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Axxonis Pharma AG, Berlin, is preparing a submission for market approval of its transdermal lisuride formulation Leovan® also for Restless Legs Syndrome (RLS)

Axxonis Pharma AG, Berlin, today announces that results from two large phase III studies with the new lisuride patch (transdermal lisuride, proposed trade name Leovan®) have shown excellent efficacy of this innovative application form for patients with Restless Legs Syndrome (RLS), and therefore now an EMEA application for marketing can be prepared.

RLS is a neurological condition which occurs in up to 10% of the population, and which in serious cases disrupts patients' sleep as well as quality of life on the subsequent day. Lisuride is a strong dopamine agonist and moreover an antifibrotic and antiproliferative iso-ergot derivative, which in its oral formulation has been approved for the treatment of Parkinson's disease. Axxonis Pharma AG (formerly NeuroBiotec) develops innovative application forms of this drug (Leovan®-patch) for continuous dopaminergic stimulation (CDS) in RLS and Parkinson disease.

"The new efficacy results of the lisuride patch are excellent and support earlier findings. This is the first time a transdermal dopamine agonist has demonstrated clinically superior efficacy over oral standard treatment in relevant efficacy parameters", said Dr. Reinhard Horowski, CMO/CSO of Axxonis Pharma AG. "With this successful study the clinical development program for Leovan® now has been completed."

In two large double-blind studies headed by principal investigator Dr. Heike Beneš, Schwerin, lisuride patches with a patch size of either 10, 20, or 30 cm² titrated individually caused a statistically significant dose related improvement of all symptoms of RLS. The patches were applied every other day in the morning. The primary endpoint for the clinical trials was improvement on the International RLS (IRLS) rating scale (baseline vs. end of treatment), with comparison of the lisuride

patch with placebo and oral ropinirole. Ropinirole is the first oral dopamine agonist approved for treatment of RLS in Europe and the USA.

Treatment with Leovan[®] was also associated in relevant endpoints with a statistically significant superiority, compared to standard treatment of RLS, reported Dirk Palla, study manager at Axxonis Pharma AG. This applies, e.g., to the number of patients with more than 50 % improvement as well as for the percentage of patients showing a full remission (less than 10 % of baseline score). It is quite important that the lisuride patch has shown significant superiority over placebo and ropinirole also in improving day-time symptoms including sedation.

Dr. Johannes Tack, CEO of Axxonis explained that Leovan[®] TDS works by the continuous dopaminergic stimulation principle which is of advantage over currently approved oral RLS drugs. Therefore it is hoped that the lisuride patch soon may offer an alternative therapeutic option for patients whose lives are burdened by RLS symptoms.

Continuous dopaminergic stimulation which is under discussion since the 90`s as a promising future therapeutic principle, requires a strong dopamine agonist to be of practical value for the patients. Lisuride, the active principle of Leovan[®] TDS is one of the most potent dopamine agonists now becoming available for such continuous dopaminergic stimulation. Experts expect a new quality of treatment of Parkinson`s disease and RLS by these new ways of application, combined with ease of administration. All results obtained so far with the lisuride patch not only demonstrate strong efficacy but good general tolerability as well. The RLS experts involved in this last study soon will present their new results at scientific meetings and in specialized publications.

About Leovan[®] (Lisuride) patch TDS (10cm²):

Leovan[®] (Lisuride) patches which at a size of 10 cm² release 0.1 mg lisuride per day have been developed as a new application form of the strong dopamine agonist lisuride in order to enhance efficacy and to improve tolerability. The Leovan[®] patch works by non-invasive transport of lisuride across the skin and thus provides continuous dopaminergic stimulation over two days (application every second morning).

Submission to the European Drug Authorities

The European Drug Authority (EMA) in a pre-submission meeting has accepted to evaluate the lisuride patch for RLS and for combination therapy of Parkinson`s disease as well as s.c. lisuride for advanced Parkinson`s disease in a central procedure. Axxonis Pharma AG intends to submit applications for marketing to EMA in December 2007

About Axxonis

Axxonis Pharma AG, Berlin, is a pharmaceutical company specialized on CNS products. Axxonis is developing a portfolio of internally discovered or licensed product candidates to improve the therapeutic benefits of existing drugs and develop the products for indications of higher value. Axxonis' most advanced product candidate, Leovan[®] TDS (lisuride patch), is the subject of a Phase III clinical program for the treatment of RLS which has now been completed successfully. Axxonis has also reported positive results from a Phase III clinical trial of transdermal Lisuride (as separate brand) in patients with advanced Parkinson's disease.

To learn more about Axxonis, please visit the website at www.axxonis.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, without limitation, all statements related to our clinical development program with Leovan[®] 5µg/hr TDS and the timing thereof; the potential filing of a NDA with Leovan[®] 5µg/hr TDS; the therapeutic and commercial potential; potential milestone and royalty payments; and future commercialization plans. 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 publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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