

Sativex[®] approved in Denmark for the treatment of spasticity due to Multiple Sclerosis (MS)

- **The Danish Interior and Health Minister approves Sativex[®], the first cannabis-based medicine in Denmark**
- **Launch of Sativex[®] in Denmark is expected later this month**

Barcelona, Spain and Porton Down, UK; 8th June 2011: Almirall, S.A. (ALM:MC) and GW Pharmaceuticals plc (AIM:GWP) today announced that the health authorities in Denmark have granted regulatory approval for Sativex[®] (Delta-9-Tetrahydro-cannabinol (THC) and Cannabidiol (CBD)) oromucosal spray as an add-on therapy for the treatment of moderate to severe spasticity due to MS in patients who have not responded adequately to other anti-spasticity medicationⁱ.

Regulatory approval for Sativex[®] has been granted after the recent change in the local laws. Sativex[®] is a first in class endocannabinoid system modulator for the treatment of spasticity in MS, currently available in the UK and Spain.

Evidence generated from clinical trials shows that Sativex[®] has a positive impact on spasticity in multiple sclerosis, while alleviating associated symptoms including pain, bladder or sleep disturbance. By relieving the symptoms of MS, Sativex[®] can improve patients' quality of life and allow them greater independence in performing their daily activities.ⁱⁱ

Approval in Denmark follows successful completion in March 2011 of the European Mutual Recognition Procedure (MRP) with all countries involved recommending approval. Approval for Sativex[®] was granted in Germany on 26th May 2011 and the product is expected to be launched there in July. In addition to Germany and Denmark, launch is also expected in Sweden before the end of 2011. Launches in Italy, Czech Republic and Austria are expected in 2012.

A further MRP is planned for later 2011 involving other European countries, in order to make this medicine available to more patients suffering from MS.

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).

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Notes to Editors

Sativex[®]

Sativex[®] was developed by UK-based GW Pharmaceuticals plc in specific response to the MS population's unmet need for a prescription cannabis-based medicine. Manufactured under Home Office licence at an undisclosed location in the UK it will be marketed in Europe (except the UK) by Almirall.

Sativex[®] 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 medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Sativex[®] is delivered by an oromucosal spray (sprayed into the mouth either onto the inside of the cheek or under the tongue) and has a flexible dosing regime, particularly appropriate given the variable nature of both spasticity and multiple sclerosis from patient to patient.

Sativex[®] contains active ingredients called 'cannabinoids', which are extracted from cannabis plants grown and processed under strictly controlled conditions. Cannabinoids react with cannabinoid receptors that occur naturally throughout our bodies, including in our brains.ⁱⁱⁱ A receptor is a site on a brain cell where certain substances can stick or "bind" for a while. If this happens, it has an effect on the cell and the nerve impulses it produces, which causes a 'dimming down' of the symptoms of spasticity. In patients who respond to Sativex[®], it is this effect which helps to improve their symptoms of spasticity and to help them cope better with their usual daily activities.^{iv}

Spasticity

There are almost 500,000 people suffering of MS in the top five EU countries^v, and 10,000^{vi} of them are reported to live with the condition in Denmark. Spasticity (otherwise known as muscle stiffness) is one of the most common symptoms of MS, occurring in as many as 75% of people with MS and 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.^{vii} 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

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), gastrointestinal disorders, 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.

Almirall ApS started its activities in Denmark in early 2010 with the aim of establishing the required infrastructure to support future launches of products from its own pipeline in the Scandinavian countries. This affiliate covers the following markets: Denmark, Finland, Iceland, Norway and Sweden from a regional head office located in down-town Copenhagen. The main focus of the affiliate is dermatology, through an experienced sales force of Key Account Managers. The pharmaceutical market in the Nordic countries combined ranks the 6 th largest market in Europe.

For further information please visit the website at: www.almirall.com.

GW Pharmaceuticals

GW Pharmaceuticals plc (AIM:GWP) was founded in 1998 and is listed on the AiM, a market of the London Stock Exchange. Operating under licence from the UK Home Office, the company researches and develops cannabinoid pharmaceutical products for patients who suffer from a range of serious ailments, in particular MS and cancer pain. GW has assembled a large in-house scientific team with expertise in cannabinoid science as well as experience in the development of both plant based prescription pharmaceutical products and medicines containing controlled substances. GW occupies a world leading position in cannabinoids and has developed an extensive international network of the most prominent scientists in the field.

For further information, please visit www.gwpharm.com.

This news release may contain forward-looking statements that reflect GW's current expectations regarding future events, including development and regulatory clearance of the GW's products. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of the GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex[®] and other products by consumer and medical professionals.

ⁱ Sativex[®] Summary of Product Characteristics, 2011.

ⁱⁱ Multiple Sclerosis Trust. A-Z of MS – Spasticity. Available at: <http://www.mstrust.org.uk/atoz/spasticity.jsp> (Last accessed: 26/07/10).

ⁱⁱⁱ GW Pharmaceuticals. Cannabinoid Science: Mechanism of action. Available at <http://www.gwpharm.com/mechanism-of-action.aspx> (Last accessed: 01/07/10).

^{iv} GW Pharmaceuticals. Cannabinoid Science: Cannabinoid Compounds. Available at <http://www.gwpharm.com/types-compounds.aspx> (Last accessed: 01/07/10).

^v 2010 EMSP, MSIF, www.europeanmapofms.org, 16/06/2010. Top five EU countries include: France, Germany, Italy, Spain and UK.

^{vi} Danish Sclerosis Association

^{vii} Prevalence and treatment of spasticity reported by multiple sclerosis patients – MA Rizzo et al – Multiple Sclerosis 2004; 10:589-595.