Dr Harald Enzmann
Chair of the CHMP
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

13 October 2020

Withdrawal of Marketing Authorisation Application for:
Tibsovo 250 mg Film-coated Tablets (Ivosidenib, INN)
EMA Product Number: EMEA/H/C/005056

Dear Dr Enzmann

We write to inform you that, at this point in time, Agios Netherlands B.V. (Agios) has taken the decision to withdraw the Conditional Marketing Authorisation Application for Tibsovo 250 mg Film-coated Tablets (ivosidenib, INN) which was intended to be used for the treatment of relapsed or refractory acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation in adult patients who have received at least 2 prior regimens, including at least 1 standard intensive chemotherapy regimen, or who are not candidates for standard intensive chemotherapy and have received at least 1 prior non-intensive regimen.

This withdrawal is based on feedback from the CHMP that the available clinical data from a single arm, Phase 1 study do not allow the Committee to conclude on a positive benefit-risk balance for the proposed indication.

The withdrawal of this application has no impact on ongoing clinical trials with ivosidenib.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

Agios would like to take this opportunity to thank the CHMP and PRAC (Co-)Rapporteurs, CHMP and PRAC Members, and the EMA for the time and effort dedicated to their review of this application, and the guidance provided during the procedure.

We agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,

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