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Ebola Scare: USFDA approves â€œTKM-Ebolaâ€?

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Ebola Emergency: USFDA approved â€œTKM-Ebolaâ€?

The US FDA has modified the clinical status of the drug TKM-Ebola, manufactured by Canada-based Tekmira Pharmaceutical, the company has announced. This move will enable its potential use in humans infected with the virus. The drug was, previously, on a full clinical hold, which has now been changed to partial by the regulator.

"We are pleased that the FDA has considered the risk-reward of TKM-Ebola for infected patients," said Dr Mark Murray, Tekmira's chief executive officer. He added, "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 recent Ebola outbreak has killed nearly 1,000 people in West Africa.

The World Health Organization (WHO) said it would convene a meeting of medical ethics experts next week to consider the implications of making experimental Ebola drugs more widely available.

Tekmira's Ebola treatment is only the third, after ZMapp and Defrys, that has shown especially promising results in monkeys, but it is unproven in humans. It has only been tested in a few dozen healthy people.

The FDA stopped the study of the drug in July because of safety concerns among people taking the highest doses of the drug. Some of subjects experienced immune response problems. A source within the FDA informed, "Anything that would shift the risk-benefit to a more favourable outcome could potentially allow the authorization of that study. A company would have a partial clinical hold in which the original study in healthy patients remained on hold but a new study in sick patients could proceed."