Full Phase III data highlight the efficacy and tolerability of Sativex® as therapy for the treatment of spasticity in MS

- **Data from three Phase III trials involving over 1,500 MS patients as well as first everyday clinical practice data were presented by a panel of international experts at the European Congress of Multiple Sclerosis (ECTRIMS) in Amsterdam**

- **Almirall announces sponsorship of two post-graduate clinical research projects**

Barcelona, 24th October 2011 - Almirall, S.A. (ALM:MC) presented full results from three Phase III studies with Sativex®, in a satellite symposium at the 27th ECTRIMS congress, which took place in Amsterdam from 19th to 22nd October 2011.

These Phase III studies provide evidence of the long term efficacy of Sativex® (2.7 mg delta-9-tetrahydrocannabinol and 2.5 mg cannabidiol per spray) 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 led to the approval of this first-in-class medication in the UK, Spain, Denmark, Germany and Czech Republic, with additional countries expected to grant approvals in the near future.[1,2,3]

Professor H.P. Hartung, Chair of Neurology at Heinrich-Heine University, Dusseldorf, Germany and Chairman of the satellite symposium, commented: *"Sativex® has proven to reduce the severity of symptoms and improve patients' quality of life and functional status, in patients with spasticity in multiple sclerosis, meaning that they can undertake everyday tasks more easily. Also, importantly, clinical experience to date has demonstrated that the tolerability profile of this medicine is favourable, with limited relevant adverse effects and - particularly reassuring - the drug does not appear to lead to withdrawal effects if patients suddenly stop using it."*

"The Sativex® data show this is a unique opportunity to help patients with MS spasticity, a clearly underserved indication. We believe Sativex® will offer a new way to help the patients with MS spasticity", said Bertil Lindmark, Chief Scientific Officer at Almirall.

Professor Xavier Montalbán, Director of the Multiple Sclerosis Center of Catalunya and the Unit of Clinical Neuroimmunology, Vall d´Hebron University Hospital, Barcelona, also announced the award of 2 post-graduate clinical research grants by Almirall, aimed at fostering clinical research in multiple sclerosis spasticity across Europe. The project selection board is comprised of Professor Montalbán, who will provide guidance on the development of project proposals, Professor Hartung and Almirall's global Medical Affairs Department. The resulting projects will be developed in 2012, and results will be published by authors in Q2 2013.

Sativex® has been developed by the UK-based company GW Pharmaceuticals plc and is 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 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 medication[4] and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.[4]

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. Manufactured by GW Pharmaceuticals under Home Office licence, Sativex® is 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

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[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, 2011.

[5] 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.

[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.