Early Termination BUMAUTEP – EudraCT No: 2016-000106-11

Justification for the early termination of the trial;

- It was planned to include 88 patients in this study; however, a recently redone feasibility study shows that only 66 patients could be included within the planned inclusion period (30 months), so an extension of the inclusion period would be necessary.
- Regarding the supplies of the investigational drug, 1/3 of the drugs are already expired, the second production campaign is underway; however, there is no commitment from the laboratory for the third campaign. Due to the expected extension of the inclusion period, a fourth campaign might be necessary, without assurance of its financing.
- A competing European phase 3 study is about to start.

The number of people in France receiving the treatment at the time of the early termination of the trial and the planned care for these people;

No patients have taken the treatment.

The consequences of the early termination regarding the evaluation of results and the assessment of the benefit-risk ratio of the investigational drug.

Since no patients have taken the treatment, there is no risk to the patients. There will be no evaluation of the results.