



## **Sativex<sup>®</sup> enters Phase III clinical programme in oncological pain**

- First pivotal Phase III trial of Sativex<sup>®</sup> in oncological pain has been initiated in Europe
- In Europe, Sativex<sup>®</sup> is approved in the UK and Spain for the treatment of spasticity in Multiple Sclerosis (MS)

**Barcelona (Spain), 23<sup>rd</sup> November 2010.-** Almirall (ALM:MC) announces the initiation of the Phase III clinical trials programme of Sativex<sup>®</sup> in the treatment of pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy. The Phase III programme is being performed by GW Pharmaceuticals in conjunction with their licensing partner in the US, Otsuka Pharmaceutical Co. Ltd.

The programme includes two Phase III randomised placebo-controlled multi-centre multinational trials as well as a long term extension study. Each Phase III trial will include approximately 370 patients from Europe, North America, Latin America and Asia and will evaluate the efficacy and safety of Sativex<sup>®</sup> versus placebo over a 5-week treatment period.

The first Phase III trial site has now been initiated in Europe and the first patient is expected to be recruited during December 2010. The principal investigator of the first study is Dr. Russell K. Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York City. The second Phase III study is expected to commence in mid 2011.

Almirall is responsible for the commercialization of Sativex<sup>®</sup> and to make this innovative medicine available to healthcare professionals and patients in Europe (except the UK).

### **About Almirall**

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercializes 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: [www.almirall.com](http://www.almirall.com)

### **Sativex**

Sativex<sup>®</sup> is an endocannabinoid system modulator composed mainly of two cannabinoids: CBD (cannabidiol) and THC (delta-9-tetrahydrocannabinol). Sativex<sup>®</sup> is administered as an oromucosal spray. Each 100µl spray contains 2.7 mg of THC and 2.5 mg of CBD.

### **Enquiries:**

**Almirall:** Emanate PR  
Amanda Moulson  
+44 (0)20 7611 3553  
[amanda.moulson@emanatepr.com](mailto:amanda.moulson@emanatepr.com)

**Full text of GW Pharmaceuticals' press release with complete information is available at:**  
<http://www.gwpharm.co.uk/Sativex%20Enters%20Phase%20III%20Clinical%20Programme%20In%20Cancer%20Pain.aspx>