

06 March 2009

Dr. Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Dr. Abadie,

For the withdrawal of Type II variation linked to an extension of indication for a medicinal product already authorised

I would like to inform you that, at this point of time, Orion Corporation has taken the decision to withdraw the application for a new indication for Stalevo® (levodopa, carbidopa, entacapone) film-coated tablets, which was intended to be used for initiation of levodopa therapy in early Parkinson's disease.

This withdrawal is based upon the Rapporteur's and Co-Rapporteur's assessment indicating that the data provided to date were insufficient to support approval of this indication, and the company is unable to provide additional clinical data to the European Medicines Agency within the permitted timeframe.

The withdrawal has no impact on ongoing clinical trials and no compassionate use programmes are active.

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

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

Yours sincerely,

SVP, Global Sales

President and CEO

Orion Corporation Orion Pharma

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