Marvel LifeSciences Ltd.

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15th November 2012

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

Subject: Withdrawal of **Solumarv 100 IU/ml; Isomarv 100 IU/ml; Combimarv 100 IU/ml, Insulin solution/suspension for injection in a cartridge**
EMEA H-C-2506, EMEA H-C-2610 and EMEA H-C-2609

Dear Dr Salmonson

We would like to inform you that, at this point of time, Marvel LifeSciences Ltd has taken the decision to withdraw the application for Marketing Authorisation of Solumarv 100 IU/ml which was intended to be used for the treatment of "Patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis".

The decision to withdraw is in order to have sufficient time to repeat and submit bioequivalence T1D PK/PD data on each clamp study in order to comply with the planned new insulin guideline (update to soluble insulin guideline EMEA/CHMP/BMWP/32775/2005 and insulin concept paper EMA/CHMP/BMWP/506470/2011), at a validated CRO.

These studies will contribute to what the applicant believes is the balance of the substantial complete body of evidence available to support equivalence and biosimilarity of the Marvel product Solumarv, Isomarv and Combimarv to the corresponding reference medicinal product Humulins. Other CHMP/EMA Objections will also be responded to at the same time in a near future resubmission, which includes the final report of the immunogenicity phase III study completed with the safety results of its extension phase.

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

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

Yours sincerely,

[redacted]

Marvel LifeSciences Ltd