

THE WALL STREET JOURNAL

Ebola Virus: Experimental Drugs Approved for Use in Fighting Outbreak in West Africa

World Health Organization Gives Green Light, Given Size of Deadly Outbreak

The World Health Organization gave a green light to the use of experimental drugs to combat the Ebola outbreak in West Africa, with demand for—and questions about—untested treatments growing after two infected Americans received some.

Workers have their temperature taken before entering the Freeport area, an important commercial port facility, Monrovia, Liberia, on Aug. 11.

A panel of ethicists convened by the WHO said on Tuesday that it is ethical to use the treatments given the size of the outbreak, which has killed at least 1,013, and the challenges of controlling it through regular measures that have stopped other Ebola outbreaks.

"We find ourselves facing a dilemma," Marie Paule Kieny, a WHO assistant director-general, said about a handful of medications and vaccines that have been developed but never tested in humans. "Far too many lives are being lost right now."

Also Tuesday, the Canadian government said it would donate 800 to 1,000 doses of experimental Ebola vaccine to the WHO for use in combatting the outbreak. The vaccine has shown promise in animal research, said the Public Health Agency of Canada. The vaccine was developed by scientists at the agency's National Microbiology Laboratory. The Canadian government owns the intellectual property and licensed the rights to a U.S. company, BioProtection Systems Corp. The WHO's endorsement came after Liberia's government confirmed that it had ordered three courses of the same treatment that was given to the Americans. Bernice Dahn, the nation's chief medical officer, said the drug, called ZMapp, should arrive in Liberia on Wednesday and would be given to three doctors.

Health authorities in Liberia expressed concern last week that the drug had been given to the two Americans, but not to infected Liberians, and said they would explore getting some on their own. But three courses of the treatment won't go far in a country that has had nearly 600 cases, including a recent resurgence, with 45 new cases between Thursday and Saturday.

The WHO's decision is meant to assure manufacturers that there will be a market for their drugs if they boost production for this outbreak. But it isn't clear whether the manufacturers would be able to meet demand quickly enough. The maker of ZMapp, San Diego-based Mapp Biopharmaceutical Inc., on Monday said it exhausted its available supply after filling its request from West Africa.

Chatsworth Charter High School Medical Careers and Sciences Academy Common Core Standards Preparation Article #3

Moreover, it is far from clear what effect, if any, ZMapp actually had on the two infected Americans, Kent Brantly and Nancy Writebol, who remain in isolation at Emory University Hospital in Atlanta. A 75 year-old Spanish priest who had been airlifted to Madrid from Liberia last week was also administered the same drug, a representative of his religious order told Europa Press Television. Members of the order were hopeful for his recovery, but the priest, Rev. Miguel Pajares, died.

"Whether ZMapp works, this is difficult to state with any definitive opinion right now," said Dr. Kieny. "We have to see if this is a definite cure or not."

Emory and the charities for which the two work declined to comment on the condition of Dr. Brantly and Ms. Writebol. Ebola experts say most deaths from the disease occur during the eighth to 10th day of illness.

Dr. Brantly said last week that he felt initial symptoms on July 23, putting him at 20 days of illness on Tuesday. Ms. Writebol was diagnosed nearly at the same time as Dr. Brantly, also putting her past that critical stage.

ZMapp is a cocktail of three so-called monoclonal antibodies, which are derived from living cells and are designed to bind to and neutralize the Ebola virus. The product has shown promise in monkey studies, but the drug's safety hasn't been established in human clinical trials. A unit of tobacco-products maker Reynolds American Inc. RAI -0.28% manufactures ZMapp using tobacco plants in Kentucky.

Mapp last week said it was working with government agencies to increase production of the drug. The company declined to comment on Tuesday on the WHO's endorsement of the use of experimental drugs. A Reynolds spokesman last week said it could take several months to significantly boost production.

The U.S. Defense Threat Reduction Agency, an arm of the Defense Department, recently said it would expand a contract awarded to Mapp to include funding for the preparation of an application to the U.S. Food and Drug Administration to start human clinical trials of ZMapp, and to make sufficient quantities of the drug for a study.

Another Ebola drug developer, Canada's Tekmira Pharmaceuticals Corp., also declined to comment on the WHO's statement. Tekmira is developing an experimental treatment called TKM-Ebola, which is designed to harness a drug technology known as ribonucleic acid interference to combat the virus. Tekmira has a contract valued at as much as \$140 million from the U.S. Defense Department to develop the drug.

This year, Tekmira started a small safety study of TKM-Ebola in healthy volunteers. In July, the FDA placed a "clinical hold" that paused the study while the FDA assesses more information about how the drug works. Last week, the FDA modified its stance to enable testing of Tekmira's drug in infected patients, although the hold on healthy volunteers is still in place, the company said. Tekmira hasn't disclosed specific plans for further testing.