



European Medicines Agency
Press office

London, 10 March 2009
Doc. Ref. EMEA/147137/2009

PRESS RELEASE
Orion Corporation withdraws its application for an extension of indication for Stalevo (levodopa/carbidopa/entacapone)

The European Medicines Agency (EMA) has been formally notified by Orion Corporation of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Stalevo (levodopa/carbidopa/entacapone) film-coated tablets.

On 10 April 2008, Orion Corporation submitted an application to extend the marketing authorisation for Stalevo to use in the initiation of levodopa therapy in early Parkinson's disease. At the time of withdrawal, the application was under review by the EMA's Committee for Medicinal Products for Human Use (CHMP).

Stalevo was first authorised in the European Union on 17 October 2003. It is currently authorised for use in patients with Parkinson's disease, who are being treated with a combination of levodopa and an inhibitor of dopa decarboxylase but are having 'fluctuations' (a wearing-off of the medicine's effects and re-emergence of symptoms) towards the end of the period between two doses of their medication, which cannot be stabilised with the standard combination alone.

In its official letter, the company stated that the withdrawal of the application was based on feedback from the evaluation of the application that indicated that the data provided were insufficient to support approval for this indication. In addition, the company also stated that it is unable to provide additional clinical data to the CHMP within the permitted timeframe.

Stalevo continues to be authorised for the currently approved indication.

More information about Stalevo and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Stalevo is available in the European Public Assessment Report (EPAR): <http://www.emea.europa.eu/humandocs/Humans/EPAR/stalevo/stalevo.htm>
3. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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