News Release
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Following the serious incident occurred with one of BIAL's experimental molecules at the Phase I stage with healthy volunteers in France, BIAL deeply regrets the death of one of the volunteers participating in the trial.

We are continually and closely following the health state conditions of the other 5 volunteers who had been hospitalized and we are encouraged by the most recent news. The volunteer who had no symptoms has already returned home, two other volunteers were transferred to local hospitals within their residence areas, and two volunteers still remain at the University Hospital of Rennes. We have been informed that the most recent medical examinations present a positive scenario. We will continue to accompany the volunteers' condition, and expect a full recovery.

The experimental molecule tested in the referred clinical trial, under the code name BIA 10-2474, is a long-acting inhibitor of FAAH (Fatty Acid Amide Hydrolase) – and not a derivative of cannabis sativa - resulting in increased anandamide levels, an endogenous cannabinoid, and consequent amplification of its actions on the central nervous system and in peripheral tissues. It has long been known that the increased availability of anandamide in the body produces analgesic and anti-inflammatory effects, mood changes, sedation, and vasodilation, among others effects.

It is worth noting that over the past several years, other pharmaceutical companies have been investigating FAAH (fatty acid amide hydrolase) inhibitors with a similar profile, with no reports of significant adverse effects.

This project of investigation was initiated in 2005, and studies with this compound began in 2009 with pre-clinical *in vitro* and *in vivo* pharmacological and toxicological evaluation. The results obtained in these pre-clinical studies have shown a safety and tolerability profile that allowed, in June 2015, the approval of the phase I clinical trial in humans with healthy volunteers by the French Regulatory Authorities and by the French Ethics Committee, in accordance with Good Clinical Practices, with the Declaration of Helsinki and the inherent clinical trials related legislation.

This clinical trial included a total of 116 volunteers, of which 84 were administered previously the experimental compound, and no severe or moderate adverse effects were reported.

As soon as BIAL was informed about the occurrence of an adverse effect in a volunteer on the 11th January, BIAL immediately decided to discontinue the medication to all the participants in the trial.

On the 14th January, and complying with the legal deadlines, BIAL and Biotrial agreed to make a report to the authorities and, on that same day, on behalf of BIAL, Biotrial has reported to the French National Agency for Medicines and Health Products Safety (ANSM) and to the Ethics Committee the occurrence of severe adverse effects. Biotrial is a company with considerable and established experience in the area of clinical investigation, and had worked with BIAL since 2007.

BIAL maintains a team in Rennes to collaborate with several entities and authorities involved in clarification of the causes and the origin of this situation. It is BIAL's absolute priority to find the causes of this serious incident, whether it has been caused by the compound or any other external reason.

At present, there are no other trials ongoing with the experimental molecule in question, and BIAL will not conduct any trial with this compound until the causes of this serious incident are known and understood.

BIAL‘s mission is to develop, find and provide new therapeutic solutions within the area of Health. Deeply shaken by this unfortunate situation, we maintain our commitment to research and health, guided by the high standards of quality that we have always followed. The development of new therapeutic solutions that improve the quality of people’s life is mandatory within our scientific community and for the companies focused on research, even during painful times such as these.