LUCANE pharma

[redacted]
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

3rd April 2018

Subject: Withdrawal of Prohippur, (sodium benzoate), 750 mg/g, granules - EMEA/H/0004150

Dear [redacted]

For the withdrawal of initial marketing authorisation application, I would like to inform you that, at this day, Lucane Pharma has taken the decision to withdraw the application for Marketing Authorisation of Prohippur, (sodium benzoate), 750 mg/g, granules, which was intended to be used as chronic adjunctive therapy of urea cycle disorders for the following:

- carbamoyl-phosphate synthase-1 deficiency,
- ornithine transcarbamylase deficiency,
- citrullinaemia type 1,
- argininosuccinic aciduria,
- hyperargininaemia,
- ornithine translocase deficiency
- lysinuric protein intolerance
- n-acetylglutamate synthase deficiency;

and indicated as adjunctive therapy in the chronic management of non ketotic hyperglycinemia.

This withdrawal is based on the following reasons:

- the CHMP considers that the current data provided do not allow the committee to conclude on a positive benefit risk balance;
- the several major issues which need extended period to prepare adequate answers.

Lucane Pharma will prepare a Scientific Advice request in order to discuss and define the strategy and level of data to re-submit the Application.

There is no clinical trials ongoing; and the compassionate use program approved in France (Cohort ATU) will continue as the Applicant still commits to submit a MAA.

I agree for this letter to be published on the EMEA website.

Yours sincerely,

[redacted]