

Axxonis Pharma AG  
Schoeneberger Str. 15  
10963 Berlin  
Germany

Phone: +49(0)30-2693429-0  
Fax: +49(0)30-2693429-22  
Websites: [www.axxonis.com](http://www.axxonis.com)  
[www.lisurid-cds.de](http://www.lisurid-cds.de)  
Email: [info@axxonis.com](mailto:info@axxonis.com)

**Press release, 4<sup>th</sup> June, 2008**

**Axxonis Pharma AG Berlin submits a European marketing authorisation application for Nenad<sup>®</sup> (lisuride) transdermal patch and subcutaneous infusion**

**Berlin, Germany - Axxonis Pharma AG today announces the submission of a marketing authorisation application to the European Medicines Agency (EMA) for Nenad<sup>®</sup> (lisuride transdermal patch as add-on therapy for Parkinson's Disease and for Restless Legs Syndrome, and subcutaneous (sc) lisuride infusion for advanced Parkinson's Disease)**

Lisuride, the active principle of Nenad<sup>®</sup>, is a potent dopamine agonist which in its parenteral forms (transdermal patch and sc infusion) has been developed to provide continuous dopaminergic stimulation (CDS). Experts expect from CDS a new quality of treatment of Parkinson's Disease and RLS combined with ease of administration. All results obtained so far not only demonstrate strong efficacy but also a good general tolerability of Nenad<sup>®</sup> and an improved quality of life for those affected by these neurological conditions.

**About Nenad<sup>®</sup>:**

**Nenad<sup>®</sup>** 10 cm<sup>2</sup> and 20 cm<sup>2</sup> transdermal patches, which release 2.5 µg lisuride and 5.0 µg lisuride per hour, respectively, have been developed as a new application form of the strong dopamine agonist lisuride in order to enhance efficacy and to improve tolerability. The Nenad<sup>®</sup> patch works by non-invasive transport of lisuride across the skin and provides continuous dopaminergic stimulation (CDS) over two days. For Parkinson's Disease, one or two 20 cm<sup>2</sup> patches are applied every other evening; for RLS, one or two 10 cm<sup>2</sup> patches are applied every other morning. With

these schedules, only one up-titration step is required in Parkinson's Disease with a rapid onset of action (significant after only one week treatment) with a simultaneous reduction in early adverse events. In RLS, most patients respond satisfactorily to just one 10 cm<sup>2</sup> patch or, in severe cases, two patches of 10 cm<sup>2</sup>, with improvement also in day-time symptomatology.

Lisuride sc (**Nenad<sup>®</sup> Powder for solution for sc infusion**) was developed for the treatment of patients in an advanced stage of Parkinson's Disease. The continuous application of this parenteral dopamine agonist using a small portable minipump provides stable individual drug levels and thereby achieves superior therapeutic results in treatment-resistant stages of Parkinson's Disease complicated by motor fluctuations. Studies showed good therapeutic efficacy on "Off" (hypomobility) and "On" with troublesome dyskinesia (hypermobility).

Lisuride also has antifibrotic and antiproliferative effects as a strong antagonist of 5-HT (serotonin) 2B receptors and therefore is expected to cause no cardiac valvulopathy as is the case with some other dopamine agonists.

### **Information about Parkinson's Disease**

Parkinson's Disease is a very frequent severe neurological illness of the higher age affecting about 2-3 out of 1.000 people. A cell decline in certain brain areas – the so-called "substantia nigra" – with reduction of the neurotransmitter dopamine is the basis for this disease and causes the typical motor symptoms of Parkinson's Disease.

### **Information about RLS (Restless Legs Syndrome)**

RLS is another neurological disease which occurs in up to 10 % of the population, and which in serious cases strongly interferes with patients' sleep and quality of life on the subsequent day.

### **About Axxonis Pharma AG**

Axxonis Pharma AG, Berlin, is a pharmaceutical company specialised on developing new products in neurodegenerative diseases.

To learn more about Axxonis, please visit the website at <http://www.axxonis.com>.

### ***Forward-Looking Statements:***

*This press release contains „forward-looking“ statements related to our clinical development programm with Nenad<sup>®</sup>. These forward-looking statements are based upon Axxonis´ current expectations. Forward-looking statements involve risks and uncertainties. Axxonis´ actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the ability of the company to successfully conduct the clinical trials, the uncertainty of the EMEA approval process and other regulatory requirements, the therapeutic and commercial value of the company´s products and issues relating to regulatory approval, manufacturing and commercialization, Axxonis expressly disclaims any obligation or undertaking to release publicity any updates or revisions to any forward-looking statements contained herein to reflect any change in the company´s expectations with regard there to*

*Axxonis is a registered trademark.*