

Sativex[®] data presented at ECTRIMS congress highlights its efficacy as an add on therapy for the treatment of spasticity in people with multiple sclerosis

- **This is the first satellite symposium where Sativex[®] data has been presented to the scientific community and was held during the ECTRIMS European congress**
- **Efficacy data from 3 Phase III trials involving over 1,500 MS patients were presented by a panel of international experts in multiple sclerosis (MS)**

Gothenburg, Sweden, 14th October 2010.- Almirall, S.A. (ALM) announces that results from three pivotal clinical studies of Sativex[®] were presented today in a Satellite Symposium at Europe's leading multiple sclerosis conference, the 26th annual congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), which is taking place in Gothenburg, Sweden from 13-16 October.

These Phase III studies, the main results of which were first announced some months ago, provide robust evidence of the long term efficacy of Sativex[®] (27 mg delta-9-tetrahydrocannabinol and 25 mg cannabidiol) in symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. These data have in recent months led to the approval of this first-in-class medication in the UK, Canada and Spain (this last country pending pricing and reimbursement conditions).^{1,2,3}

Sativex[®] is administered as a mouth spray. Individual patients have the flexibility to adjust their dosage in the way which best suits their own level of spasticity and also the daily variations in their symptoms.

Professor Patrick Vermersch, Head of Neurology, University Hospital of Lille, France said, *"Sativex has produced highly promising results in the treatment of spasticity due to multiple sclerosis. Sativex[®] has shown it reduces the severity of symptoms as well as improving patients' quality of life and functional status, meaning that they can complete everyday tasks more easily. As the first new treatment for patients with this condition in ten years, Sativex[®] is a welcome option for a disease area in which there is a clear unmet need."*

In clinical trials, the proportion of multiple sclerosis spasticity patients achieving a $\geq 30\%$ improvement in their symptoms was significantly higher with Sativex[®] than with placebo.^{1,2,3} Sativex[®] also demonstrated improvements in spasticity associated symptoms, including spasms, sleep disruption and everyday functionality.^{2,3} During these studies, Sativex[®] was not associated with the adverse events which typically occur with recreational cannabis use, demonstrating very low potential for causing psycho activity or intoxication. The most frequent adverse events were transient dizziness or somnolence, usually of mild to moderate severity.

Sativex[®] obtained regulatory approval in Spain in July 2010 and is now undergoing pricing and reimbursement approval from the Spanish Ministry of Health which is expected to be completed during the 4th Quarter of 2010. It is currently marketed in the UK and Canada.

Sativex[®] has been developed by the UK-based company GW Pharmaceuticals plc and will be marketed in Europe (except the UK) by Almirall, S.A.

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Notes to Editors

Sativex®

Sativex® is a first-in-class endocannabinoid system modulator and is indicated as add-on 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 medication⁴ and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.¹^{Error!}
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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 microlitre 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 for Sativex®. Manufactured by GW Pharmaceuticals under Home Office licence, Sativex® will be marketed in Europe (except the UK) by Almirall, S.A.

Spasticity

There are almost 500,000 people suffering of MS in the top five EU countries.⁵ 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.⁶

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

References

- ¹ Collin C, Davies P, Mutiboko IK, *et al.* Randomized controlled trial of cannabis-based medicine in spasticity caused by multiple sclerosis. *Eur J Neurol* 2007;14:290–296.
- ² Collin C *et al.* A double-blind, randomized, placebo-controlled, parallel-group study of Sativex, in subjects with symptoms of spasticity due to multiple sclerosis. *Neurol Res* 2010 ;32:451-459.
- ³ Ambler Z, Davies P, Gasperini C, *et al.* A two-phase study of Sativex in the relief of spasticity due to multiple sclerosis: Phase A single-blind response assessment followed by Phase B double-blind randomized, placebo-controlled, parallel-group study. *Mult Scler* 2009;15:S258.
- ⁴ Sativex® Summary of Product Characteristics, 2010.
- ⁵ ©2010 EMSF, MSIF, www.europeanmapofms.org, 16/06/2010. Top five EU countries include: France, Germany, Italy, Spain and UK.
- ⁶ Rizzo MA Hadjimichael OC, Preiningerova J, *et al.* Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler* 2004; 10:589-595.