

11 August 2025

For the attention of Mr. Bruno Sepodes

European Medicines Agency
Domencio Scarlattiilaan 6
1083 HS Amsterdam,
The Netherlands

Subject: Withdrawal of mozafancogene autotemcel, Fanskya $2 \times 10^7 - 1 \times 10^9$ cells dispersion for infusion
- EMEA/H/0005537

Dear Mr. Sepodes,

Rocket Pharmaceuticals, B.V. (Rocket Pharmaceuticals) hereby notifies the European Medicines Agency (EMA) of its decision to withdraw its application for Marketing Authorisation of mozafancogene autotemcel, Fanskya $2 \times 10^7 - 1 \times 10^9$ cells dispersion for infusion, which was intended to be used for the treatment of Fanconi Anaemia Type A (FA-A) in paediatric patients aged 1 to 18 years.

The decision was made after extensive evaluation of all relevant factors and is based solely on business considerations. It is not related to any concerns regarding the safety, quality, or efficacy of the product. Rocket believes that all remaining comments from EMA Rapporteurs Day 180 Assessment Report are addressable, and that the overall benefit/risk assessment remains positive for mozafancogene autotemcel.

Rocket Pharmaceuticals reserves the right to make a further Marketing Authorization Application submission at a future date in this therapeutic indication.

Rocket Pharmaceuticals agrees that this letter may be published on the EMA website.