News Release

As part of a clinical trial that was being held in a Phase 1 clinical trial unit in France, since June 2015, with an experimental molecule of BIAL, we were informed that five participants showed severe symptoms. Following the best international medical practices, they were immediately transferred by the company responsible for conducting the clinical trial to observation at the University Hospital of Rennes, being currently under permanent medical supervision.

Several BIAL representatives are currently at the site to monitor the situation with the research center and the hospital, ensuring the necessary cooperation with these entities, as well as with the relevant authorities.

Our main concerns at this time are with the monitoring of the trial participants, in particular the five hospitalized volunteers, one of whom in the resuscitation service in a state of brain death.

The development of this new molecule, in the area of pain (a FAAH enzyme inhibitor), has been conducted since the beginning in accordance with all the good international practices guidelines, with the completion of tests and pre-clinical trials, particularly in the area of toxicology. The results obtained in accordance with international guidelines have permitted the start of the clinical trials in humans. Throughout this trial, the new drug had already been administered to 108 patients without any moderate or serious adverse reaction.

This trial was approved by the French Regulatory Authorities, as well as by the French Ethics Committee, in accordance with the guidelines of Good Clinical Practices, with the Declaration of Helsinki and according to the laws inherent in clinical trials.

Together with all the relevant authorities, BIAL is strongly committed to ensuring, first of all, the well-being of all participants in this trial and to determine thoroughly and exhaustively the causes which are at the origin of this situation.