erytech

[redacted]

Lyon, June 22nd 2018

Dr. Tomas Salmonson
CHMP Chair

European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB (United Kingdom)

Subject: Withdrawal of GRASPA (L-asparaginase encapsulated in red blood cells), dispersion for infusion (PROCEDURE NO: EMEA/H/C/004736)

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, ERYTECH Pharma S.A. has taken the decision to withdraw the application for Marketing Authorisation of GRASPA, (L-asparaginase encapsulated in red blood cells, dispersion for infusion), which was intended to be used for the treatment of children and adult patients with Philadelphia chromosome negative acute lymphoblastic leukaemia, who have either relapsed or failed first line treatment (in combination with multi-agent chemotherapeutic regimens).

This withdrawal is based on the following reasons: The CHMP considers that the data provided are not sufficiently mature to conclude on the benefit-risk balance, particularly those related to the characterisation of the Pharmacokinetic and Pharmacodynamic parameters in the pivotal trial.

The Company believes that GRASPA is a valuable anti-cancer therapy and is further developing this compound in the other oncology therapeutic areas.

The Company confirms there is no impact for the patients in ongoing clinical trials.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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

I would like to thank the (Co)Rapporteurs, the EMA and the CHMP for the time dedicated to reviewing this application and the support provided to the Company during the review process.

Yours sincerely,

[redacted]

[redacted]