

Almirall extends Sativex® marketing rights to Mexico

- **Sativex® is marketed by Almirall in several European countries**
- **The medicine is undergoing a second wave of approvals in Europe through Mutual Recognition Procedure**
- **Sativex® is currently in phase III for oncological pain**

Barcelona, 15 March 2012.- Almirall, S.A. ("Almirall") announces the signature with GW Pharma Ltd. ("GW") of an amendment to their existing agreement for Sativex®. As part of the amendment, Almirall has been granted rights to market Sativex® in Mexico.

Under the terms of the original licence agreement signed in December 2005, Almirall was granted exclusive rights to market Sativex® in Europe (excluding the UK). Almirall has now been granted exclusive rights to commercialise Sativex® in Mexico, a country in which Almirall has had an affiliate for more than a decade.

Luciano Conde, Chief Operating Officer at Almirall, said "We have been very pleased with our partnership with GW and the initial market response to Sativex®. It is a new therapeutic option to alleviate suffering from the physical impairment caused by muscle spasticity and Almirall has been committed to ensuring its availability across Europe and now also in Mexico."

Almirall has recently launched Sativex® as a prescription medicine for spasticity in multiple sclerosis in Spain, Germany and Denmark. Further launches are expected during 2012 in Italy, Sweden, Austria and the Czech Republic. In addition, a Mutual Recognition Procedure (MRP) regulatory filing is currently underway to expand Sativex® approvals to other ten European countries. It is expected that this new MRP process should be completed along 2012.

Sativex® is approved as a treatment for spasticity in people with Multiple Sclerosis. The medicine is also in Phase III clinical development as a treatment for cancer pain.

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Notes to Editors

Sativex®

Sativex® is a first-in-class endocannabinoid system modulator and is indicated as treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medicationⁱ and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.ⁱ

The main active ingredients, delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD), are extracted from selected chemotypes of Cannabis Sativa. Sativex® is administered as a mouth spray, which provides optimal delivery of the active ingredients and allows for dosing flexibility in order to enable each individual patient to manage the variable nature of their spasticity.

Sativex® is manufactured through a controlled series of processes resulting in a reproducible finished product manufactured to Good Manufacturing Standards. Each 100 microliter spray contains 2.7 mg THC and 2.5 mg CBD. The formulation also contains other cannabinoids, terpenoids and flavonoids at standardized doses, which contribute to the uniqueness of the medicine. Sativex® was developed by UK-based GW Pharmaceuticals plc.

Sativex® is a registered trade mark of GW Pharmaceuticals plc and GW Pharmaceuticals plc is the Marketing Authorisation holder. Manufactured by GW Pharmaceuticals under Home Office licence, Sativex® is marketed in Europe (except the UK) by Almirall, S.A.

Spasticity

There are approximately 500,000 people suffering of MS in the top five EU countries.ⁱⁱ Spasticity is a symptom defined by patients and carers as muscle spasms, stiffness, rigidity and/or difficulty to move, and is one of the most common symptoms of MS, occurring in as many as 75% of people with MS. Spasticity can affect many aspects of MS patients' daily life, and is a major contributor to their distress and disability.ⁱⁱⁱ

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.

Almirall focuses its research resources on therapeutic areas related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), gastrointestinal disorders, 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. For further information please visit the website at: www.almirall.com

ⁱ Sativex® Summary of Product Characteristics, 2011.

ⁱⁱ Multiple Sclerosis International Federation. European map of ms database. ©2010 EMSP, MSIF, www.europeanmapofms.org. Top five EU countries include: France, Germany, Italy, Spain and UK.

ⁱⁱⁱ Rizzo MA Hadjimichael OC, Preiningerova J, *et al.* Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler* 2004; 10:589-595.