (RSV) is a highly contagious virus that causes infections in the respiratory tract, particularly in the lungs and breathing passages.

Sixty years after initial failed trials, a vaccine for respiratory syncytial virus (RSV) has been approved by the U.S. Food and Drug Administration (FDA).

Arexvy, the world's first approved vaccine for RSV, was greenlit by the FDA on Wednesday for the prevention of lower respiratory tract disease caused by RSV in people aged 60 and above. The vaccine is manufactured by GlaxoSmithKline Biologicals.

"Today's approval of the first RSV vaccine is an important public health achievement", said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. The vaccine

prevents “a disease which can be life-threatening,” he continued, saying that the approval “reflects the FDA’s continued commitment to facilitating the development of safe and effective vaccines for use in the United States.”

The highly contagious virus circulates seasonally, usually beginning in the cooler months and peaking in winter. Dr. Marks noted that “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.” It causes infections of the lungs and breathing passages, according to the FDA, and is a common cause of lower respiratory tract disease (LRTD) in older adults. LRTD can lead to pneumonia and swelling of the bronchioles – the small airways in the lungs. In the U.S. the Centres for Disease Control and Prevention (CDC) estimates that RSV kills up to 10,000 adults 65 and older each year.

The FDA says the main clinical study of Arexvy included 25,000 participants, half of whom received the vaccine with the other half receiving a placebo. The vaccine cohort was found to have approximately 94% less risk of developing severe RSV-associated LRTD, and over 82% less risk of developing any RSV-associated LRTD. Two other studies were conducted with people age 60 and older, in which approximately 2500 participants received the Arexvy vaccine.

The federal agency is requiring GlaxoSmithKline to conduct further studies to assess serious risk signals for the development of two conditions observed during the studies. In one study, which administered Arexvy alongside an approved influenza vaccine, two participants developed ADEM after seven and 22 days respectively. Acute disseminated encephalomyelitis is a rare condition in which the brain and spinal cord become inflamed. One of the two people with ADEM died. The other study contained a vaccine recipient who after nine days developed Guillain-Barré syndrome where the body attacks nerve cells, which causes muscle weakness and sometimes paralysis.

Although not required by the FDA, GSK says it will also assess the signals of serious risks for atrial fibrillation, after it was observed in 0.04% of vaccine recipients in the main study within 30 days of receiving Arexvy.

The FDA evaluated data on Arexvy collected over one RSV season. Study participants will be monitored for the next two seasons “to assess the duration of effectiveness and the safety and effectiveness of repeat vaccination,” according to the FDA.

In a world where people both young and old have been left with compromised cardiopulmonary systems, the specter of RSV has been looming large, making the approval of Arexvy particularly timely.

GSK Chief Scientific Officer Tony Wood called the vaccine’s approval a “turning point in our effort to reduce the significant burden of RSV.” Researchers have been working for decades to find a safe, effective vaccine for the virus, since trials in the 1960s failed after children inoculated with the vaccines were shown to develop more severe RSV infections than unvaccinated children. Two children who had been vaccinated in the trials died from their infections before those trials were scrubbed. It was later discovered that those early vaccine candidates contained a malformed protein that in turn spurred the children’s immune systems to produce antibodies that did not work against the virus, and caused further inflammation that made the disease more severe.

It was only after National Institutes of Health researchers discovered how to ensure the protein in question would remain in the correct confirmation that a successful RSV vaccine could be developed. Apart from GSK’s offering, vaccines from Pfizer and Moderna are reportedly nearing or at the end of Phase III trials, and will soon come up for review by the FDA.

Meanwhile, Arexvy is likely to be considered for approval by the CDC when that agency’s advisory committee for immunizations meets in June. Only after approval by the CDC can the vaccine go to market.