May 13, 2022

Protocol: B12CS-B13CS
Study title: ***« A multicentre, randomised, controlled versus placebo, double-blinded, 4 parallel arms, dose-ranging main study, to evaluate the efficacy, safety and tolerability and acceptability of repeated doses of ADV7103, after 7 days of treatment, in patients with cystinuria, and an efficacy and safety exploratory study in the youngest children. »***
EudraCT n°: 2017-002067-18

Advicenne, sponsor of B12CS-B13CS clinical trial, decided to prematurely terminate the trial due to comments received from the Committee of Orphan Medicinal Products (COMP) and from the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA).

A total of 6 adult patients have been included in this trial in France. No serious or unexpected adverse events related to ADV7103 were reported for these 6 patients.

The clinical data are currently being analyzed and they will be described in a simplified clinical study report.

Advicenne should be able to publish the results of B12CS-B13CS study before end of 2022.

Yours faithfully,

Rosanna Rende-Fournier
Clinical Studies Director