

# Novartis starts testing swine flu vaccine

August 5 2009, By MARIA CHENG , Associated Press Writer

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A girl looks on as she waits to test for swine flu virus at Kasturba Gandhi hospital in Mumbai, India, Wednesday, Aug.5, 2009. The western Indian city Pune reported the country's first swine flu fatality two days ago. India has confirmed 574 swine flu cases, according to the Health Ministry. (AP Photo/Rajanish Kakade)

(AP) -- Swiss drugmaker Novartis has begun injecting its swine flu vaccine into people in the company's first human tests, a spokesman said Wednesday. The vaccine is being tested in a yearlong trial of 6,000 people of all ages in Britain, Germany and the United States, Novartis spokesman Eric Althoff told The Associated Press, adding that the vaccine will likely be on the market before the trial finishes.

A person in Britain became the first to get the swine [flu vaccine](#) about 10 days ago, he said.

Sanofi-Pasteur, which makes about 40 percent of the world's flu

vaccines, expects to start testing its [swine flu vaccine](#) within days in the U.S. and Europe, according to spokesman Benoit Rungeard. Sanofi-Pasteur is a unit of Paris-based Sanofi-Aventis SA.

Since swine flu was declared to be a [pandemic](#), or global outbreak, by the [World Health Organization](#) in June, pharmaceuticals have been racing to get their vaccines ready. Last month, Australian drugmaker CSL became the first vaccine maker to start testing its vaccine in humans in Australia.

"We initiated clinical trials about 10 days ago," Althoff said.

Half of Novartis' vaccines being tested are grown in chicken eggs, the traditional way of making flu vaccines, while the other half use a new cell-based technology.

The trial will test the vaccine's safety and whether one or two shots are necessary.

"Our assumption is that two doses will be required," Althoff said.

The vaccines being tested in Europe have an adjuvant, an ingredient used to boost the body's [immune response](#). In the U.S., Althoff said [Novartis](#) will be testing both vaccines with and without adjuvants.

WHO recommends that countries use vaccines with adjuvants, to stretch the global supply of swine flu vaccine. Flu vaccines in Europe often contain adjuvants. However there are no licensed flu vaccines with adjuvants in the United States.

Once Novartis AG has preliminary data from the trial, they will submit that to drug regulators including the European Medicines Agency. European and U.S. regulators have a fast-track process for approving

swine flu vaccine, to ensure it is available before the [flu season](#) starts in the fall, when swine flu is expected to surge.

The European Medicines Agency has previously said swine flu vaccines based on a pre-approved bird flu vaccine could be licensed within five days, even without extensive testing in humans.

Last month, WHO reported that the swine flu viruses being used to make the vaccine were not growing enough of a key ingredient, and said they were only producing half as much "yield" as regular flu viruses. The agency asked its laboratory network to produce a new set of viruses for vaccine makers to use.

Althoff confirmed that Novartis is only getting about 30 to 50 percent of the usual yield it gets from flu viruses to make vaccines. Novartis made its vaccines with WHO's original set of flu viruses, and hasn't yet started working with the new viruses.

The low virus yield could mean delays in when countries get their vaccine orders filled.

More than 35 countries have placed orders with Novartis for swine flu, or H1N1 vaccine, including France, the Netherlands, and Switzerland. The U.S. has ordered \$979 million worth of bulk vaccine and Novartis' adjuvant.

Althoff said the company expected to start shipping vaccine in the last quarter of 2009 and will continue the deliveries next year.

GlaxoSmithKline PLC, which has orders for 291 million doses of vaccine from countries including Britain, has not yet started testing its vaccine in humans. The U.S. has also ordered \$250 million worth of vaccine ingredients from Glaxo.

Since swine flu emerged in April, it has killed at least 1,154 people worldwide and is estimated to have infected millions.

In India on Wednesday, hundreds of anxious people crowded a hospital waiting to be tested for swine flu. Panic spread in the city of Pune and fights broke out at the city's top hospital after authorities reported the country's first swine flu fatality two days ago.

In other efforts to fight swine flu, a Saudi health ministry official said Wednesday that authorities will require religious pilgrims to have a medical certificate showing they don't suffer from chronic diseases.

Khaled al-Merghalani also said children and the elderly will be banned from the annual hajj pilgrimage. WHO officials have said [swine flu](#) appears to be striking younger people particularly hard, with the median age from 12 to 17.

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