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## **Chiron Wins \$63M Contract For Avian Influenza Vaccine**

By Karen Pihl-Carey

Staff Writer

As scares of an avian flu pandemic circulate following recent cases in Southeast Asia and parts of Europe, the U.S. government has awarded a \$62.5 million vaccine contract to Chiron Corp.

The Emeryville, Calif.-based company will supply the government with vaccine for a stockpile to protect against the H5N1 avian influenza virus strain.

"Chiron has been working on avian flu since it first appeared in Hong Kong in 1997," said Alison Marquiss, a company spokeswoman. "So we are certainly committed to providing the solutions we can to protect public health, and we recognize the best way to do that is through a public-private partnership."

Chiron will deliver a bulk stockpile of the vaccine to the Department of Health and Human Services (HHS) sometime in the first half of next year, at which point the company will receive the \$62.5 million. HHS is building a stockpile to supply 20 million people with avian influenza vaccine and another 20 million people with antiviral medication.

Chiron expects to produce the stockpile at its Liverpool, UK, manufacturing facility - the same one that was suspended last year due to sterility issues, preventing the company from providing any of its Fluvirin flu vaccine to the U.S. during the 2004-2005 season. (See BioWorld Today, Oct. 6, 2004, and Sept. 1, 2005.)

On top of the Fluvirin problems, Chiron said in July that it would not

provide Begrivac flu vaccine to the German and UK markets because of bacterial contamination, leaving some analysts to question management's credibility. Begrivac is manufactured at the company's Marburg, Germany facility.

But Marquiss said that everything at the Liverpool facility is up to standard, and Chiron is well prepared for this new government contract. The FDA gave the green light in August for the facility to manufacture Fluvirin for this year.

"We did an extensive remediation plan to improve our facility," Marquiss told BioWorld Today. "It's been inspected several times by regulatory authorities from the United Kingdom and the United States. Our employees are very happy to be back on the market. It was really their dedication and commitment that got us there."

Chiron originally expected to provide up to 30 million doses of Fluvirin this year to the U.S., but it reduced that projection to 18 million to 26 million, citing a lower production output due to new processes and procedures. Producing the avian influenza vaccine will not interfere with the Liverpool facility's manufacturing of Fluvirin, which is expected to wrap up within the next few months.

"It'll be done in [Fluvirin's] downtime, essentially," Marquiss said.

The vaccine is based on an inactivated influenza strain similar to the H5N1 avian subtype that has been found not only in Southeast Asia, but also more recently in Eastern Europe.

A pandemic occurs when a new virus emerges and is easily passed among humans resulting in a worldwide outbreak. It occurred three times in the last century, killing an estimated 40 million people in 1918. While Avian influenza, or the bird flu, typically does not infect humans, there have been recent cases in which it was transmitted to people. The current outbreak in Southeast Asia, for instance, has resulted in more than 100 human cases, with about 50 percent of them dying as a result. The H5N1

strain has destroyed an estimated 150 million birds.

In addition to Chiron, a number of other companies are working on products that could combat the avian flu, including Peregrine Pharmaceuticals Inc., of Tustin, Calif.; MultiCell Technologies Inc., of Lincoln, R.I.; GenereX Biotechnology Corp., of Toronto; Novavax Inc., of Malvern, Pa., in partnership with Wave Biotech LLC, of Somerset, N.J.; as well as Philadelphia-based Hemispherx Biopharma Inc.

Peregrine said on Friday that it is ramping up its efforts to develop and promote products that may help treat influenza, including the H5N1 avian flu strain. The company is working with the National Institutes of Allergy and Infectious Diseases to study the use of its hepatitis C candidate Tarvacin as a treatment of avian flu. Tarvacin is an antibody that acts on a phospholipid on the outside of an infected or malignant cell membrane. Previous studies have shown that it binds to six different virus families including the avian flu's influenza A virus.

Chiron also is studying the use of adjuvants with vaccines, which the HHS heavily supports. Results released Friday from a study sponsored by the National Institute of Allergy and Infectious Diseases of Chiron's H9N2 avian influenza vaccine candidate showed promising results. Like H5N1, H9N2 is a potential pandemic influenza strain that has caused serious illness in three people in Hong Kong in recent years

Data from the 96-patient study showed that Chiron's adjuvant MF59 significantly enhanced immune response. The lowest dose tested contained 3.75 micrograms of antigen per dose, only a quarter of the dose used in seasonal influenza vaccines. The company expects to soon conduct clinical studies of an adjuvanted H5N1 vaccine.

"What's really exciting about it is it shows that an adjuvant has great potential to make an avian flu vaccine more effective," Marquiss said, "first of all, because it would boost the immune response so you would need less vaccine per person and you could reach more people."

A second advantage, she said, is the adjuvant can provide a cross-protective effect, meaning the vaccine can protect against different strains.

Chiron's stock (NASDAQ:CHIR) rose 74 cents Friday to close at \$43.40.

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