CONSUMER MEDIA RELEASE



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<u>Please note this is not a new announcement. This media release has been uploaded retrospectively,</u> <u>following consultation with Medicines Australia.</u>

New treatment for most common form of MS now available on PBS

Australians living with the most common form of multiple sclerosis (MS) will gain access to a new treatment option with the listing of Zeposia (ozanimod) on the Pharmaceutical Benefits Scheme (PBS) for relapsing-remitting MS (RRMS) today (March 1, 2021).¹

Zeposia (ozanimod) is an oral treatment for adult patients with relapsing forms of MS.² It is known as a disease modifying therapy (DMT), which alters immune system activity to help reduce the frequency of attacks to the central nervous system, which includes the brain, spine and optic nerve.^{3,4}

The PBS listing of Zeposia coincides with the publication of an article in the <u>Medical Journal of</u> <u>Australia's Insight+</u> highlighting the role DMTs have played over the past few decades in managing RRMS, the current management of the disease, and the hope that continued advances in research and treatment will enable some patients to avoid major disability in the future.

According to article author, Clinical Associate Professor Todd Hardy, Co-Director of the MS Clinic, Brain and Mind Centre, The University of Sydney, treatment for MS must be tailored to the individual, given the highly varying and unpredictable nature of the disease.³

"MS affects how the body and brain communicates.⁵ The disease causes the immune system to attack the central nervous system, resulting in irreversible scarring on the nerves. This scarring causes messages that travel along the nerves from the brain to the body to be blocked or distorted, compromising physical and cognitive function.^{5,6}

"The symptoms of MS are extremely varied and unpredictable, depending on which part of the central nervous system is affected, and to what degree.⁷ Cognitive, physical and psychosocial symptoms of MS can vary greatly between person to person. Even a person's own symptoms can vary over time,"⁸ said A/Prof Hardy.

"In Australia, patient access is enhanced by the availability of RRMS treatment options via the PBS.

"As clinicians, we welcome the availability of an additional treatment option to help reduce the frequency of relapses, and slow the progression of disability in our patients living with RRMS," A/Prof Hardy said.



More than 25,600 Australians are currently living with MS,^{9,10} with an estimated 30 new people diagnosed each week.¹¹ MS is the most commonly diagnosed neurological disease in younger adults, with most people diagnosed between the ages of 20 - 40 years.^{9,10}

Representing 85 per cent of MS diagnoses,¹² RRMS is marked by relapses of new, or worsened symptoms or 'attacks', which can last for days or months, with intervals of partial, or complete remission in between.¹²

MS Australia CEO, Mr Rohan Greenland, today welcomed the reimbursement of a new treatment option for those living with RRMS.

"While research is advancing into the cause, prevention and cure of the disease, to date, MS remains incurable. Treatment can, however, help people with MS manage their symptoms, relapses, and importantly, slow disability progression.¹³

"The nature and experience of those living with MS is varied and individualised, which is why MS Australia advocates for more affordable and accessible treatments, to help improve the lives of those living with the incurable disease.¹⁴

"The PBS listing of Zeposia represents a valuable addition to the repertoire of affordable treatments available to those living with RRMS in Australia," said Mr Greenland.

Common physical symptoms of MS can include fatigue, limb weakness, altered sensations, such as pins and needles or numbness, muscle spasms or tremors, neurological pain, slurred speech, visual disturbances, incontinence, and constipation.¹⁵ MS can cause cognitive symptoms, including brain fog, slow thinking, and impaired memory and concentration, in addition to personal and emotional changes, anxiety, depression, and difficulties sleeping.¹⁵

The symptoms of MS can diminish quality of life by compromising one's relationships, education, finances and career.¹⁶

Learning Support teacher, children's storybook author, and mother-to-three, Nadine (49), was diagnosed with RRMS almost seven years ago. Although initially overwhelmed by her diagnosis, Nadine chose to embrace life, and use her MS to fuel her zest for life.

"Everyone's journey with MS is completely different, from the symptoms we face, to the realities of managing the disease. MS has an impact on our physical and emotional well-being, and I am passionate about sharing my experience to help shed light on the variable nature of symptoms," Nadine said.

"My symptoms come in cycles, as is the nature of RRMS. Fatigue can hit me hard, and quite suddenly, like the flick of a switch, which prevents me from working full-time, and impacts my daily activities.

"I just try to get on with my life as much as possible and take each day as it comes. I'm fortunate my symptoms have been fairly manageable, but MS is such an unpredictable disease and I live in fear it may all change overnight," said Nadine.

Neil MacGregor, General Manager of Bristol-Myers Squibb Australia and New Zealand, said today's listing is another milestone for Australian patients living with MS.



"We share this achievement with the MS patient community, and are pleased another treatment option is available from today," Mr MacGregor said.

About Zeposia (ozanimod)

Zeposia can affect the ability of some white blood cells to move freely within the body, and stops them from reaching the central nervous system (the brain, spine and optic nerve), where they can cause inflammation and damage. In doing so, Zeposia may help protect against attacks on the nerves, reduce inflammation and damage to the nerves' protective coating, and slow down the progression of disability.¹⁷ The reimbursement of Zeposia was supported by data from the randomised, active-controlled Phase 3 SUNBEAM and RADIANCE clinical trials, which enrolled more than 2,600 patients across 150 sites in more than 20 countries. Zeposia 920 mcg* was generally well tolerated in the Phase 3 studies, with low rates (1%) of serious infection, and approximately 3% of patients discontinued due to adverse events.^{18,19}

Zeposia Consumer Medicines Information can be found here.

About multiple sclerosis

Multiple sclerosis (MS) is a condition of the central nervous system (CNS) that interferes with nerve impulses within the brain, spinal cord and optic nerves.⁹ MS causes the immune system to attack the myelin sheath - a white fatty substance that coats and protects CNS nerve cells.²⁰ The damage to the myelin sheath causes lesions which disrupt communication signals between the brain and the rest of the body.^{10,21} This breakdown of communication signals manifests into various symptoms, depending on where MS lesions develop on the brain and spinal cord.^{9,21} Ultimately, the nerves themselves may deteriorate - a process that is currently irreversible.¹⁵

While the cause of MS remains unknown, a combination of genetic, immunologic, environmental and infectious factors have been found to contribute to disease onset.^{15,22}

Disclosure

Bristol-Myers Squibb[™] supports disclosure and transparency on interactions between the healthcare industry and healthcare professionals to ensure public trust and confidence. No expert spokespeople have been offered compensation for their involvement in this media campaign. All expert spokespeople have been briefed on the approved use of this product and their obligations, with regard to promotion to the general public. A/Prof Todd Hardy was a member of the Zeposia (ozanimod) Advisory Board in 2020, and was reimbursed for his time.

About Celgene™

Celgene, a Bristol-Myers Squibb[™] Company, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialisation of innovative therapies for the treatment of cancer and inflammatory diseases, through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, visit www.celgene.com.au.

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