FLU PUTS OLD DRUG BACK ON FAST TRACK

By Julie Schmit, USA TODAY
October 30, 2015

The rush to stockpile anti-virals for a potential avian flu pandemic has revived interest in an abandoned drug and sent its company's stock soaring.

Peramivir was left to languish in 2002 after its pill form did not absorb well in the blood.

Now, scientists for the National Institutes of Health are testing the drug from BioCryst Pharmaceuticals (BCRX) in shot form to see if it could work against the deadly avian flu strain.

Peramivir is similar to Tamiflu and Relenza, two anti-virals that governments worldwide are stockpiling. Anti-virals reduce flu symptoms, but their effectiveness against the H5N1 avian flu is uncertain because the virus has not yet mutated to spread rapidly from human to human.

Animal studies on peramivir are underway, and human trials could begin next year, BioCryst CEO Charles Bugg says. He says the drug could be stockpiled as soon as next year.

"I think it has real promise as long as there isn't some unexpected safety issue," says Frederick Hayden, a professor of virology at the University of Virginia School of Medicine. Hayden is consulting with the World Health Organization to set up clinical trials in Southeast Asia for anti-flu drugs, including Tamiflu. If peramivir tests in animals go well, the drug could be tested in Asia, too, he says.

When tested in mice, peramivir has been effective against regular flu and an avian flu strain, says Hayden, who has consulted for BioCryst. Ferret studies are next.

More anti-virals are crucial to building avian flu defenses for several reasons.

The two leading anti-virals are Roche's Tamiflu, the biggest seller, and GlaxoSmithKline's Relenza, a far smaller rival. Both drugmakers are boosting production, but they cannot make either drug fast enough to quickly fill government stockpile orders.

Also, viruses can become resistant to drugs. But a flu strain that becomes resistant to one anti-viral may take longer to become resistant to another, so having more anti-virals is key, says Jeremy Carver, CEO of the International Consortium on Anti-Virals.

Peramivir is one of several anti-virals that Robert Sidwell, a professor of virology at Utah State, is testing for the NIH. Peramivir is the furthest along because of its past development, says Sidwell, who also used to consult for BioCryst. "We're doing a lot of work with peramivir right now because of interest by the NIH," he says, adding that several other drugs under review also show promise.

Rising stock

Investors are betting on BioCryst's success. Its shares, which hit a 52-week high of $18.42 about two weeks ago, closed Friday at $13.63, up 160% for the year.

BioCryst, based in Birmingham, Ala., has incurred more $137 million in operating losses since being founded in 1986 and has never brought a drug to market.

In the mid-1990s, the Food and Drug Administration cited the company for not following good drug trial practices while testing a potential lymphoma drug. BioCryst submitted incorrect data to the FDA. Its regulatory filings still warn investors that its clinical studies may receive increased scrutiny as a result.

Peramivir is not the only reason for the company's stock rise. BioCryst's other drugs in development include one for leukemia, Fodosine. Vinny Jindal, equities analyst at Wedbush Morgan Securities, expects the company to win FDA approval for Fodosine by mid-2007.

Jindal estimates Roche will take years to fill Tamiflu orders from 40 governments, including the U.S. Even if Roche and Glaxo substantially boost production of their anti-virals, Jindal says others will be needed to battle resistance.

BioCryst's Bugg says millions of treatments of peramivir could be produced monthly by Swiss company Cilag, which was tapped years ago to manufacture the drug.

Peramivir, with a shelf life of at least five years, initially wouldn't be manufactured for sale to consumers, just government stockpiles, Bugg says. If there's an avian flu pandemic and a shortage of Tamiflu pills, Bugg says peramivir shots would be an acceptable alternative. "If you have a deadly infection, getting a shot becomes the least of your problems," he says.

To enter emergency stockpiles, Bugg says the drug wouldn't need the FDA's full formal approval, which often takes years. Instead, it could be stockpiled on the strength of positive results from two animal studies to prove efficacy and some human studies to identify safe dosing.

Last year, the Department of Health and Human Services ordered 75 million doses of a new anthrax vaccine from VaxGen under similar conditions. Earlier this month, the FDA announced a new Rapid Response Team to speed reviews of new anti-virals and manufacturing of already approved ones.

Bugg says peramivir in intravenous form, for hospitalized patients, could be ready for stockpiling by mid-2006 and the intramuscular-shot formulation after that.

Past demand modest

While anti-virals for the flu attract high demand now, they haven't always. GSK's revenue from Relenza, also known as zanamivir, last year was just $5.5 million. Roche's revenue from Tamiflu, also known as oseltamivir, was $255 million. Cholesterol-lowering Lipitor, the No. 1-selling drug, generated almost $11 billion.

When BioCryst was first testing peramivir, it had partnered with Johnson & Johnson. J&J pulled out of the partnership because other drugs' prospects looked better, BioCryst said.

Because anti-virals have never attracted much attention from drugmakers, Carver's non-profit has identified a handful of anti-virals for flu being tested in academic labs. He's trying to raise tens of millions of dollars in government funding to continue research.

"There's no business model to develop a drug for a hypothetical disease," Carver says. "But we're going to need dozens of drugs to control this virus."