Almirall announces filing Sativex® regulatory submission

- **Sativex® has proven to be effective for the treatment of spasticity in multiple sclerosis, in a recent phase III study developed with patients who had failed to gain improvement with other treatments**

- **Almirall holds the marketing rights of Sativex® all over Europe, except the UK**

Barcelona, 20th May 2009.- Almirall announces today that the file for a regulatory submission for Sativex® for the treatment of spasticity due to multiple sclerosis has been submitted in UK and Spain under the European decentralised procedure. The UK regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA), is acting as Reference Member State and has validated the application.

This submission follows the recent announcement of positive results in a Phase III study where Sativex® showed relevant improvement of the spasticity's evolution in multiple sclerosis patients. It is expected that an outcome of the regulatory submission will be known around the end of 2009 or early 2010.

Following approval in the UK and Spain, submissions for approval would be made in other European countries during 2010 under the mutual recognition procedure. Almirall has the marketing rights of Sativex® all over Europe, except the UK.

Treatment of spasticity due to multiple sclerosis is expected to be the first indication which is presently undergoing other Phase IIb clinical trials for the treatment of cancer pain.

"Sativex® will be the first new treatment for the symptomatic relief of spasticity in 10 years and these are encouraging news for patients suffering of spasticity due to multiple sclerosis," comments Luciano Conde, Chief Operating Officer at Almirall. *"Sativex® will represent an interesting add-on to Almirall's pipeline in the central nervous system arena"* he added.

About Sativex®
Sativex®, researched and developed by GW Pharmaceuticals (UK), is a plant-based medicine and its formulation is basically a combination of two cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). This unique formulation brings out the therapeutic benefits of the cannabinoids while at the same time minimizing adverse and unwanted effects such as intoxication, sedation or psychotropic effects.

Sativex® is administered through an oralmucosal spray. The formulation allows a flexible dosage depending on each patient –at all times following medical instruction-, making it particularly appropriate due to the variable nature of spasticity and multiple sclerosis (MS).

Sativex® is approved and marketed in Canada for the treatment of cancer pain and MS neuropathic pain. In addition, this medicine is available on prescription in the UK on a "named patient" basis and has to date been exported to 21 countries around the world.

Spasticity, a serious symptom of MS
Spasticity (muscular spasms and stiffness) is one of the most common symptoms of MS occurring in approximately 75% of patients. Spasticity can affect many aspects of daily life, such as walking and sitting. Sativex® aims to treat high need patients who have previously failed to gain adequate benefit from currently available anti-spasticity treatments.

Results of a Phase III Trial on spasticity in MS
On 11th March 2009, GW announced positive preliminary results from a pivotal Phase III double-blind randomised placebo-controlled study of Sativex® in patients with spasticity due to Multiple Sclerosis (MS), who have achieved inadequate spasticity relief with existing therapies. This study was requested by the UK regulator in order to gain approval in this indication.

The prospectively defined primary efficacy endpoint of the study -the difference between the mean change in spasticity severity with Sativex vs Placebo- was highly statistically significantly in favour of Sativex (p=0.0002). The difference between Sativex and placebo was also highly significant for a number of secondary endpoints, including the 30% responder analysis (p=0.0003), spasm frequency (p=0.005), sleep disturbance (p<0.0001), patient global impression of change (p=0.023), and physician global impression of change (p=0.005).

About Almirall
Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it 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 dermatology.

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

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