



## *Press Release*

### Reaction of the Club Phase 1 on reading information related to the BIA 10-2474 clinical trial protocol published by the ANSM

Paris, Friday 22/01/2016

The Club Phase 1, ahead of the outcome of the inquiry lead by the Health and Justice Authorities, has been made aware of the BIA 10-2474 clinical trial protocol.

This protocol does not contain any obvious methodological differences from those that are currently practised for this type of first-in-human study in healthy volunteers, in the way these studies have been carried out in specialized clinical trial centers for many years, in Europe, the United States, and the rest of the world.

Furthermore, the French Health Authority (ANSM : Agence Nationale de Sécurité du Médicament) and the ethics committee (CPP : Comité de Protection des Personnes) procedures , and review times have been carried out in complete accordance with the current European and French regulatory environment , which is extremely well-structured and strictly oversees this type of study.

The Club Phase 1 is dedicated to soliciting the expertise of its members, working with the Health Authorities, and other specialized European partner societies, to help understand and identify any lessons learned in order to recommend, if necessary, revisions to the regulations and practices in this already highly regulated domain.

The association Club Phase 1 is a scientific and professional society that includes individuals involved in Translational Medicine, Clinical Pharmacology and the early clinical development stage of medical research. [www.clubphase1.com](http://www.clubphase1.com)

The Club Phase I is a founder member of the European Federation for Exploratory Medicines Development (EUFEMED - [www.eufemed.eu](http://www.eufemed.eu) ) regrouping its sister associations across Europe.

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