

MEDIA RELEASE

SATIVEX® NOW AVAILABLE IN AUSTRALIA FOR MS SPASTICITY

- *Sativex (nabiximols) is the only prescription cannabinoid medicine licensed by the TGA in Australia for the treatment of moderate and severe spasticity due to multiple sclerosis (MS)*
- *Availability of Sativex in Australia follows UK, Canada, various European and other countries where Sativex is prescribed routinely for this indication*

6 November 2017 (Sydney) – GW Pharma Ltd together with Emerge Health today announced that Sativex®, the first and only oromucosal cannabinoid treatment, is now available on prescription (Schedule 8) in Australia for the treatment of adults with spasticity due to multiple sclerosis.

Sativex is registered on the Australian Register of Therapeutic Goods (ARTG) specifically for 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

Based on information from the NARCOMS registry of MS patients (n=20,969), 16% of the patients reported no spasticity, 31% minimal, 19% mild (occasional), 17% moderate (frequently affects activities), 13% severe (need to modify daily activities) and 4% total (prevents daily activities). About one third of the respondents reported moderate or worse spasticity despite ongoing single and multiple drug use.²

Dr John Parratt, leading Sydney neurologist, based at Royal North Shore Hospital, welcomes the availability of Sativex in Australia.

“Treating MS patients every day is rewarding but also challenging, especially managing symptoms such as spasticity. For these people this muscle stiffness causes rigidity and pain which may prevent them from being able to move their limbs. We have a good range of disease modifying treatments available for MS in Australia but treatment options specifically designed to address complex, interrelated symptoms like spasticity are limited. Spasticity as a symptom due to MS has a major impact on patients and carers’ lives so anything that can ease that burden is definitely useful to have as part of the treatment options” said Dr Parratt.

“There has also been a fair bit of hype around cannabis based products as a clinical solution. I think this is a great time to stress that Sativex, as with any pharmaceutical product registered by the TGA for use in Australia, is an approved, standardised medicine” he added.

Sativex is a clinically tested, standardized, cannabinoid-based medication produced from cultivated Cannabis sativa L. plants. The drug substances are partially purified extracts. The plants have been specifically bred to produce two separate chemotypes, expressing their cannabinoid content as high delta-9-tetrahydrocannabinol

(THC) or high cannabidiol (CBD) chemotypes. Each 100 microlitre spray contains 2.7 mg THC and 2.5 mg CBD. Each 100 microlitre spray also contains up to 0.04 g alcohol.¹

Sativex modulates the body's endocannabinoid system, which plays an important role in signal transduction in the central nervous system.^{3,4} In some diseases, such as multiple sclerosis, the activity of the endocannabinoid system can be altered which in turn can lead to spasticity and other associated symptoms.⁵

Certain active substances from the cannabis plant, so-called Phytocannabinoids, can be used to mimic the effect of the body's endocannabinoid system and alleviate spasticity symptoms in MS.^{4,6}

More than 1500 patients have been treated with Sativex in the clinical studies programme to date. More than 3500 patients have been monitored for safety and efficacy in observational studies in the EU with over 50,000 patient year's exposure through clinical studies and prescription use for Sativex.⁷

Sativex is now registered across 29 countries worldwide.

About GW Pharma Ltd

Since 1998 GW has established a world leading position in the development of plant-derived cannabinoid therapeutics through its proven drug discovery and development processes, intellectual property portfolio and regulatory and manufacturing expertise.

GW commercializes a plant-derived cannabinoid prescription drug, Sativex, which is approved for the treatment of spasticity due to multiple sclerosis in 29 countries.

GW Pharma Ltd is listed on the NASDAQ Global Market (GWPH). The company has operations in both the US and the UK. In Australia GW has partnered with a local company Emerge Health Pty Ltd based in Melbourne who hold the marketing authorisation for Sativex.

For further information, please visit www.gwpharm.com

About Emerge Pty Ltd

Emerge Health Pty Ltd is an innovative, specialised Australian pharmaceutical company focused on the marketing and sales of niche, high quality medicines to the hospital sector.

Emerge Health is the Sponsor of Sativex in Australia and New Zealand and will be responsible for the distribution of the product across both countries.

For further information, please visit www.emergehealth.com.au

About MS spasticity

Up to 84% of patients with MS experience spasticity during the course of their disease.² Spasticity is a painful and disabling symptom that significantly limits quality of life. Although some people with MS experience little disability during their lifetime, up to 60% are no longer fully ambulatory 20 years after onset, with major implications for their quality of life and the financial cost to society.⁸ The more severe the spasticity due to MS, the lower the quality of the patient's life.⁹

About pivotal trials

Sativex has been studied in Phase 1-Phase 3 studies, the same as any other pharmaceutical product, for registration to obtain marketing authorization in Europe, Australia and other countries. Additionally since 2012 a further seven post-marketing studies have been completed and reported in Europe to validate the efficacy, tolerability and safety data from the pivotal studies.

Administration

Treatment must be initiated and supervised by a specialist neurologist or rehabilitation physician with expertise in treating patients with spasticity due to multiple sclerosis. Sativex is for oromucosal use only. The number of sprays a patient needs depends on the individual. Based on the number of sprays used in the pivotal clinical studies and post marketing data from other countries one pack (3x10 ml vials) may last between 4 to 6 weeks.

Sativex safety

The most commonly reported adverse reactions in the first four weeks of exposure were dizziness, which occurs mainly during the initial titration period, and fatigue. High doses of Sativex increase the risk of serious psychiatric adverse events including psychosis, hallucinations, delusions, and homicidal and suicidal ideation. Care should be taken with hypnotics, sedatives and drugs with potential sedating effects as there may be an additive effect on sedation and muscle relaxing effects. The abrupt withdrawal of long-term Sativex treatment has not resulted in a consistent pattern or time-profile of withdrawal-type symptoms and the likely consequence will be limited to transient disturbances of sleep, emotion or appetite in some patients.¹

Further information about the safety profile of Sativex can be found in the Product Information.

The full Sativex® Product Information is available at-

<https://tga-search.clients.funnelback.com/s/search.html?query=sativex&collection=tga-artg>

PBS Information: Sativex is not listed on the PBS.

— ENDS —

Sativex® (nabiximols) is a registered trademark of GW Pharma Ltd.

Notes to editor: Dr John Parratt has received honoraria as a chairperson for an educational meeting from GW Pharma Ltd and from Bayer Schering, Biogen, CSL Biotherapeutics, Teva, Novartis & Sanofi/Genzyme for education and research grants from Merck, Genzyme, Biogen, Teva and Novartis pharmaceuticals in the past.

References

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