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1 August 2022

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

Subject: Withdrawal of Marketing Authorisation Application for Sevsury (surufatinib), 50 mg, Capsules (hard); EMEA/H/C/005728

Dear Dr Enzmann,

I would like to inform you that, at this point of time, HUTCHMED Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of Sevsury (surufatinib), 50 mg, hard capsules which was intended to be used as monotherapy for the treatment of adult patients with low grade (grade 1 [G1] or intermediate grade (grade 2 [G2]) progressive neuroendocrine tumours of extrapancreatic or pancreatic origin that are unresectable, locally advanced or metastatic.

This withdrawal is based on the totality of the remaining major objections including: applicability of the SANET studies to the EU patient population and EU medical practice; study design and conduct including GCP compliance; and overall benefit risk in the proposed indication in the European patient population.

There is no impact on the conduct of ongoing clinical trials.

HUTCHMED are discussing the potential paths forward for continued development of surufatinib with regulators globally.

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 EMA website. Yours sincerely,

[redacted]