CANGENE

13 June 2013

Dr Tomas Salmonson,
Chair of CHMP
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of IXinity™ (IB1001) 500 IU, 1000 IU and 1500 IU powder and solvent for solution for injection Marketing Authorisation Application - EMEA/H/C/002349/0000

Dear Dr Salmonson,

We would like to inform you that, at this point in time, Cangene Europe Ltd has taken the decision to withdraw the application for Marketing Authorisation of IXinity™ (IB1001) 500 IU, 1000 IU and 1500 IU powder and solvent for solution for injection. IXinity™ is recombinant Factor IX (trenonacog alfa) which was intended to be used for treatment and prophylaxis of bleeding in previously treated patients (PTP) that are at least 12 years of age with haemophilia B (congenital factor IX deficiency).

This withdrawal is based on the request by CHMP for clinical data with 'polished' product as a result of inclusion of an additional step in the drug substance manufacturing process. The results of this clinical study will not be available within the timeframe allowed in the Centralised Procedure. Cangene intend to re-file the MAA when this data is available on the understanding that we will retain the same Rapporteur(s), if feasible, and the current PIP deferral will stand for the resubmission.

Patients in ongoing clinical trials with IB1001 will continue on study as per protocol, switching to 'polished' product as soon as approvals to clinical trial application amendments allow.

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

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

Yours sincerely,

[redacted]

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