

Sativex[®] starts a third Phase III clinical trial in cancer pain

Barcelona, Spain, 22nd May 2012: Almirall, S.A. (ALM:MC) is pleased to note the announcement by GW Pharmaceuticals plc (AIM:GWP) on the start of a third Phase III clinical trial of Sativex[®] in cancer pain in patients who experience inadequate analgesia during optimized chronic opioid therapy.

Full text of the announcement from GW Pharmaceuticals plc follows:

THIRD PHASE III SATIVEX[®] CANCER PAIN TRIAL COMMENCES

Porton Down, UK; 22 May 2012: GW Pharmaceuticals plc (AIM: GWP) today announced the initiation of a third Phase III Sativex[®] clinical trial in the treatment of pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy.

GW's cancer pain clinical programme is being wholly funded by Otsuka Pharmaceutical Co. Ltd, which has licensed the US commercialisation rights to this product. The trials are designed to obtain approval in this indication from the Food & Drug Administration (FDA) in the US, and these data will also be used by GW for future regulatory applications in this indication in Europe and around the world.

GW has previously announced the start of two pivotal 380 patient Phase III cancer pain studies, both of which are proceeding on track and are expected to complete recruitment around the end of 2013. Regulatory filings are intended to be made upon completion of these two studies. This newly commenced third Phase III trial is a supportive study intended to provide, as needed, supplementary data to that generated in the first two studies.

The third Phase III trial differs in design from the first two studies, employing an "enriched study design" akin to that which was successfully employed in the MS spasticity trials programme. The study involves exposing patients to Sativex[®] in a single blind phase of two weeks duration ("Phase A"), following which responders will be randomised either to stay on Sativex[®] or switch to placebo in a double blind phase for a five week treatment period ("Phase B"). The primary efficacy analysis will be the mean change from baseline in Phase B as measured using a 0-10 Numeric Rating Scale (NRS). The study will aim to recruit 540 patients into Phase A and target 216 patients to enter Phase B.

Prior to commencing the Phase III programme, GW completed two Phase II studies with positive results including over 500 patients in total. The most recent Phase IIb study was published last month in the *Journal of Pain*¹, the official journal of the American Pain Society.

Dr. Stephen Wright, GW's R&D Director, said, *"We are pleased to have commenced this third Phase III study evaluating the efficacy and safety of Sativex[®] as a potential treatment for cancer pain. This clinical development programme, being performed in partnership with Otsuka, is the largest ever undertaken by GW. With significant numbers of patients with advanced cancer around the world suffering pain in spite of treatment with opioid therapy, Sativex[®] has the potential to meet a very significant unmet need."*

Sativex[®] is licensed to Otsuka in the US, Almirall S.A. in Europe (excluding the United Kingdom) and Mexico, Bayer HealthCare AG in the UK and Canada, Novartis Pharma AG in Australasia, Asia (excluding Japan and China), Middle East (excluding Israel) and Africa, and Neopharm Group in Israel.

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Notes to Editors:

Sativex[®] in Multiple Sclerosis

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 period². 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).³

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.⁴ 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.⁵

About Almirall

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, 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 respiratory, gastrointestinal, dermatology and pain. Almirall's products are currently present in over 70 countries in the five continents. It has direct presence in Europe and Mexico through 12 affiliates.

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

References

¹ [http://www.jpain.org/article/S1526-5900\(12\)00019-3/abstract](http://www.jpain.org/article/S1526-5900(12)00019-3/abstract)

² Patient leaflet

³ *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.

⁴ GW Pharmaceuticals: Cannabinoid Science: Mechanism of action. Available at: <http://www.gwpharm.com/mechanism-of-action.aspx> (latest access: 26/04/2012).

⁵ GW Pharmaceuticals: Cannabinoid Science: Cannabinoid Compounds. Available at <http://www.gwpharm.com/types-compounds.aspx> (Last accessed: 26/04/12).