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AstraZeneca Pauses Vaccine Trial for Safety Review

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6-7 minutes

The company halted late-stage trials of its coronavirus vaccine because of a serious suspected adverse reaction in a participant.

Credit...Amanda Perobelli/Reuters

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The pharmaceutical company AstraZeneca halted large, late-stage global trials of its coronavirus vaccine on Tuesday because of a serious suspected adverse reaction in a participant, the company said. It is not yet known whether the reaction was directly caused by the company's vaccine or was coincidental.

The pause, which was first reported by STAT, will allow AstraZeneca, a British-Swedish company, to conduct a safety review and investigate whether the vaccine caused the illness. How long the hold will last is unclear.

Drug companies are racing to complete a coronavirus vaccine that could bring an end to a pandemic that has already claimed more than 890,000 lives globally. AstraZeneca is a front-runner, with late-stage clinical trials underway around the world, and has said it hoped to have a vaccine ready before the end of the year. If the cause of the reaction turns out to be related to the vaccine, those efforts could be derailed.

Late-stage vaccine testing remains crucial, as large trials can turn up rare but serious side effects that would surface only if many thousands of people received a vaccine.

"This is the whole point of doing these Phase 2, Phase 3 trials,"

said Dr. Phyllis Tien, an infectious disease physician at the University of California, San Francisco. “We need to assess safety, and we won’t know the efficacy part until much later. I think halting the trial until the safety board can figure out whether or not this was directly related to the vaccine is a good idea.”

President Trump has repeatedly pushed for the approval of a vaccine by Election Day, Nov. 3. On Tuesday nine companies, including AstraZeneca, made a joint pledge to “stand with science” on coronavirus vaccines, reaffirming that they would not move forward with such products before thoroughly vetting them for safety and efficacy.

In a statement, AstraZeneca described the trial’s halt, which was instituted voluntarily, as a “routine action which has to happen whenever there is a potentially unexplained illness in one of the trials, while it is investigated, ensuring we maintain the integrity of the trials.”

The company said that in large trials like the ones it is overseeing, participants do sometimes become sick by chance “but must be independently reviewed to check this carefully.”

The company said it was “working to expedite the review of the single event to minimize any potential impact on the trial timeline,” and reaffirmed its commitment “to the safety of our participants and the highest standards of conduct in our trials.”

A spokeswoman for the Food and Drug Administration declined to comment.

A person familiar with the situation, who spoke on the condition of anonymity, said that the participant who experienced the suspected adverse reaction had been enrolled in a Phase 2/3 trial based in the United Kingdom. The individual also said that a volunteer in the U.K. trial had received a diagnosis of transverse

myelitis, an inflammatory syndrome that affects the spinal cord and is often sparked by viral infections. However, the timing of this diagnosis, and whether it was directly linked to AstraZeneca's vaccine, is still unknown.

Transverse myelitis can result from a number of causes that set off the body's inflammatory responses, including viral infections, said Dr. Gabriella Garcia, a neurologist at Yale New Haven Hospital. But, she added, the condition is often treatable with steroids.

AstraZeneca declined to comment on the location of the participant and did not confirm the diagnosis of transverse myelitis. "The event is being investigated by an independent committee, and it is too early to conclude the specific diagnosis," the company said.

Some said the company's halt was evidence that the process was working as it should.

"At this stage, we don't know if the events that triggered the hold are related to vaccination," said Dr. Luciana Borio, who oversaw public health preparedness for the National Security Council under Mr. Trump and who was acting chief scientist at the F.D.A. under President Barack Obama. "But it is important for them to be thoroughly investigated."

AstraZeneca's vaccine uses a viral vector that ferries coronavirus genes into human cells. The viral vector in this case is a modified chimpanzee adenovirus, altered to render it harmless to people. The coronavirus components of the vaccine are intended to spark a protective immune response that would be roused again should the actual coronavirus try to infect a vaccinated individual.

In a paper published in The Lancet in July, researchers behind

AstraZeneca's formulation reported that the majority of participants in the vaccine's Phase 1/2 trials, which are designed to assess the product's safety, had experienced some mild or moderate side effects, including muscle aches and chills. None of the reactions, however, were considered severe or life-threatening, and resolved quickly. The vaccine was deemed safe enough to proceed to further testing.

AstraZeneca's vaccine is in Phase 2/3 trials in England and India, and in Phase 3 trials in Brazil, South Africa and more than 60 sites in the United States. The company intended for its U.S. enrollment to reach 30,000, and started its American trials on Aug. 31.

Phase 3 trials evaluate whether vaccine candidates protect people from infection or severe disease compared to a placebo.

Among F.D.A.-approved vaccines, serious side effects are extremely rare. If identified in late-stage trials, these events can factor strongly in the agency's decision whether to greenlight a product.

AstraZeneca is one of three companies whose vaccines are in late-stage clinical trials in the United States. One of those companies, Moderna, said on Tuesday that the pause by AstraZeneca had not affected its own trial.

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