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News Release

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Sativex[®] launched in UK for the treatment of spasticity due to Multiple Sclerosis

Newbury, Berkshire, 21st June 2010 – Sativex[®] (delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)), the first cannabinoid medicine derived from whole plant extracts from the *cannabis sativa* plant, is launched today to treat spasticity associated with Multiple Sclerosis (MS) by Bayer Schering Pharma.¹ Available as a prescription only medicine and given as a mouth spray, the launch of Sativex[®] means that now, for people with MS experiencing the spasms and cramping associated with spasticity, there is another option to add to their standard treatment.

There are approximately 100,000 people with MS in the UK and spasticity is very common, affecting most people with the condition at some point.^{2,3} It causes uncontrollable stiffness, muscle tension and spasms,⁴ which are often extremely painful and immobilising. Simple day to day activities that people take for granted like unscrewing the lid off a milk bottle or being able to get out of a car can become very difficult. Not only does this cause people with MS huge distress, quality of life, self-image and mood can be greatly affected.⁴

Speaking about the availability of Sativex[®], Pam Macfarlane, Chief Executive of the MS Trust said, 'We have been aware for a long time, based on comments from people with MS, that cannabis based medicines can significantly improve spasticity which is a common, complex symptom of MS. For this reason the MS Trust has campaigned for the availability of a licensed medicine that can be properly controlled and prescribed. We have also invested money and resources in developing the body of knowledge by funding clinical research into the effectiveness of cannabis based medicines. The launch of Sativex[®] is therefore a milestone for the NHS and the MS Trust, and we are delighted. It will now be down to specialist professionals to assess people and we hope that this can happen quickly'.

As with many medicines, Sativex[®] does not work for everyone. The clinical trials show that about half of all people who add it to their existing medication find that it can provide relief from the debilitating symptoms of spasticity associated with MS.⁵ It contains active ingredients called cannabinoids which are extracted from cannabis plants grown in a strictly controlled environment.

Professor John Zajicek, Consultant in Neurology at Derriford Hospital, Plymouth and a world leader in cannabinoid research commented, 'The launch of Sativex[®] is a milestone in the journey of cannabinoid medicines.' He continued, 'Existing treatments used to help people experiencing spasms and cramps often produce side effects that can be difficult to cope with. Sativex[®] has mainly mild to moderate side effects which are usually controlled by simply adjusting the dose. It is a good addition to existing treatments which will be of great benefit in the future.'

Talking about the launch of Sativex[®], Simon Gillespie, Chief Executive of The MS Society said, 'The launch of any new medicine to help people with MS is good news and we know from our members that Sativex[®] has been long awaited. We hope that it will be made freely available on the NHS to anyone who might benefit from it.'

Sativex[®] is only available on prescription from specialist doctors with experience in treating MS spasticity. It is sprayed into the mouth either onto the inside of the cheek or under the tongue. The person with MS decides how many sprays they need in any one day which is typically 8 sprays per day (daily limit of up to 12 sprays).¹ Extensive clinical trials mean that there is now about one thousand patient years exposure to Sativex[®] in the UK.⁶

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Note to Editors

About MS

Multiple sclerosis (MS) is a condition that affects approximately 100,000 people in the UK in which damage occurs within the central nervous system (CNS - brain and spinal cord).² As the nerves of the CNS control the functions of the whole body, symptoms can affect many different areas.⁷ 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.^{7,8} MS is twice as common in women than in men.^{7,8}

More information can be found on the following patient group websites:

- MS Society <http://www.mssociety.org.uk/>
- MS Trust <http://www.mstrust.org.uk/>

About spasticity

Spasticity is a common symptom associated with Multiple Sclerosis (MS)³ and is a major contributor to disability.⁹ 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.¹⁰

In a survey, 84% of people with MS reported symptoms of spasticity.¹¹ 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.³ In addition to causing a great deal of distress to the person with MS, mood, self-image and motivation can also be affected.⁴

About Sativex[®]

Sativex[®] was developed by UK-based GW Pharmaceuticals plc in specific response to the MS population's unmet need for a prescription cannabis based medicine. Manufactured under Home Office licence at an undisclosed location in the UK, Sativex[®] will be marketed in the UK by Bayer Schering Pharma.

Sativex[®] is indicated as add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.¹

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 occur naturally throughout our bodies, including in our brains.¹² A receptor is a site on a brain cell where certain substances can stick or "bind" for a while. If this happens, it has an effect on the cell and the nerve impulses it produces, which causes a 'dimming down' of the symptoms of spasticity. In patients who respond to Sativex[®], it is this effect which helps to improve their symptoms of spasticity and to help them cope better with their usual daily activities.¹³

Sativex[®] is primarily made up of a 1:1 ratio of two particular cannabinoids - cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC).¹⁴ The CBD:THC formulation is believed to provide a good balance of clinical effect - a significant decrease in MS spasticity- to THC-related side effects.^{13,14}

Main effects of CBD and THC:¹³

CBD	THC
Anti-inflammatory, anticonvulsant, antipsychotic, anti-oxidant, neuroprotective, immunomodulatory	Analgesic, anti-spasmodic, anti-tremor, anti-inflammatory, appetite stimulant, anti-emetic

The most common side effects of Sativex[®] are dizziness, which occurs mainly in the first few weeks of treatment, and fatigue. These reactions are usually mild to moderate and improve within a few days even if treatment is continued.¹

Of the 84% of people with MS who have reported symptoms of spasticity, approximately 11,500 would be eligible for treatment with Sativex (those who are already on combination therapy). Of these about 50% will have a good response from Sativex[®].⁵ The NHS price for Sativex[®] is £125 per 10ml vial which for a typical patient means approximately £11 per day.¹⁵

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

More information for the press can be found at www.sativex.co.uk

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Haematology & Neurology, Oncology and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialised markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of patients' lives.

Further information can be found at www.bayerscheringpharma.co.uk

About GW Pharmaceuticals

GW Pharmaceuticals plc (AIM: GWP) 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

Forward-Looking Statements

This 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.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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