

“FAAH inhibitors” CSST

Summary of conclusions

31 March 2016

Following the tragic accident that occurred in Rennes, France, last January within a clinical trial on healthy volunteers, the French National Agency for Medicines and Health Products Safety (ANSM) set up a Temporary Specialist Scientific Committee (CSST) on FAAH (Fatty Acid Amide Hydrolase) inhibitors. This Committee held its second and last meeting on 24 March 2016 in order to develop the main hypotheses discussed at the first meeting held on 15 February 2016.

After analysing the expert accounts and supplementary information provided by BIAL laboratories at the request of the CSST, the Committee confirmed that the mechanism that triggered the accident at Rennes went beyond simple FAAH inhibition. The BIA 10-2474 molecule itself was most likely involved, either through direct action or indirectly through a metabolite.

The animal studies have been re-examined in detail, including additional documents, but no new information has been uncovered, particularly on the mechanism of toxicity.

A full report, describing the main hypotheses to explain the toxicity of the molecule produced by BIAL laboratories, together with the Committee's conclusions and recommendations, will be made available shortly.