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France health

2ND LEAD French drug trial gone awry leaves volunteers with coma, brain damage By Jessica Camille Aguirre, dpa

Paris (dpa) - One man is in a coma and two others are in serious condition after a medical trial in France saw several participants hospitalized for taking a drug being tested to treat mood disorders, Health Minister Marisol Touraine said Friday.

A total of six men, aged 28 to 49, have been hospitalized since Sunday after having negative reactions to the medication they were taking as part of a clinical trial in the north-western French city of Rennes.

The drug used in the trial had been developed by Portuguese pharmaceutical company Bial and tested by Biotrial, Touraine said.

Tests on the medication began on January 7 with 90 healthy volunteers in different groups, times and doses, the minister said. The six men were all part of the first group that received multiple doses of the oral medication.

One of the men, who is now brain dead, was the first to show adverse symptoms last Sunday.

Four other volunteers in the trial, which was suspended Monday, began showing symptoms progressively over the course of the week, Touraine said.

The trial represents the first time that the drug was being tested on humans, its effects having first been assessed on several species of animals.

Brain damage experience by three of the men could possibly be "irreversible," said Gilles Edan, the chief of neuroscience at the Rennes hospital where the men are being treated. But he warned that it was impossible to draw any concrete conclusions.

"We cannot, at the moment, make a definitive prognosis," Edan said, adding that doctors are holding out for the patients' improvement and could not predict the effects of an untried drug.

Edan added that one of the men in the hospital had not yet presented symptoms but was being monitored. There is no known effective treatment or antidote to the effects, Edan said.

According to Touraine, the drug works on a system in the brain that plays a role in various psychological processes including anxiety and harm-sensing. The system, known as the endocannabinoid system, has been studied by scientists seeking to understand cognitive conditions.

Multiple investigations have been opened, including by Touraine's ministry and the prosecutors of Rennes and Paris.

Biotrial acknowledged in a statement that "serious adverse effects" had occurred during the study but that it had complied with all safety regulations.

Based in Rennes, Biotrial also has offices in London and in New Jersey, US. Volunteers who agree to participate in trials in France can earn between 100 and 4,500 euros (110 and 4,933 dollars), Biotrial said.

Drug manufacturers often contract independent clinical trial companies to conduct tests, and experimental medications go through multiple phases of testing before they are approved for commercial use.

In the first phase, researchers test a drug on a small group of volunteers to check for side effects before administering the drug in phase two to a larger group to evaluate effectiveness.

A drug usually goes through one more pre- and one post-market testing phase to gather more information about effects.

Only rarely does being in a clinical drug trial pose a risk to participants.

The last major drug trial disaster in the pharmaceutical industry was in 2006, when German company TeGenero had a potential multiple sclerosis drug tested in Britain.

Within moments of having the drug administered, six volunteers in the 2006 study began showing severe reactions, and one participant remained in a coma for three weeks.

TeGenero declared bankruptcy a few months later, and dosages allowances for testing were subsequently lowered.

# Notebook

## Note to editors

- Re-leads with press conference, adds Touraine, adds Edan

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The following information is not intended for publication

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