NEWS RELEASE
2016.05.23

BIAL became aware of the final report of the *Inspection Générale des Affaires Sociales* (IGAS), on the incident in a Phase 1 clinical trial performed by Biotrial, with BIA 10-2474 molecule last January 2016.

This report does not enable to determine the causes of the accident, nor on the death of one of the volunteers who participated in the clinical trial.

BIAL notes that it had no access to the complete medical data of the volunteers, namely to the autopsy data of the volunteer who unfortunately died, which is an essential element to pursuit a full investigation on the accident. BIAL notes that the IGAS report does not clarify the procedures carried out by the Rennes University Hospital, a key part in the management of the occurred accident.

The report does not question the Clinical Trial Protocol´s approval by the French National Agency for Medicines and Health Products Safety (ANSM), stating that it complies the existing legislation and recommendations, namely on the evolution of the forecasted doses.

Thereby, BIAL reinforces that the decisions on the escalating doses were properly taken. Towards the report conclusion regarding the escalating doses, including the passage from 20mg to 50mg, BIAL notes that the safety and tolerability profile of BIA 10-2474 was favorable up to 20 mg. There were no alerts, or signals in any of the safety parameters collected from any of the previous cohorts that could have anticipated the tragic accident. The integrated analysis of single (up to 100 mg) and multiple doses of drug exposure did not reveal any unexpected behavior of the molecule.

Therefore, given the data collected in the previous phases of the trial, there was no reason to modify the escalation of doses forecasted and approved by the authorities in the trial protocol.

Regarding the notification to the authorities, BIAL emphasizes that it has been informed by Biotrial about the occurrence of an adverse effect in a volunteer on 11th January. BIAL immediately decided to discontinue the medication to all the participants in the trial. Formal aspects mentioned in the IGAS report do not explain what happened or could have had any influence on this regrettable situation.

Until the date of the accident, no previous signs that could have prevented what happened were detected, nor did any comparable toxicity occur in the preclinical trials in animals.

It has been BIAL's key priority to accurately and exhaustively understand what happened in the clinical trial with the experimental molecule BIA 10-2474.

Although deeply shaken by this regrettable accident, BIAL maintains its commitment to research and to the quality of life and people's Health.