Regulators in UK and Spain confirm Sativex® is approvable

- **Sativex® receives positive recommendation and process enters national approval phase in UK and Spain.**

- **Regulatory approvals expected Q2 2010.**

- **Launch in Spain expected in 2nd half 2010.**

Barcelona, Spain, 20 May 2010: Almirall, S.A. (ALM) and GW Pharmaceuticals plc (GWP:AIM) today announced that the regulatory authorities in the UK and Spain have reached consensus that all issues related to the Sativex® application have been resolved. The decentralised procedure has therefore been closed with a positive recommendation that Sativex® is approvable.

The regulatory process will now enter its final phase. This final phase, known as the national phase, takes place separately -in this case- in the UK and Spain and its purpose is to finalise local wording on product packaging and related documents. After this phase is completed, national marketing approvals can be granted in each respective country.

Following regulatory approval in the UK (reference member state), submissions for approval will made in additional European countries under the mutual recognition procedure.

Sativex® -an endocannabinoid system modulator- is indicated as add-on treatment for symptom improvement in patients with spasticity due to multiple sclerosis, who has not responded adequately to other anti-spasticity medication. Sativex® is administered through an oromucosal spray and has a flexible dosing regime, making it particularly appropriate for this condition given the variable nature of both spasticity and multiple sclerosis.

A £2.5m milestone is payable by Almirall to GW following both regulatory and pricing approval in Spain, expected 2nd half 2010.

Sativex will be marketed in Europe (except the UK) by Almirall S.A.

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Notes to Editors

Regulatory Process
The Sativex regulatory submission was filed in the UK and Spain under the European decentralised procedure in May 2009, with the UK acting as the Reference Member State.

On 18 March 2010, GW announced that the regulatory process had reached “Day 150” of the decentralised procedure -when regulatory authorities deem the product to be or not approvable, subject to resolution of any “point for clarification”- both the UK and Spanish regulators concluded that there were no major quality, safety or efficacy issues remaining to be resolved. This announcement stated that resolution was required only of points of clarification related to finalisation of wording on the patient information leaflet.

Once all major and minor issues are deemed resolved, the decentralised procedure closes and the process enters its final phase. This final phase, known as the national phase, takes place separately in the countries -UK and Spain- and its purpose is to finalise local wording on product packaging and related documents.

MS Spasticity
There are approximately 670,000 people with MS in Europe (source: European MS Platform-EMSP). Spasticity (spasms and stiffness) is one of the most common symptoms of MS occurring in as many as three quarters of people with MS. It can affect many aspects of daily life, such as walking and sitting. Sativex® aims to treat (high need) patients who have previously failed to gain adequate benefit from currently available anti-spasticity treatments.

About 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.

About GW
GW was founded in 1998 and listed on the AiM, a market of the London Stock Exchange, in June 2001. Operating under license 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 multiple sclerosis 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.