

Sativex[®] launched in Spain to treat spasticity in multiple sclerosis (MS)

- Sativex[®] is available from today in Spain. The approved indication is treatment of spasticity due to MS in patients not responding to other therapies
- Almirall is also launching a website for patients, carers and family members to provide information on symptoms associated with MS and a 24h medical care phone service

Barcelona, Spain - March 14th, 2011: Almirall, S.A. (ALM) announces that Sativex[®] is now available to health professionals and patients in the Spanish hospital pharmacies. It is the first specific treatment for spasticity in MS patients who have not responded adequately to other treatments. Sativex[®] is administered as oromucosal spray enabling flexible dosage, which is particularly appropriate given the variable nature of spasticity and MS itself.

Evidence from clinical trials shows that Sativex[®] has a positive impact on spasticity, sleep quality and mobility and enables patients to carry out everyday tasks such as getting up, getting dressed or washed. This affords patients greater independence and reduces the frequency of spasms. It is estimated that in Spain there are around 40,000 people with MS¹ and up to 75% of them suffer from spasticity in the course of their disease.

Doctor Rafael Arroyo, head of the Multiple Sclerosis unit of the Department of Neurology in Hospital Clinico San Carlos in Madrid said, *"This is encouraging for patients and really interesting news for healthcare professionals, because it provides another treatment option for our MS patients who up to now had not been able to obtain an improvement of symptoms such as spasticity, muscle spasms, cramps or stiffness"*.

Spasticity (otherwise known as muscle stiffness) has a negative impact on patients' daily lives as it reduces their capacity to carry out everyday activities such as walking, keeping upright, as well as having an impact on their general mobility, bladder function, and quality of sleep. This means patients have to modify or give up certain activities and often require help from a family member or carer. About half of people with MS do not manage to find relief from these symptoms with currently available treatments.

Two websites and a 24h patient medical care phone service

Almirall has set up a specific website on symptoms related to MS -www.vivirconem.com- for patients and family members or carers, which contains a variety of audiovisual content aimed at providing a clear understanding of the specific symptoms of the disease and useful tips for daily life. There is also a second website -www.tupuntodeapoyo.com- and a 24h telephone medical care service to help patients follow their treatment guidelines (dose titration of Sativex[®] in order to find the optimal number of daily doses). This website has restricted access for patients to whom Sativex[®] has already been prescribed.

"In line with our philosophy of providing innovative solutions to patients, we are introducing in Spain the novel medicine Sativex[®], the first drug offering those affected by Multiple Sclerosis a proven alternative to help them improve their spasticity and associated symptoms. This launch is complemented with on-line initiatives to support and inform them about its use, reinforcing our commitment to wellness and health", said Luciano Conde, Chief Operating Executive of Almirall. *"We also expect to launch Sativex[®] in other European countries later in 2011",* he said.

According to the official communication from the Spanish Ministry of Health, Sativex® is financed by the National Health System with 100% reimbursement and the product is required to be dispensed from hospital pharmacies for outpatients.

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

- Ends -

Notes to Editors

Sativex®

Sativex® is an endocannabinoid modulator made of two actives - THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol)-, which was developed and is manufactured by GW Pharmaceuticals plc, UK., Almirall holds marketing rights in Europe (except United Kingdom).

Sativex® is indicated as an add-on treatment for patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not adequately responded to other anti-spasticity medications and who have demonstrated a clinically significant improvement in symptoms related to spasticity during an initial treatment testing period².

Sativex® contains active ingredients known as 'cannabinoids' which are extracted from the plant *C. Sativa* grown and processed under strictly controlled conditions. Cannabinoids react with cannabinoid receptors that exist naturally throughout our body, including the brain.³ A receptor is a site located in a brain cell in which certain substances can stick or "bind" for a while. If this happens, this binding has an effect on the cell and the nerve impulses it produces, causing a 'dimming-down' of the spasticity symptom. In patients who respond to Sativex®, this is the effect that improves their spasticity symptoms and helps them cope with their daily activities.⁴

Spasticity

In the five main EU markets there are around 500,000 people suffering from MS⁵ and in Spain around 40,000 cases of the disease have been reported.¹ Spasticity is a symptom defined by patients and carers as muscle spasms, seizing-up, stiffness and/or difficulty in moving muscles and it is one of the most common symptoms of MS, occurring in up to 75% of MS sufferers in the course of the disease. Spasticity can affect many aspects of the daily lives of patients with MS and is one of the main factors contributing to their distress and disability.⁶

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

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Bibliography

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- ² Patient leaflet
- ³ GW Pharmaceuticals: Cannabinoid Science: Mechanism of action. Available at: <http://www.gwpharm.com/mechanism-of-action.aspx> (latest access: 11/08/2010).
- ⁴ GW Pharmaceuticals: Cannabinoid Science: Cannabinoid Compounds. Available at <http://www.gwpharm.com/types-compounds.aspx> (Last accessed: 01/07/10).
- ⁵ Multiple Sclerosis International Federation: European map of ms database. ©2010 EMSP, MSIF. Available at: www.europeanmapofms.org (latest access: 11/08/2010). *Top five EU countries include: France, Germany, Italy, Spain and UK.*
- ⁶ Rizzo MA *et al.* Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler* 2004;10:589–595.