

## **The EMEA/CHMP adopts a positive opinion for silodosin**

**Barcelona, 27 November 2009.**- Further to the recent announcement by Recordati, Almirall is also pleased to inform that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for silodosin, recommending granting a Marketing Authorisation for the medicinal products Urorec® and Silodyx® 4 mg, 8 mg, hard capsules intended for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and by which the registration process is moving forward.

As per the habitual regulatory procedure, the European Commission's decision is expected to be issued within 67 days from adoption of the CHMP opinion.

In April this year Almirall signed a co-marketing agreement with Recordati by virtue of which Recordati granted Almirall marketing rights for silodosin in Spain under the trademark Silodyx®. The agreement enables Almirall to strengthen its core business over the coming years and reinforce its product pipeline in the urology area.

Silodosin is a urological medicinal product (ATC G04CA04). The active ingredient is a selective  $\alpha 1A$ - antagonist of the adrenoreceptors. Blockade of these receptors causes smooth muscle in the prostate, urinary bladder base and neck and prostatic capsule and prostatic urethra to relax, thus decreasing the bladder outlet resistance associated with BPH.

The compound was originally developed by Kissei Pharmaceutical Co. Ltd. in Japan and has been obtained under licence by Recordati for the whole of Europe (45 countries), and a further 18 countries in the Middle East and Africa. Silodosin is now available in North America, Japan and other countries in Asia.

### **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)

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