MedicalXpress

Experimental Ebola drug ZMapp begins clinical trials in Liberia

March 3 2015, by Monte Morin, Los Angeles Times

ZMapp, the experimental Ebola drug that won notoriety when it was given to a handful of infected aid workers at the height of the epidemic, will now begin clinical testing in Liberian treatment centers, U.S. health authorities said.

"Although ZMapp has been used to treat several Ebola-infected patients in recent months, we cannot determine if the drug actually benefited those patients because it was not administered within the context of a clinical trial," said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases.

"This clinical trial will help us determine if ZMapp and other treatments are safe and effective for use in the current devastating outbreak in West Africa as well as in future outbreaks," Fauci said in a prepared statement.

The clinical trial was launched Friday, in partnership with the Liberian government and the U.S. institute. The trial will enroll Ebola patients at Liberian treatment units, as well as infected aid workers returning to the United States-or anyone who acquires an infection here through secondary transmission, officials said.

Not everyone who enrolls in the trial will receive the drug, however.

Patients who consent to participating in the trials will be divided into two groups-one group that gets the drug, and a control group that does not.

Their outcomes will then be compared statistically to determine whether the treatment resulted in fewer deaths.

Although some researchers and medical officers have said that it is unethical to withhold experimental Ebola treatments from patients, Fauci and others at the U.S. Food and Drug Administration have argued that the approach is the only way researchers can determine whether the drug works.

FDA officials say patients in both arms of the trial will receive the best supportive care available, which in itself will improve survival rates.

ZMapp is a cocktail of proteins called monoclonal antibodies that bind to surface "spikes" on the Ebola virus and, ideally, can inactivate the pathogen. The antibodies are grown in tobacco plants, which has made it difficult to produce the drug quickly. The treatment, which consists of three intravenous infusions, was developed by Mapp Biopharmaceutical Inc. of San Diego.

The drug has shown promising results in tests involving monkeys and "has rescued the animals from death as late as five days after infection," the National Institute of Allergy and Infectious Diseases said.

The trial is beginning at a time when new Ebola cases have declined from about 800 a week at the height of the outbreak to about 100 a week. The reduction in cases has been greatest in Liberia, one of three West African nations affected by the outbreak.

This drop in cases has raised the possibility that researchers may not be able to enroll enough patients to get a clear picture of the treatment's effectiveness.

"Study investigators anticipate the need for flexibility in the conduct and

design of the trial to address the changing nature of the outbreak in West Africa," the U.S. institute said. "Consideration will also be given to other sites in the outbreak region that express interest."