Launch in Spain of Urorec®/Silodyx™, a new treatment for symptoms associated with benign prostatic hyperplasia (BPH)

- **Silodosin is an uroselective α-blocker that has demonstrated a good safety profile (particularly at cardiovascular level) and fast onset of action**

- **The *European Study*, results of which were presented at the European Urology Congress, show that Silodosin provides significant improvement for the most bothersome symptoms for the BPH patient, with no cardiovascular effects**

- **Prevalence of BPH is 10% in men in their 50s[1]. This percentage increases to 34% in men over 60, 40% in those in their 70s[2], and over 80% in men over 80.**

Barcelona, 4th October 2010.- There is now a new treatment for benign prostatic hyperplasia (BPH), a pathology that affects 80% of men over the age of 80, with the recent launch in Spain of Silodosin. The medicine will be marketed in Spain by Recordati and Almirall under the trademarks Urorec® and Silodyx™.

Almirall signed a co-marketing agreement with Recordati in April 2009, by virtue of which Recordati granted Almirall marketing rights to Silodosin in Spain. Urorec®/Silodyx™ is a uroselective α-blocker, and has demonstrated a good safety profile (especially at cardiovascular level) and fast onset of action.

Men suffering from symptoms associated with BPH frequently indicate that this disease affects their daily activities (for example insomnia, limitations to travel, sport, etc). In this sense Silodosin presents a statistically significant improvement in reducing symptoms that most concern and bother the patient such as nocturia, frequency and incomplete emptying, compared to tamsulosine.[3]

According to Dr. Joaquin Carballido, Professor of Urology at the Autonomous University of Madrid and Clinical Director of the Urology Service at the University Hospital Puerta de Hierro - Majadahonda in Madrid: "*in patients diagnosed with benign prostatic hyperplasia the impact of the disease on quality of life and wellbeing is accepted. In practice, this means interference with sleep patterns, less mobility, anxiety and modification of daily leisure activities and personal relationships. Data from latest clinical investigations have shown us that the pharmacological treatment option of urinary symptoms with Silodosin represents a highly effective alternative, achieved with a fixed daily dose of 8 mg and low incidence and intensity of side effects".*

Alpha blocker medicines are usually used to treat symptoms associated with BPH". Urorec®/*Silodyx™* are the latest generation of this family; a new α_{1A} receptor antagonist with greater selectivity for receptors at prostate level. This pharmacological feature contributes to a better safety profile, in particular reducing the risk of orthostatic hypertension commonly associated with these kinds of medicines.

Dr. Carlos Llorente, Head of the Urology Service at the University Hospital Alcorcón Foundation (Madrid) comments: "*clinical trials that have assessed the efficacy of Silodosin indicate that it is a drug characterised by its fast onset, whereby its effect on symptoms and quality of urinary flow can be appreciated in the first few hours. Also, for symptoms such as*

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1 de la Rosette J, et al. *Guidelines on Benign Prostatic hyperplasia*. EAU 2004.

2 Lepor H. *Pathophysiology, epidemiology, and natural history of benign prostatic hyperplasia*. Rev Urol. 2004 Suppl 9: s3-s10

3 Montorsi F. Profile of Silodosin. Eur Urol. 2010; Suppl 9: 491-495

urinary frequency at night and the feeling of incomplete emptying, it has shown a greater efficacy than current medicines of reference".

***European Study:* excellent efficacy profile**
Over 35 clinical trials carried out in Japan, the United States and Europe (the latter performed by Recordati) endorse the efficacy and safety of Silodosin. One of the most recent is the *European Study*, results of which were presented at the European Urology Congress 2010. It is a phase III, multicentre, three-arm (controlled with placebo and active control), pivotal study. The study consisted of a random double blind first phase to investigate the effect of 8 mg once a day of Silodosin in BPH symptoms at 12 weeks of treatment. At the end of the study the long-term efficacy and safety of Silodosin was investigated in a 40 – weeks open-label extension phase.

The investigation showed that Silodosin presents a significant improvement to **nocturia** (a disorder that forces sufferers to habitually get out of bed more than once during the night), **frequency** and **incomplete emptying**, compared to tamsulosine. The percentage of patients with simultaneous improvement of the **three most distressing symptoms** of BPH was higher with Silodosin than with tamsulosine (35% compared to 27.7%; p=0,03). This study also revealed silodosin's superiority against placebo in improvement of nocturia (reduction of at least one episode).

In addition, the continuation of the study for 40 weeks in 500 subjects demonstrated that silodosin caused minimal or no effect on cardiovascular parameters, with a modest impact on blood pressure (low incidence of orthostatic hypertension) and cardiac frequency.

"The increase of life expectancy globally is causing considerable increase in cases of men suffering from BPH, and, along with the higher efficacy and safety profile shown in clinical studies, this means there are high expectations for Urorec®/Silodyx™", stated Miguel Isla, Managing Director of Recordati Spain.

Enrique Domínguez, General Manager of Almirall Spain added: *"We are quite sure that Urorec® and Silodyx™ will be very well received in Spain as it is a new therapeutic option for BPH sufferers that will relieve their symptoms and improve their quality of life, both of which are fundamental objectives when treating this disease* ".

Silodosin: an effective solution for treating BPH
Silodosin blocks alpha-1 adrenergic receptors in the prostrate, bladder and urethra to reduce prostate enlargement symptoms. It is administered through a capsule taken once a day.

The FDA in the United States, approved Silodosin in 2008 to treat BPH symptoms. In Europe, the European Commission gave its approval at the beginning of 2010.

The drug has been marketed in Japan since May 2006 by Kissei. In Europe, Africa and the Middle East, Silodosin is being marketed by Recordati, with collaboration by other pharmaceutical companies through co-marketing agreements like the one with Almirall in Spain.

About BPH [(1)]
Benign prostate hyperplasia is a nonmalignant (noncancerous) enlargement of the prostate. Enlargement of the prostrate gland is caused by an umbalance between oestrogens (female hormones) and testosterone (male hormone), which occurs in ageing men.

When the prostate is enlarged it can progressively compress the urethra and cause difficulties in urinating. This occurs because compression impedes the flow of urine from the bladder to the urethra and to the outside. Possible consequences are urine retention in the bladder or urine flowing to the

kidneys and the need to urinate frequently. If the inflammation is serious it can completely block the urinary system.

Men who suffer from the disease often talk of the negative effect on their lives, as it reduces their sleep time (nocturia), interferes in their daily activities (limits ingestion of liquids, forces them to stop when driving, restricts the playing of sports, travelling and social activities), and reduces sexual function. They also express their fear of a potential risk of prostate cancer.

The disease has become a growing disorder due to the worldwide increase in life expectancy. BPH is a very common disease in men: even though it usually starts from the age of 30, it rarely manifests itself before the age of 40. It has a 10% prevalence in men in their 50s. This percentage increases to 34% in those over 60, 40% in those in their 70s and over 80% in men over 80.

Recordati

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 2,800, 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 around 1,400 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 2009 was € 747.5 million, operating income was € 162.2 million and net income was € 110.6 million.

About Almirall

Almirall, an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and other dermatological conditions.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 12 affiliates.

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