



NEWS RELEASE

RECORDATI: SILODOSIN (UROREC[®]/SILODYX[™]) APPROVED BY THE EUROPEAN COMMISSION FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF BPH (BENIGN PROSTATIC HYPERPLASIA)

Milan, 3 February 2010 – Recordati announces that it has been granted Marketing Authorization by the European Commission for the medicinal products Urorec[®] and Silodyx[™] 4 mg, 8 mg, hard capsules, intended for treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Following national post-authorization procedures, as relevant, product launch could take place by end 2010 or beginning 2011.

Benign prostatic hyperplasia (BPH, enlargement of the prostate) is characterized by urination difficulties such as weak urine stream, increased frequency and urgency, nocturia. The prevalence of this condition is increasing due to the progressive ageing of the male population. BPH is frequently observed in men over fifty, and its symptoms significantly reduce quality of life.

The compound was originally developed by Kissei Pharmaceutical Co. Ltd. in Japan and was obtained under license by Recordati for the whole of Europe (45 countries) and for a further 18 countries in the Middle East and Africa. Recordati also has the right to appoint co-marketers where deemed appropriate. Development of the drug was conducted by Recordati for its territories, by Watson Pharmaceuticals in North America and by Kissei Pharmaceutical Co. Ltd. for the rest of the world. Silodosin is already available in North America, in Japan and other countries in Asia.

In two Phase III placebo-controlled clinical trials conducted in the US by Watson Pharmaceuticals and in one placebo- and active-controlled trial conducted in Europe by Recordati, over 800 patients received silodosin 8 mg once daily. In these studies, patients treated with silodosin had a significant decrease in BPH symptoms, both irritative (frequency, urgency, nocturia) and obstructive (hesitancy, incomplete emptying, intermittency, weak stream). In addition, an improvement in the quality of life linked to urinary symptoms (measured by the International Prostate Symptom Score, IPSS) was observed with silodosin. Furthermore, in the active-controlled study conducted in Europe, silodosin 8 mg once daily was not inferior to tamsulosin 0.4 mg once daily, with an adjusted mean difference between treatments in the IPSS Total Score in favour of silodosin.

The significant improvement in BPH symptoms was observed within the first week of treatment, and was maintained long-term. In addition, significant improvements in the maximum urine flow-rate (Q_{max}) were evident within a few hours after the first dose of silodosin, and were also maintained long-term.

The safety of silodosin was extensively evaluated in a total of 1600 patients. As should be expected for a drug with low affinity for α_{1B} adrenergic receptors, only minimal cardiovascular side-effects were observed. No changes were seen in supine blood pressure or heart-rate, and the incidence of orthostatic hypotension was very low (1.2% with silodosin, *versus* 1.0% with placebo). Furthermore, no effects on cardiac repolarization were observed, even at high doses of silodosin. Retrograde ejaculation (i.e., orgasm with reduced semen), due to silodosin's selective receptor binding properties, was the most frequent adverse reaction reported. However, this did not represent a safety concern (the dropout rate due to retrograde ejaculation was very low), and is reversible upon discontinuation of the treatment.

“The authorization to market silodosin confirms the validity of this new treatment for the symptoms of benign prostatic hyperplasia”, declared Giovanni Recordati, Chairman and CEO. “The product, under the brands Urorec[®] and Silodyx[™], will be available in all European markets upon finalization of the national registration procedures. During 2009 a number of licensing and co-marketing agreements were entered into with leading pharmaceutical companies for both European and non-European markets which will allow us to obtain wide coverage and the acceptance of the medical community for this modern treatment for a condition which increasingly affects the male population”.

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of over 2,950, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. It has headquarters in Milan, Italy, operations in the main European countries, and a growing presence in the new markets of Central and Eastern Europe. A European field force of over 1,450 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati's current and growing coverage of the European pharmaceutical market makes it a partner of choice for new product licenses from companies which do not have European marketing organizations. Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2008 was € 689.6 million, operating income was € 144.7 million and net income was € 100.4 million.

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