

## **Silodosin, indicated for benign prostatic hyperplasia (BPH), has been approved by the European Commission**

**Barcelona, February, 8th 2010.-** Almirall informs that the European Commission has granted a marketing authorisation for silodosin. The product will be marketed in Spain by Almirall and Recordati under the trademarks *Silodyx*<sup>®</sup> and *Urorec*<sup>®</sup>, respectively, 4 mg and 8 mg in hard capsules for the treatment of benign prostatic hyperplasia (BPH).

In April 2009 Almirall signed a co-marketing agreement with Recordati, by virtue of which Recordati grants Almirall marketing rights in Spain for silodosin. The agreement enables Almirall to strengthen its core business over the coming years and reinforce its product pipeline in the urology area.

"This is good news as authorisation from the European Commission to market silodosin will offer a new therapeutic option for the medical collective and BPH sufferers", said Enrique Domínguez, General Manager of Almirall Spain. "Almirall will be marketing the product under the trademark *Silodyx*. This will be available in Spain when the national registration procedure has been completed at the end of 2010 and could contribute to Almirall sales in the second half of this financial year."

### **Silodosin: an effective solution for BPH**

Silodosin blocks alpha-1 adrenergic receptors in the prostate, bladder and urethra to reduce prostate enlargement symptoms. It is administered through a capsule taken once a day.

The FDA, the maximum health authority in North America, approved silodosin in 2008 for the treatment of BPH symptoms.

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 <sup>(1)</sup>**

Benign prostate hyperplasia is a nonmalignant (noncancerous) enlargement of the prostate. Enlargement of the prostate gland is caused by a relative increase of oestrogens (female hormones) over 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.

BPH is a very common disease among men: although it usually starts from the age of around 30, it rarely shows before the age of 40. By 60, fifty percent of men suffer from BPH and between 70 and 80 up to 90% experience some of the symptoms.

<sup>(1)</sup> Source: Institute of Advanced Urologic Surgery

## **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 11 affiliates.

For further information please visit the website at: [www.almirall.com](http://www.almirall.com)

### **More information:**

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