

GW FILES SATIVEX® REGULATORY SUBMISSION

Porton Down, UK, 20 May 2009: GW Pharmaceuticals plc (GWP:AIM) today announces that it has filed a regulatory submission for Sativex® for the treatment of spasticity due to Multiple Sclerosis. This submission follows the recent announcement of a positive Phase III trial in this indication.

The regulatory submission has been filed in the UK and Spain under the European decentralised procedure. The UK regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA), is acting as Reference Member State and has validated the application.

It is expected that an outcome of the regulatory submission will be known towards the end of 2009 / early 2010.

Following approval in the UK and Spain, submissions for approval will be made in additional European countries during 2010 under the mutual recognition procedure.

Sativex will be marketed in the UK by Bayer HealthCare, and in the rest of the European Union by Laboratorios Almirall S.A.

Dr Stephen Wright, GW's R&D Director, said, "We are pleased to have completed and filed the regulatory submission within a very short period of time of receiving the latest positive Phase III data. We look forward to working with the regulatory authorities in their review of the application."

Enquiries:

GW Pharmaceuticals plc
Dr Geoffrey Guy, Chairman
Justin Gover, Managing Director

(Today) + 44 20 7831 3113
(Thereafter) + 44 1980 557000

Financial Dynamics
Ben Atwell / John Dineen

+ 44 20 7831 3113

Investec Bank plc
Patrick Robb

+ 44 20 7597 4000

Notes to Editors

MS Spasticity

There are approximately 500,000 people with MS in Europe. Spasticity (spasms and stiffness) is one of the most common symptoms of MS occurring in as many as three quarters of people with MS. Spasticity 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.

Sativex Phase III Trial

On 11 March 2009, GW announced positive preliminary results from a pivotal Phase III double-blind randomised placebo-controlled study of Sativex® in patients with spasticity due to Multiple Sclerosis (MS), who have achieved inadequate spasticity relief with

existing therapies. This study was requested by the UK regulator in order to gain approval in this indication.

The prospectively defined primary efficacy endpoint of the study - the difference between the mean change in spasticity severity of Sativex vs Placebo - was highly statistically significantly in favour of Sativex ($p=0.0002$). The difference between Sativex and placebo was also highly significant for a number of secondary endpoints, including the 30% responder analysis ($p=0.0003$), spasm frequency ($p=0.005$), sleep disturbance ($p<0.0001$), patient global impression of change ($p=0.023$), and physician global impression of change ($p=0.005$).

Sativex Prescription Use

Sativex is approved and marketed in Canada for the treatment of cancer pain and MS neuropathic pain. In addition, Sativex is available on prescription in the UK on a “named patient” basis and has to date been exported to 21 countries around the world.

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.