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Sunesis Europe Limited
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Dr Tomas Salmonson
Chair of the CHMP
Medical Products Agency / Läkemedelsverket
Uppsala Science Park
Dag Hammarskjölds väg 42
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10 May 2017

Marketing Authorisation Application (MAA) for:
Qinprezo 10 mg/ml Solution for Injection (vosaroxin, INN)
Centralised Procedure Number: EMEA/H/C/004118/001
WITHDRAWAL OF APPLICATION

Dear Dr Salmonson

We regretfully write to inform you that, at this point in time, Sunesis Europe Limited (Sunesis) has taken the decision to withdraw the Marketing Authorisation Application for Qinprezo 10 mg/ml Solution for Injection (vosaroxin) which was intended to be used, in combination with cytarabine, for the treatment of adult patients ≥ 60 years of age with relapsed or refractory acute myeloid leukemia (AML).

This withdrawal is based on the following reasons:

- Feedback from the (Co-)Rapporteurs that the application was unlikely to receive the number of votes from CHMP Members necessary for the Committee to adopt a Positive Opinion for granting a Community Marketing Authorisation to Qinprezo at this time based on data from a sub-group of a single pivotal trial that had missed reaching full statistical significance by a narrow margin in its primary analysis of the intent-to-treat (ITT) population.

- As an SME company, Sunesis has chosen to shift an increasing portion of its resources to other development programmes rather than to continue to pursue a Marketing Authorisation for Qinprezo at this time.

There are no ongoing clinical trials investigating the use of vosaroxin sponsored by Sunesis. We expect to continue to advance the development of vosaroxin through investigator-sponsored group trials and will carefully assess the feasibility of conducting another pivotal trial to achieve future regulatory approval of vosaroxin. Sunesis, therefore, reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

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We intend to make vosaroxin available to appropriate patients via a managed access programme.

Sunesis would like to take this opportunity to thank the (Co-)Rapporteurs, EMA and CHMP for the time dedicated to reviewing this application, and their valuable support and helpful guidance during the course of the procedure.

We agree for this letter to be published on the EMEA website.

Yours sincerely
On behalf of Sunesis Europe Limited