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## \$8.7 million bolsters bird-flu battle

Newark biotech firm receives Gates grant

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A nonprofit research group in Newark has received an \$8.7 million grant from the nation's largest foundation to continue development of a plant-based vaccine for bird flu.

The Fraunhofer Center for Molecular Biotechnology expects to add at least 10 Ph.D.-level scientists to its staff of 80 to help move its vaccine candidate toward clinical trials in humans.

The grant builds on a \$2.6 million award to Fraunhofer two years ago from the Bill & Melinda Gates Foundation to find potential flu vaccines.

Vidadi Yusibov, Fraunhofer's executive director, said the latest grant shows the foundation believes Fraunhofer's technology -- which makes vaccine materials by coaxing plants into producing certain proteins -- can yield commercially viable vaccines.

The grant "will help us to establish all the processes of making a suitable product you can take into human trials," Yusibov said.

Avian influenza, or bird flu, is a contagious disease that has largely been confined to animals. The World Health Organization has tracked 403 human cases of a virulent flu strain known as H5N1, resulting in 254 deaths, most of those in Asia.

But the WHO warns that the virus could mutate and become as contagious as normal influenza, causing a pandemic of widespread illness and millions of deaths worldwide. China has reported three cases of H5N1 infection this month in humans, resulting in two deaths so far.

The Fraunhofer research is targeting the H5N1 virus, and the group is working with commercial partner iBioPharma Inc., a Newark biotech firm that has an exclusive license on Fraunhofer's plant-based technology.

Fraunhofer has also worked with the Gates Foundation to develop vaccines for sleeping sickness and malaria, which afflict the developing world.

"It is essential that new vaccines reach the people who need them most," said Doug Holtzman, senior program officer for the Gates Foundation. "If successful, this project could help developing countries respond quickly to outbreaks of influenza and other infectious diseases to significantly limit their impact on vulnerable populations."

Yusibov said Fraunhofer will seek Food and Drug Administration guidance on conducting toxicity studies in animals for its vaccine candidate. Fraunhofer would use data from those studies to submit an investigational new drug application with the FDA.

If the application is approved, Fraunhofer could begin Phase 1 trials to test the vaccine candidate's

safety in humans. Yusibov said he expected the Gates Foundation grant to carry development to the end of Phase 1 trials, after which the research partners would look for a larger commercial partner with vaccine development experience to help take the product to market.

Fraunhofer, aided by a \$5 million grant from the state, is building a 14,000-square-foot pilot-scale production facility to produce material for clinical trials at its home in the Delaware Technology Park. Yusibov said the facility should be complete by June. Fraunhofer is now looking to hire at least 10 engineers and scientists.

"We have a very talented R and D staff," Yusibov said, "but now we need to bring the people who are experienced in clinical development."

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