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12 July 2023

Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: **Withdrawal of Marketing Authorisation Application for Jesduvroq (daprodustat), 1mg, 2mg, 4mg, 6mg, 8mg immediate release film-coated tablets EMEA/H/C/ 005746**

Dear Dr Enzmann:

I would like to inform you that GlaxoSmithKline Trading Services Limited has taken the decision to withdraw the application for Marketing Authorisation of Jesduvroq (daprodustat), 1mg, 2mg, 4mg, 6mg, 8mg immediate release film-coated tablets, which was intended to be used for treatment of anaemia associated with chronic kidney disease (CKD) in adults.

This withdrawal is based on the Committee for Medicinal Products for Human Use (CHMP) recommendation that Jesduvroq be authorised for use only in adults on chronic maintenance dialysis (and not in patients not on dialysis) and the implications for the Company's strategy.

There are not any consequences of the withdrawal on ongoing clinical trials or compassionate use programme.

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

GlaxoSmithKline Trading Services Limited would like to sincerely thank the (Co)Rapporteurs, EMA, PRAC and CHMP members for the time they dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

[redacted]