

Sativex[®] granted reimbursement in Spain, for the treatment of spasticity in multiple sclerosis

- **This is the first specific treatment for spasticity associated with multiple sclerosis (MS) which will be available in the Spanish hospital pharmacies shortly**
- **Approval of Sativex[®] in additional EU member states is expected in 2011**

Barcelona, February 16th, 2011: Almirall, S.A. (ALM) announces that the Spanish Ministry of Health granted the reimbursement of Sativex[®] in Spain, as confirmed by the Spanish Ministry of Health through their web page. It is the first treatment specifically designed for patients with MS-related spasticity who have not responded to other treatments. Sativex[®] is administered as an oral spray, enabling flexible dosage, which is particularly appropriate given the variable nature of spasticity and MS itself.

The approval of Sativex[®] in additional EU member states is expected in 2011.

It is estimated that there are around 40,000 people suffering from MS in Spain¹ of whom around 75% suffer from spasticity, a painful and debilitating disorder that causes stiffness in muscles, painful cramps and sudden uncontrolled movements in limbs (spasms) that increase tiredness and reduced mobility. Even daily activities such as unscrewing a bottle top or getting out of bed can become difficult, affecting the patients' quality of life and state of mind.²

Sativex[®] is an endocannabinoid system modulator made up principally of two active ingredients -THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol)-, and developed by GW Pharmaceuticals (UK). The Phase III programme for Sativex[®] in cancer pain started late 2010.

Almirall, S.A. has the marketing rights in Europe (except the UK).

This is the first prescription medicine approved in Spain derived from cannabis and will be available with full reimbursement to MS patients in hospitals.

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Notes to editors

Sativex[®]

Sativex[®] was developed by GW Pharmaceuticals plc, United Kingdom as a specific response to unmet needs of the population suffering from MS. The medicine is manufactured in the United Kingdom and Almirall holds marketing rights in Europe (except United Kingdom).

Sativex[®] is indicated as an add-on treatment for patients with moderate to serious spasticity due to multiple sclerosis (MS) who have not adequately benefitted from other anti-spasticity medications and who have demonstrated a clinically significant improvement in symptoms related to spasticity during an initial treatment testing period.²

Spasticity

Spasticity or muscle stiffness is one of the most common symptoms of MS, affecting around 80% of patients with MS. It has a negative impact on their daily lives, as muscle stiffness reduces their ability to perform daily activities such as walking, keeping upright, movement in general or bowel function (bladder), as well as causing sleep problems.

If spasticity is not properly controlled, these patients' quality of life is greatly affected. They are forced to modify or abandon certain activities and often require help from a family member or carer.

In the five most important markets in the EU there are around 500,000 people suffering from MS and 40,000 cases of the disease have been diagnosed in Spain.¹

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

Bibliography

¹ Atlas of MS database (<http://www.atlasofms.org/>)- MSIF. Latest update 2008.

² Multiple Sclerosis International Federation. Spasticity in MS. *MS in focus*. Issue 12. 2008. Available at: <http://www.msif.org/docs/MSinFocusIssue12EN.pdf> (latest access: 11/08/2010).