

GW Pharmaceuticals Announces Agreement on Sativex® Pricing in Germany

Written by Australian Business

LONDON, Sept. 23, 2013 /PRNewswire/ -- GW Pharmaceuticals plc (AIM: GWP, Nasdaq: GWPH, "GW") announced today that agreement for a revised mutually-acceptable reimbursement price for Sativex® has been reached between Almirall S.A., GW's commercial partner in Germany, and the German National Association of Statutory Health Insurance Funds (GKV-SV). This new agreement has resulted in an increase to the previously reduced price imposed by the German authorities in March 2013 which Almirall had considered to be unacceptable.

"We are pleased to have a positive outcome to discussions that result in an acceptable reimbursement price for Sativex® in Germany, Europe's largest potential market for Sativex®. This agreement ensures that people suffering from Multiple Sclerosis spasticity in Germany will have long-term access to this important medicine," stated Justin Gover, GW's Chief Executive Officer.

It is estimated that approximately 4,000 patients are currently being treated with Sativex in Germany.

"Almirall is committed to meeting the needs of MS patients and this is the reason we have been determined over recent months to achieve an appropriate resolution of the reimbursement price in Germany," said Farid Taha, General Manager of Almirall Hermal Company. "Sativex® represents an important advance in the symptomatic treatment of MS spasticity and this new agreement provides doctors and patients in Germany with the necessary assurance that Sativex® represents not only a recognised therapeutic benefit, but will also be available on prescription for the long-term."

The full text of the joint announcement issued by Almirall and the GKV-SV is below. (NOTE: the following press release is translated into English for the convenience of the reader. Some variation may have occurred in this translation.)

Reimbursement amount for therapeutic agent for MS agreed upon

Berlin, 23 September 2013 – The pharmaceutical company Almirall Hermal GmbH and the National Association of Statutory Health Insurance Funds agreed on 23 September 2013 on a reimbursement amount for the medicine Sativex®.

Sativex® is approved as an add-on therapy for the alleviation of symptoms in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medications. This is the first medication based on two cannabinoids – delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). These plant-derived cannabinoids are able to modulate the body's own cannabinoid system, which leads to improved regulation of nerve impulse in responders. This in turn leads to a decrease in spasticity. The basis for the negotiations was the decision on benefit assessment by the Joint Federal Committee dated 21 June 2012

, in which the medication was said to show indications of a slight added benefit. This was the second negotiation regarding this medication and the new outcome reflects the impact of changes, in the interim period, to the framework upon which the reimbursement criteria are determined. New negotiations commenced as a result of Almirall issuing an orderly termination of the existing contract as at June 2013

.

Farid Taha, managing director of Almirall Hermal GmbH, and Johann-Magnus v. Stackelberg, deputy chairman of the National Association of Statutory Health Insurance Funds, stated that the negotiations were constructive and fair.

"Both parties to the negotiations were interested in a solution that would benefit patients," said Taha and v. Stackelberg. "That was the foundation on which an agreement was finally reached."

About GW Pharmaceuticals plc

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 22 countries. Sativex is also in Phase 3 clinical development as a potential treatment of pain in people with advanced cancer. This Phase 3 program is intended to support the submission of a New Drug Application for Sativex in cancer pain with the U.S. Food and Drug Administration and in other markets around the world. GW has established a world leading position in the development of plant-derived cannabinoid therapeutics and has a deep pipeline of additional cannabinoid product candidates, including two distinct compounds, GWP42004 and GWP42003, in Phase 2 clinical development for Type 2 diabetes and ulcerative colitis, respectively, and GWP42006 in Phase 1 clinical development for the treatment of epilepsy. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release may contain forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the therapeutic and commercial value of the company's compounds, the pricing of Sativex® in Germany and any other commercial markets, assurances of long-term availability of Sativex® and assurances of acceptability of Sativex® pricing and stability of such pricing. 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. A further list and description of risks, uncertainties and other risks associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the prospectus related to the NASDAQ offering filed by GW with the SEC on May 1, 2013

. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

SOURCE GW Pharmaceuticals plc

GW Pharmaceuticals Announces Agreement on Sativex® Pricing in Germany

Written by Australian Business

RELATED LINKS <http://www.gwpharm.com>