

Axxonis Pharma AG • Schöneberger Str. 15 • D-10963 Berlin

Date: 30 November 2009

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

**Subject: Withdrawal of Marketing Authorisation Application for Nenad (lisuride)
2.5 and 5.0 microgram/h transdermal patch - EMEA/H/C/1020**

Dear Dr Abadie,

I would like to inform you that, at this point in time, Axxonis AG has taken the decision to withdraw the application for Marketing Authorisation for Nenad (lisuride) 2.5 and 5.0 microgram/h transdermal patch, which was intended to be used for the treatment of Restless Legs Syndrome.

Axxonis took this decision after being informed that the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance in the claimed indication. Axxonis now intends to prepare and submit a new Marketing Authorisation Application (MAA) that will include clinical trial data not available at the time of the initial MAA.

The decision to withdraw the MAA for Nenad has no consequences on the ongoing clinical trials and compassionate use programme.

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

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

Yours sincerely,

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