13 October 2011

Dr Eric Abadie, Chairman of the CHMP
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB

Subject: Withdrawal of Marketing Authorisation Application for Luveniq (voclosporin), 10 mg soft capsules – EMEA/H/C/2069

Dear Dr Abadie,

I would like to inform you that, at this point of time, Lux Biosciences GmbH has taken the decision to withdraw the application for Marketing Authorisation of Luveniq (voclosporin), 10 mg soft capsules, which was intended to be used for the treatment of patients with chronic non-infectious uveitis involving the posterior or intermediate segments of the eye as characterized by a high degree of inflammation and in whom corticosteroids are inappropriate, do not provide adequate control, or cannot be tapered below 10mg/day. Voclosporin was designated as an orphan medicinal product for this indication (EU/3/07/472).

The company has been unable to demonstrate to the satisfaction of the CHMP that the effects of the above mentioned medicinal product are overwhelming, showing meaningful benefit that outweighs the risk, and thus would qualify for authorisation with one pivotal study only.

Currently, patients are being enrolled in an on-going clinical trial in the targeted therapeutic field that should support a re-submission to the Agency. The conduct of this trial will not be impaired by the withdrawal.

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

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

Yours sincerely,

Managing Director