



Press Release - For Immediate Release

## Sativex - Novel cannabis derived treatment for MS pain now available in Canada by prescription.

TORONTO, Ontario – (June 20, 2005) – Sativex® (Cannabis sativa L.extract), the only adjunctive treatment for symptomatic relief of neuropathic pain in adults with multiple sclerosis (MS), is now available in Canada. The novel treatment can now be obtained by prescription through Canadian pharmacies. In April 2005, Canada became the first country in the world to approve Sativex, an effective and safe cannabis derived prescription medicine. Health Canada has approved Sativex with conditions, under the Notice of Compliance with Conditions (NOC/c) policy. This authorization reflects the promising nature of the clinical evidence, which will be confirmed with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use.

"Effective pain control and management are extremely important in a disease like MS," said Dr. Allan Gordon, Neurologist and Director of the Wasser Pain Management Centre, and of the Edward Bronfman Family Foundation MS Research Clinic at Mount Sinai Hospital, Toronto, Ontario. "The availability of Sativex addresses the great demand for an effective treatment option in the field of neuropathic pain in MS. Many patients, including some in my own practice, report using cannabis for

relief of their pain. People with MS and neuropathic pain should speak to their doctor to determine whether Sativex is an appropriate option for them.

"Sativex Available in Canada/2

### How it works

Sativex is administered through a spray pump under the tongue or on the inside of the cheek, providing reliable, self administered pain relief. The spray formulation allows for more flexible dosing than an oral tablet, well suited to the variable nature of neuropathic pain experienced by people with MS.

"Sativex will be welcomed by the Canadian MS community," said Dr. William J. McIlroy, National Medical Advisor, Multiple Sclerosis Society of Canada. "Neuropathic pain associated with MS is often under treated and under controlled. The availability of Sativex will now allow people living with MS and neuropathic pain a new treatment option to address one of the more debilitating symptoms associated with the disease."

### Principal components

Sativex is a product resulting from the pioneering research efforts of UK based GW Pharmaceuticals plc and is marketed in Canada by Bayer HealthCare, Pharmaceuticals Division. Its principal active cannabinoid components are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).<sup>1</sup> The ratio of THC to

CBD in Sativex is 2.7 mg : 2.5 mg per spray, ensuring a standardized dose is delivered each time it is used.

### Neuropathic pain

Pain is a common symptom of MS occurring in up to 86 per cent of people with MS.<sup>2</sup> Neuropathic or nerve pain can occur spontaneously or can be provoked by touch, temperature or movement. It is estimated that 50 per cent of people with MS suffer from chronic neuropathic pain.<sup>3,4,5</sup> The most common descriptions of neuropathic pain are of freezing, cold or burning sensations usually of the limbs and most often of the lower extremities.<sup>6</sup> Many individuals with neuropathic pain respond inadequately to current treatment options.<sup>7,8</sup>

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### Data demonstrates efficacy<sup>1</sup>

While there is no complete cure for MS or neuropathic pain, a double-blind placebo controlled parallel group study demonstrated that Sativex provided significantly greater pain relief than placebo. Sativex also significantly reduced pain-related sleep disturbance.

Sativex and side-effects<sup>1</sup>

In clinical trials, the most frequent side-effects included nausea, fatigue, dizziness and application site reactions. Side-effects were usually mild or moderate in severity and often resolved with down-titration or interruption of treatment.

### REFERENCES:

(1) Sativex Product Monograph - April 2005 (2) Ehde DM, et al. *Multiple Sclerosis* 2003; 9: 605-611. (3) Archibald CJ, et al. *Pain* 1994; 58:89-93. (4) Sketris IS, et al. *Clinical Therapeutics* 1996; 18(2):303-318. (5) Moulin DE, et al. *Neurology* 1988;38:1830-1834. (6) Multiple Sclerosis International Federation, [http://www.msif.org/en/symptoms\\_treatments/ms\\_by\\_topic/pain/ms\\_society\\_articles/](http://www.msif.org/en/symptoms_treatments/ms_by_topic/pain/ms_society_articles/) (7) Harden N and Cohen M. *Journal of Pain Symptom Management* 2003; 25 (5 Suppl): S12-S17. (8) *New Directions in Neuropathic Pain: Focusing Treatment on Symptoms and Mechanisms*. Royal Society of Medicine Press Ltd.: 2000. (9) <http://www.mssociety.ca/en/information/faq.htm>

Canadian Neuropathy Association  
*Empowering the Patient*

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### Sativex - Novel cannabis derived treatment for MS pain now available in Canada by prescription - continued

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MS is a disease of the central nervous system and is the most common neurological disease affecting young adults in Canada. Approximately 50,000 Canadian men and women have the disease and each day approximately three more people are diagnosed. MS is most often diagnosed in people between the ages of 20 to 40 years of age.

#### About Bayer HealthCare AG

Bayer HealthCare AG, a subsidiary of Bayer AG, is one of the worlds leading, innovative companies in the health care and medical products industry. In 2004, the Bayer HealthCare subgroup generated sales amounting to some 8.5 billion Euro. The company combines the global activities of the divisions Animal Health,

Biological Products, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Bayer HealthCare employed 35,300 people worldwide in 2004.

Bayer HealthCare's aim is to discover and manufacture innovative products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating disease. -more-

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*This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.*

#### About GW Pharmaceuticals plc

GW Pharmaceuticals plc is licensed by the UK Home Office to undertake a pharmaceutical research and development program to develop non-smoked cannabis-based prescription medicines. GW's shares are publicly traded on AiM, a market on the London Stock Exchange.

Full details of GW and the company's clinical trials program can be found at [www.gwpharm.com](http://www.gwpharm.com). GW's clinical research program is being carried out by a team of pharmaceutical professionals experienced in drug development and, in particular, the development of plant-based medicines and drug delivery systems.

*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.*

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#### FOR FURTHER INFORMATION, PLEASE CONTACT:

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- (1) Sativex Product Monograph - April 2005 (2) Ehde DM, et al. *Multiple Sclerosis* 2003; 9: 605-611. (3) Archibald CJ, et al. *Pain* 1994; 58:89-93. (4) Sketris IS, et al. *Clinical Therapeutics* 1996; 18(2):303-318. (5) Moulin DE, et al. *Neurology* 1988;38:1830-1834. (6) *Multiple Sclerosis International Federation*, [http://www.msif.org/en/symptoms\\_treatments/ms\\_by\\_topic/pain/ms\\_society\\_articles/](http://www.msif.org/en/symptoms_treatments/ms_by_topic/pain/ms_society_articles/) (7) Harden N and Cohen M. *Journal of Pain Symptom Management* 2003; 25 (5 Suppl): S12-S17. (8) *New Directions in Neuropathic Pain: Focusing Treatment on Symptoms and Mechanisms*. Royal Society of Medicine Press Ltd.: 2000. (9) <http://www.mssociety.ca/en/information/faq.htm>





I would like to take a few minutes and tell you about a man I met while surfing the 'Net for new treatments for Neuropathy sufferers.



**Jos Creusen**  
Maker of Grafiek (Graph) -06/06/2006  
<http://www.creusen-software.nl/>

*When you download Jos's program, you need to sign his guest book and then he will send you the activation code.*

*I really think Jos's program would benefit us as Neuropathy patients by monitoring things like:*

- a. Pain level at meal times.*
- b. Duration of pain levels.*
- c. Location of pain.*
- d. Medication check list.*

*If you can think of ways it could help us, please email me with a description of your request and I will forward it to Jos. If you have a concern with your diabetes and Jos's program, please email Jos directly. Mail to Jos: [j.creusen@chello.nl](mailto:j.creusen@chello.nl)*

Jos was born in 1950 in Eindhoven, Holland, and has 2 children. Jos has worked for more than 25 years as a system engineer for one of the biggest IT-companies in the world.

Jos has had Type 1 Diabetes since 1986. In 1997 after trying several programs from several manufacturers, Jos thought he could make a better program, more user-friendly, manufacturer independent, and most important, he could give it away for free. In 1999 it was beta-tested and in 2000 he announced that he was ready to give it away for free through his website.

Up to now he has almost 2000 users from all over the world. He works all alone on the program and website and answers all questions by email.

This program was made for persons with Type I and Type II diabetes. However, after going through the program myself, I realize that it would be a good tool for Neuropathy patients to use as well.