



Sativex[®] starts a new wave of regulatory submissions in Europe

- **Countries include Belgium, Finland, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovakia**
- **Sativex[®] is a medicine indicated for the treatment of spasticity in patients with Multiple Sclerosis (MS), who have not responded to other anti-spasticity treatments**
- **Almirall launched Sativex[®] in Spain, Germany and Denmark in 2011**

Barcelona, 7th February 2012: Almirall S.A. (ALM.MC) today announced the start of a second wave of regulatory submissions for Sativex[®] in Europe. The list of countries submitted to the Health Authorities by GW Pharmaceuticals, under a Mutual Recognition Procedure (MRP) include: Belgium, Finland, Iceland, Ireland, Luxemburg, the Netherlands, Norway, Poland, Portugal and Slovakia. The UK is acting as reference member state in this MRP.

Response from Health Authorities is expected in the first half of 2012 and, subsequently, approval processes will continue in each country separately, according to local regulatory requirements.

"We are excited by this opportunity of broadening the geographical accessibility of the unique benefits of Sativex[®] alleviating symptoms of spasticity in patients with MS", says Bertil Lindmark, Chief Scientific Officer at Almirall.

Sativex[®] offers a new therapeutic option to patients with spasticity symptoms due to MS who have previously failed to respond adequately to other anti-spasticity medication, and it is currently available in Denmark, Germany, Spain, UK, Canada and New Zealand. Additionally, four new countries are expected to get marketing approval this year: Austria, Sweden, Italy and Czech Republic. Sativex[®] is administered as an oromucosal spray (either onto the inside of the cheek or under the tongue), which provides optimal delivery of the active ingredients and allows for dose flexibility thus enabling each individual patient to manage the variable nature of their spasticity.

Sativex[®], which has been developed by GW Pharmaceuticals, is also in phase III clinical development for the treatment of cancer pain. Almirall holds the marketing rights to this medicine in Europe (except the United Kingdom).

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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

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.

Almirall focuses its research resources on therapeutic areas 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.

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.