Sativex® receives regulatory authorisation in Spain

- **Spanish health authorities grant regulatory approval for Sativex®, the first new treatment for MS-related spasticity in decades**

- **Launch expected 4th Quarter 2010**

- **Application submitted under European Mutual Recognition Procedure for approval of Sativex® in other European member states**

Barcelona, Spain and Porton Down, UK; 28th July 2010: Almirall, S.A. (ALM) and GW Pharmaceuticals plc (GWP:AIM) today announced that the health authorities in Spain have granted regulatory approval for Sativex®[i] Oromucosal Spray as an add-on therapy for the treatment of moderate to severe spasticity due to Multiple Sclerosis (MS) in patients who have not responded adequately to other anti-spasticity medication[ii]. Prior to launch, Sativex® requires pricing and reimbursement approval from the Spanish Ministry of Health. This final approval process is expected to be completed during the 4th Quarter of 2010.

In addition, GW Pharmaceuticals has submitted an application under the European Mutual Recognition Procedure (MRP) to seek marketing authorization for Sativex® in other selected European member states, including the major commercial markets, France, Germany and Italy. The UK regulatory authority, the Medicines and Healthcare product Regulatory Agency (MHRA), which approved Sativex® in June 2010, has agreed to act as Reference Member State for the purposes of the MRP procedure.

The complete list of countries to which the MRP application is being made is currently being finalized and will be provided to the MHRA later this year.

"*We are pleased to have received this regulatory approval of Sativex® in Spain and look forward to launching Sativex® later this year. Sativex addresses a significant unmet need offering relief to those MS patients who suffer from spasticity and associated symptoms who have been unable to obtain adequate benefit from currently available medication. We are also pleased to have commenced the regulatory process in other key European markets and look forward to additional approvals and launches in Europe next year.*", said Mr Luciano Conde, Chief Operating Officer at Almirall.

Mr Justin Gover, GW's Managing Director, said, "*Following the recent approval and launch of Sativex® in the UK, today's approval in Spain and filing of the European mutual recognition submission marks the beginning of the international expansion of this product. Sativex® addresses an important unmet medical need for people with MS and together with our partners Almirall, we look forward to making the medicine available across Europe."*

Sativex® is a first in class endocannabinoid system modulator for the treatment of spasticity in MS. 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® has been developed by UK-based GW Pharmaceuticals and will be marketed in Europe (except the UK) by Almirall, S.A.

Enquiries:

Almirall PR +44 (0)20 7611 3553
Amanda Moulson (Emanate) amanda.moulson@emanatepr.com

GW Pharmaceuticals plc (Today) + 44 20 7831 3113
Dr Geoffrey Guy, Chairman + 44 1980 557000
Justin Gover, Managing Director

GW PR
Financial Media: Ben Atwell / John Dineen + 44 20 7831 3113
Other Media: Mark Rogerson +44 7885 638810

GW Advisers: Piper Jaffray Ltd +44 20 3142 8700
Neil Mackison / Rupert Winckler

Notes to Editors

Mutual Recognition Procedure (MRP)
Under the MRP, the UK regulator, the MHRA, acts as Reference Member State. Following the MRP filing, the MHRA updates the assessment report which formed the basis of its recent approval, and then sends this report to other European countries selected by GW. The MHRA is expected to send the report in approximately 90 days at which time GW/Almirall must have selected the final list of countries that they wish to participate in the process. Regulatory authorities in each of the listed countries provide comments to which the MHRA and GW are expected to respond. Each country may form its own decision as to whether to approve Sativex. In the event of serious objections from a country, GW may elect to withdraw the application from that country. The MRP timescale depends on the interactions between the various authorities and GW. It is expected that the process may take up to one year to complete.

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[ii].

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 40,000 people in Spain are reported to live with the condition[vi]. 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.[vii]

Almirall
Almirall, an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of multiple sclerosis, asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, 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 11 affiliates.

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 GWs 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.

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[i] (Delta-9-tetrahydrocannabinol -THC- and cannabidiol -CBD-)

[ii] Sativex® Summary of Product Characteristics, 2010.

[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] FELEM (Spanish Federation for the fight against Multiple Sclerosis): reality, social needs and quality of life. 2005-2006

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