NEWS RELEASE
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BIAL became aware of the disclosure of the preliminary findings of the *Inspection Générale des Affaires Sociales* (IGAS) report, related to the incident in a Phase 1 clinical trial with BIA 10-2474 molecule.

The IGAS report concludes that the causes of the adverse reactions observed in the trial could not be determined, and that the Clinical Trial Protocol is in accordance with the inherent legislation as well as with the existing recommendations, as previously approved by the French Regulatory Authority (ANSM - *Agence Nationale de Securité du Medicament et des Produits de Santé*).

The preliminary report does not reveal the results of the ongoing investigations, particularly those related to the volunteers' clinical data, which will be essential to obtain a full explanation on the causes of this regrettable incident.

BIAL maintains all the efforts and commitment to transparency and information sharing, collaborating with the French Authorities to fully and accurately understand what happened in this trial.

BIAL reaffirms that the development of this new molecule (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. 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.