erytech

[redacted]

Lyon, *November 14th 2016*

Dr. Tomas Salmonson
Chair of the CHMP

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

SUBJECT: Withdrawal of GRASPA (eryaspase), dispersion for infusion
(PROCEDURE NO: EMEA/H/C/004055)

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 (eryaspase, dispersion for infusion), which was intended to be used for the treatment of children over 1 year of age 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 reason: the CHMP considers that the data provided are not sufficiently mature to conclude on the benefit-risk balance. The additional data requested would need significant time than currently allowed by the procedure in order to address the D180 list of outstanding questions, particularly those related to the comparability between the old and new eryaspase formulations, and immunogenicity assays.

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

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 European Medicines Agency 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,

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