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FDA lifts hold on experimental Ebola drug

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Federal health authorities have eased safety restrictions on an experimental drug to treat Ebola, a move that could clear the way for its use against an unprecedented outbreak of the deadly virus in West Africa.

Canadian drugmaker Tekmira Pharmaceuticals said the U.S. Food and Drug Administration modified a hold recently placed on the company's drug after safety issues emerged in human testing. The company has a $140 million contract with the U.S. government to develop its drug TKM-Ebola, which targets the genetic material of Ebola. But last month the FDA halted a small study of the injection in adults to request additional safety information.

Tekmira said Thursday the agency "verbally confirmed" changes to the hold that may allow the company to make the drug available, although it has yet to be proven as safe and effective.

The move by FDA comes amid an Ebola outbreak in West Africa that health officials warn could sicken more people than all previous outbreaks of the disease combined. More than 1,700 people have been sickened in the current outbreak, which began in March. Nearly 1,000 have died, according to the World Health Organization.

Currently, there are no licensed drugs or vaccines for the deadly disease. Several are in various stages of development, but none have been rigorously tested in humans.

Two Americans diagnosed with Ebola recently received a different experimental drug called ZMapp, made by Mapp Biopharmaceutical Inc. of San Diego. It is aimed at boosting the immune system's efforts to fight off Ebola and is made from antibodies produced by lab animals exposed to parts of the virus.

The U.S. aid workers were first treated in Liberia. And while the FDA must grant permission to use experimental treatments in the United States, it does not have authority over the use of such a drugs in other countries.

The FDA in March granted Tekmira "fast track" status for its Ebola drug, a designation designed to speed up approval of high-priority drugs by granting companies extra meetings with FDA scientists. Early studies of TKM-Ebola in monkeys suggested it could block high doses of the Ebola virus. But on July 21, the Vancouver-based company announced the FDA had halted a small dosing study of the drug in healthy adults. The company said regulators had questions about a type of drug reaction that can cause nausea, chills, low blood pressure and shortness of breath.

Tekmira's CEO praised the FDA for modifying the restriction on Thursday.

"We have been closely watching the Ebola virus outbreak and its consequences, and we are willing to assist with any responsible use of TKM-Ebola. The foresight shown by the FDA removes one potential roadblock to doing so," said Dr. Mark Murray.

Company shares rocketed 89 cents, or 6.7 percent, to close at $14.27 in regular trading. Shares climbed another 98 cents, or 6.9 percent, to $15.25 in afterhours trading.