NORGINE

Date: 18 Jul 2025

Prof. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Ifinwil (Eflornithine Hydrochloride Monohydrate) 192 mg Tablets

EMEA/H/C/006067

Dear Prof. Bruno Sepodes,

For the withdrawal of initial marketing authorisation applications

I would like to inform you that, at this point of time, Norgine B.V. has taken the decision to withdraw the application for Marketing Authorisation of Ifinwil (Eflornithine Hydrochloride Monohydrate) 192 mg Tablets which was intended to be used for the treatment of adults and paediatric patients aged 1 year and older with high risk neuroblastoma (HRNB) who have responded to prior multiagent, multimodality therapy.

This withdrawal is based on the following reasons:
Norgine B.V. require additional time to comprehensively address all the questions raised by the CHMP at Day 120 of the assessment.

This decision to withdraw the MAA has no immediate consequences for the ongoing Expanded Access Program at this stage.

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

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

Yours sincerely,

[redacted]

[redacted]

Because patients inspire us