Sativex® Mutual Recognition Procedure Closes with Recommendation for Approval in Ten European Countries

- **Sativex® is already available in the UK, Spain, Germany and Denmark. Launches currently in preparation in Italy, Sweden, Austria and Czech Republic**

- **Recommendation for approval now received in Belgium, Finland, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovakia. Launches expected from the end of 2012 onwards**

Barcelona, Spain; Porton Down, UK; 8th May 2012: GW Pharmaceuticals plc (AIM:GWP) and Almirall S.A. (ALM) today announce the successful completion of the European Mutual Recognition Procedure (MRP) for Sativex® oromucosal spray in the treatment of spasticity due to Multiple Sclerosis (MS).

Following previous positive regulatory submissions in the UK, Spain, Germany, Italy, Denmark Sweden, Austria, Czech Republic, a MRP application was made to expand the availability of Sativex® to ten additional European countries. The MRP has now closed successfully with regulatory authorities in all ten countries confirming that Sativex® meets their requirements for approval. The countries involved in the MRP and in which Sativex® is expected to be approved are: Belgium, Finland, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovakia.

"For Almirall, the successful completion of this second MRP regulatory process for Sativex® represents very good news and reinforces our commitment to expand this innovative medicine to MS patients across Europe. Sativex® is the first treatment specifically indicated for the treatment of spasticity, and related symptoms, in MS patients" said Bertil Lindmark, Chief Scientific Officer at Almirall.

The next step in the regulatory process involves separate national phases in each country to finalise local wording on product packaging and related documents and also to agree any other country-specific requirements. Following completion of the national step, each country is then expected to issue a national marketing authorisation. Launch timing in these ten new countries is dependent on national pricing and reimbursement procedures. Launches are anticipated from the end of 2012 onwards.

Dr Stephen Wright, GW's R&D Director, said, *"Today's news means that regulatory authorities in a total of eighteen European countries have now recommended Sativex® for approval. The successful outcome of this most recent regulatory process provides further endorsement of the quality, safety and efficacy of Sativex®. Sativex® has an important role in meeting the needs of people with Multiple Sclerosis and we look forward to working with our partners Almirall to make the medicine available to patients across Europe."*

In Europe, Sativex® is approved and marketed for MS spasticity in the UK, Spain, Germany, and Denmark. In addition to the ten new European markets included in this

MRP, launches are also currently being planned in Sweden, Italy, Austria and the Czech Republic.

In addition to MS spasticity, Sativex®, which has been developed by GW Pharmaceuticals, is also in phase III clinical development for the treatment of cancer pain. Almirall holds the marketing rights to this medicine in Europe (except the United Kingdom) and Mexico.

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Notes to Editors

Sativex®
Sativex® is an endocannabinoid modulator made of two actives - THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol)-, which was developed and is manufactured by GW Pharmaceuticals plc, UK., Almirall holds marketing rights in Europe (except United Kingdom) and Mexico.

Sativex® is indicated as a treatment for patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not adequately responded to other anti-spasticity medications and who have demonstrated a clinically significant improvement in symptoms related to spasticity during an initial treatment testing period[i]. Sativex® is effective in all types of MS, independently of the disability status (as per Expanded Disability Status Scale -EDSS-, a rating system that is frequently used for classifying and standardizing the condition of people with multiple sclerosis).[ii]

Sativex® contains active ingredients known as 'cannabinoids' which are extracted from the plant *C. Sativa* grown and processed under strictly controlled conditions. Cannabinoids react with cannabinoid receptors that exist naturally throughout our body, including the brain.[iii] A receptor is a site located in a brain cell in which certain substances can stick or "bind" for a while. If this happens, this binding has an effect on the cell and the nerve impulses it produces, causing a 'dimming-down' of the spasticity symptom. In patients who respond to Sativex®, this is the effect that improves their spasticity symptoms and helps them cope with their daily activities.[iv]

This medicine is also in Phase III clinical development as a treatment for cancer pain.

Spasticity
In the five main EU markets there are around 500,000 people suffering from MS [v]. Spasticity is a symptom defined by patients and carers as muscle spasms, seizing-up, stiffness and/or difficulty in moving muscles and it is one of the most common symptoms of MS, occurring in up to 75% of MS sufferers in the course of the disease. Spasticity can affect many aspects of the daily lives of patients with MS and is one of the main factors contributing to their distress and disability.[vi]

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

About 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] Patient leaflet

[ii] *A randomized, double-blind, placebo-controlled, parallel-group, enriched-design study of nabiximols (Sativex®), as add-on therapy, in subjects with refractory spasticity caused by multiple sclerosis* - Novotna A. et al, European Journal of Neurology 2011 – Sept ; 18(9):1122-31.

[iii] GW Pharmaceuticals: Cannabinoid Science: Mechanism of action. Available at. http://www.gwpharm.com/mechanism-of-action.aspx (latest access: 26/04/2012).

[iv] GW Pharmaceuticals: Cannabinoid Science: Cannabinoid Compounds. Available at http://www.gwpharm.com/types-compounds.aspx (Last accessed: 26/04/12).

[v] Multiple Sclerosis International Federation: European map of ms database. ©2010 EMSP, MSIF. Available at: www.europeanmapofms.org (latest access: 11/08/2010). *Top five EU countries include: France, Germany, Italy, Spain and UK.*

[vi] Rizzo MA *et al*. Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler* 2004;10:589–595.