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Fabentech announces the launch and first results of first-in-human clinical trial evaluating the safety of its antidote against a deadly plant-based toxin of bioterrorism interest.

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- Fabentech received approval from French Health Authority (ANSM) to launch a phase 1 clinical trial to evaluate the safety and pharmacokinetics of FBT-002, a life-saving therapeutic against a plant-based toxin, at ascending dose levels.
- The trial enrols 24 healthy volunteers in France, with a dose escalation design.
- Healthy volunteers received the anticipated therapeutic dose, and the study safety committee confirmed that FBT-002 is well tolerated at this dosage.

Fabentech, a pharmaceutical-stage biotechnology company specialized in the development, production, and marketing of polyclonal antibodies to answer emergency situations and to treat emerging infectious diseases, received approval from ANSM to conduct a phase 1 clinical trial for FBT-002. Today, the company announces that the target therapeutic dose of the clinical trial has been administrated to healthy volunteers after dose escalation and is well tolerated.

FBT-002 is an innovative post-exposure antidote designed to combat lethal plant-based toxin intoxication and to counter fatal consequences on human body.

This highly lethal toxin causes death within a few hours to a few days regardless of the intoxication route. It can be weaponized and disseminated by bioterrorists. To date, no treatment is available in the market and FBT-002 addresses this unmet medical need. The antidote, a polyclonal antibodies treatment based on Fabentech broad-spectrum technology, is capable of countering different varieties of this deadly plant-based toxin.

Conducted as a single-center, randomized, double-blind, placebo-controlled trial, this phase 1 clinical study endeavours to primarily assess treatment safety in healthy volunteers through dose-ranging studies. The secondary objective is to determine the pharmacokinetic profile of a single intravenous dose of FBT-002.

“Reaching the target dose in this safety clinical trial is a significant milestone for Fabentech and our journey to market authorization”, said Sébastien IVA, CEO of Fabentech. “Fabentech has always been committed to public health security and our antidote will contribute to building a robust shield against a top-priority bioterror agent. With promising efficacy outcomes in animal models, we remain confident in FBT-002’s capacity to save lives.”

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About Fabentech:

Founded in 2009 and based in Lyon, Fabentech is a pharmaceutical-stage biotechnology company specialized in the development, production and marketing of polyclonal antibodies for responding to emergency situations.

Specializing in biothreats, the company's goal is to build a national and European shield against the biological threats that are the greatest risk to public health by producing and marketing preventive stocks against these targeted pathogens.

This process, licensed out to Fabentech by Sanofi Pasteur, has substantial potential in the designing of antidotes against bioterrorist attacks and treatments for numerous infectious diseases.

Fabentech has 40 employees and is financially supported by prestigious shareholders such as Definvest and Institut Mérieux.

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