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December 6, 2019

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

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RE: Withdrawal of Enasidenib (AG-221, CC-90007), 50mg and 100mg film- coated tablets - EMEA/H/C/004324

Dear Dr. Enzmann,

We would like to inform you that Celgene Europe B.V. a fully owned subsidary of Bristol- Myers Squibb has taken the decision to withdraw the Conditional Marketing Authorisation Application for enasidenib (AG-221, CC-90007), 50 mg and 100mg film- coated tablets for the treatment of adults with relapsed or refractory acute myeloid leukaemia with an isocitrate dehydrogenase 2 (IDH2) mutation.

This decision was taken as the applicant cannot fully address the major objections raised by the CHMP to support a postive benefit/ risk assessment in the proposed indication.

The withdrawal does not have any impact on ongoing clinical trials with enasidenib.

Ongoing compassionate use programs will continue to be supported to provide access of enasidenib to patients.

We reserve the right to make further submissions at a future date, when data from ongoing clinical trials will become available in this and other therapeutic indications.

We would like to thank the Rapporteur, Co-Rapporteur, EMA, PRAC and CHMP members for the time and effort dedicated in their review and the guidance provided during the procedure.

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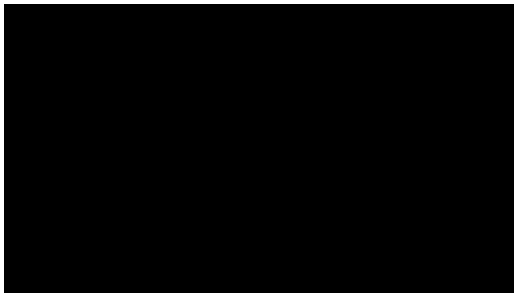

We agree for this letter to be published on the European Medicines Agency website.