



**Health Canada Grants Full Approval of Sativex®
For the Treatment of Spasticity Due to Multiple Sclerosis**

Porton Down, UK; Toronto, Canada – August 31, 2010 – GW Pharmaceuticals plc (AIM: GWP) and Bayer Inc., a subsidiary of Bayer AG, today announced that Health Canada has approved Sativex® [delta-9-tetrahydrocannabinol 27 mg/mL (from Tetrabinex® - cannabis sativa L. extract) and cannabidiol 25 mg/mL (from Nabidiolex® - cannabis sativa L. extract)] as adjunctive treatment for symptomatic relief of spasticity in adult patients with multiple sclerosis (MS). Sativex® is the first cannabinoid medicine derived from whole plant extracts from the *cannabis sativa* plant containing both delta-9-tetrahydrocannabinol and cannabidiol. This means that people in Canada with MS experiencing the debilitating symptoms of spasticity, such as painful spasms and cramps, will now have a new treatment option in addition to standard therapy.

The MS spasticity indication has received a full marketing authorization, or Notice of Compliance (NOC), from Health Canada. Sativex® is useful as adjunctive treatment for symptomatic relief of spasticity in adult patients with MS who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy.¹ In addition to this new NOC, Health Canada approved Sativex® in 2005 under its Notice of Compliance with Conditions (NOC/c) policy as adjunctive treatment for the symptomatic relief of neuropathic pain in adult patients with multiple sclerosis, and granted a further NOC/c approval in 2007 as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain.¹

“Health Canada’s approval of a third indication for Sativex® demonstrates the broad applications of this medicine,” said Dr. Shurjeel Choudhri, Chief Medical Officer and Head, Medical and Scientific Affairs, Bayer Inc. “Sativex® meets a significant unmet medical need by improving the symptoms of spasticity in patients with MS who have failed to respond to current anti-spasticity medication. We believe that this approval represents an important step forward in the available treatment options for the MS patient population in Canada.”

Dr Stephen Wright, R&D Director, GW, said: “Following recent approvals in the UK and Spain, Canada is now the third major country to approve Sativex® for symptomatic relief of spasticity in adult patients with MS. This regulatory approval has come several months earlier than anticipated and GW looks forward to working with Bayer to develop the marketing strategy for this new indication. We are delighted that the international regulatory program for Sativex® is continuing its positive momentum.”

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¹ Sativex® Product Monograph, August 2010, p.6

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About Sativex[®]

A product resulting from the pioneering research efforts of UK-based GW Pharmaceuticals plc and marketed in Canada by Bayer HealthCare Pharmaceuticals, Sativex[®] contains active ingredients called 'cannabinoids', which are extracted from cannabis plants grown and processed under strictly controlled conditions. Cannabinoids react with cannabinoid receptors that are distributed throughout the central nervous system and in immune cells.²

The principal active cannabinoid components of Sativex[®] are THC and CBD, a non-psychoactive cannabinoid. The ratio of THC to CBD in Sativex[®] is 2.7mg:2.5mg per spray, ensuring a standardized dose is delivered each time it is used.³

Standard marketing authorisation:⁴

Sativex[®] is useful as adjunctive treatment for symptomatic relief of spasticity in adult patients with multiple sclerosis (MS) who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy.

Marketing authorization with conditions:⁴

Sativex[®] may be useful as adjunctive treatment for the symptomatic relief of neuropathic pain in adult patients with MS.

Marketing authorization with conditions:⁴

Sativex[®] may be useful as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain.

Marketing authorizations with conditions reflect the promising nature of the clinical evidence which are to be confirmed with further studies.

Treatment-emergent adverse events in clinical trials with Sativex[®] which occurred with a greater than 10 per cent frequency in patients with MS included fatigue and dizziness. In patients with pain in cancer, these adverse events included nausea, neoplasm progression, somnolence and dizziness. In most patients, adverse events have resolved without treatment, and some with a reduction of dosage of Sativex[®].⁵

Sativex[®] is a registered trade mark of GW Pharmaceuticals and GW Pharmaceuticals is the Marketing Authorisation holder for Sativex[®].

² Health Canada. "Approval of SATIVEX(R) with Conditions Fact Sheet." Available at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex_fs_fd_091289-eng.php (last accessed 26/08/10)

³ Sativex[®] Product Monograph – August 2010, p. 52

⁴ Sativex[®] Product Monograph – August 2010, p. 1

⁵ Sativex[®] Product Monograph – August 2010, p.13-19

About MS

Multiple sclerosis (MS) is a degenerative neurological condition, which is associated with a wide range of distressing and disabling signs and symptoms.⁶ MS is the most common disabling disease of the CNS affecting young adults and is usually diagnosed between the ages of 20 and 40 years.⁷ MS is twice as common in women than in men.⁷ An estimated 55,000-75,000 Canadians have MS.⁸

About spasticity

Spasticity is a common symptom associated with Multiple Sclerosis (MS)⁹ and is a major contributor to disability.¹⁰ It is caused by damage to the nerves in the central nervous system which carry messages instructing muscles how to move resulting in an involuntary muscle overactivity.¹¹

In a survey, 84% of people with MS reported symptoms of spasticity.¹² Moderate, severe or total spasticity is reported in 34% of individuals.¹¹ Symptoms include loss of mobility, painful spasms, stiffness and / or weakness of muscles.¹⁰ As a consequence an individual may have difficulty in walking, picking up objects, washing, dressing and other everyday activities involving movement.⁹ In addition to causing a great deal of distress to the person with MS, mood, self-image and motivation can also be affected.¹³

About Bayer Inc.

Bayer Inc. (Bayer) is a Canadian subsidiary of Bayer AG, an international research-based group with core businesses in health care, crop science and innovative materials. Headquartered in Toronto, Ontario, Bayer Inc. operates the Bayer Group's HealthCare and MaterialScience businesses in Canada. Bayer CropScience Inc., headquartered in Calgary, Alberta operates as a separate legal entity in Canada. Together, the companies play a vital role in improving the quality of life for Canadians – producing products that fight diseases, protecting crops and animals, and developing high-performance materials for applications in numerous areas of daily life. Canadian Bayer facilities include the Toronto headquarters and offices in Montréal and Calgary.

Bayer Inc. has approximately 800 employees across Canada and had sales of \$853 million CDN in 2009. Globally, the Bayer Group had sales of over 31 billion Euro in 2009. Bayer Inc. invested approximately \$50 million CDN in research and development in 2009. Worldwide, the Bayer Group spent the equivalent of over 2.7 billion Euro in 2009 in R&D. For more information, go to www.bayer.ca.

About GW Pharmaceuticals

GW was founded in 1998 and is listed on the AiM, a market of the London Stock Exchange. Operating under licence 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 MS 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.

For further information, please visit www.gwpharm.com

⁶ Health Canada. "Approval of SATIVEX(R) with Conditions Fact Sheet." Available at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/sativex_fs_fd_091289-eng.php (last accessed 26/08/10)

⁷ Multiple Sclerosis Trust. MS Explained. 2008. Available at <http://www.mstrust.org.uk/information/publications/msexplained/> (Last accessed: 26/08/10)

⁸ MS Society of Canada. Available at http://mssociety.ca/en/information/ms_what.htm (last accessed 26/08/10)

⁹ Multiple Sclerosis Trust. Multiple Sclerosis Information for Health and Social Care Professionals. 2007. Available at http://www.mstrust.org.uk/downloads/ms_information_for_hps.pdf (Last accessed: 26/08/10).

¹⁰ Beard S, et al. Health Technol Assess 2003;7(40)

¹¹ Multiple Sclerosis Trust. Spasticity and Spasms factsheet. November 2009

¹² Rizzo MA, et al. Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Multiple Sclerosis* 2004;10:589/595

¹³ Multiple Sclerosis International Federation. Spasticity in MS. *MS in focus*. Issue 12. 2008. Available at <http://www.msif.org/docs/MSinFocusIssue12EN.pdf> (Last accessed: 26/08/10).

This news release may contain forward-looking statements that reflect GW's current expectations regarding future events, including the clinical development and regulatory clearance of its products. 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 GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies, including with respect to Sativex and GW's other products, the uncertainties related to the regulatory process, and the acceptance of Sativex and other products by consumers and medical professionals.

This new release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.ca. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.