Consumer News Release- SPRAVATO® (esketamine hydrochloride) TGA Announcement

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- *SPRAVATO® (esketamine hydrochloride) nasal spray is now available in Australia for treatment resistant depression.[1]*
- *Depression is the leading cause of disability worldwide and is forecast to be the leading cause of global disease burden by 2030.[2]*
- *One-third of Australians living with Major Depressive Disorder (MDD) cycle through multiple antidepressant treatments without relief.[3,4,5]*
- *Treatment Resistant Depression is defined as lack of improvement in MDD symptoms following adequate trials of two or more antidepressants.[6]*
- *COVID-19 has increased the prevalence of new cases of major depressive disorder (MDD) and depressive symptoms, creating a heightened state of anxiety worldwide.[4,7]*

AUSTRALIA, 23 NOVEMBER 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the availability of a novel nasal spray medication for treatment resistant depression (TRD) marking one of the most significant milestones for depression treatment in decades.[1,7,8]

The availability follows the Therapeutic Goods Administration (TGA) approval of SPRAVATO® (esketamine hydrochloride) nasal spray, in combination with an oral antidepressant, for adults with treatment resistant depression (TRD) *(Major Depressive Disorder in adults who have not responded adequately to at least two different antidepressants of adequate dose and duration to treat the current moderate to severe depressive episode).*[1]

SPRAVATO® is the only approved antagonist of the N-methyl-D-aspartate (NMDA) glutamate receptor for treatment resistant depression in Australia.[1,9] It is administered via a non-invasive nasal spray under specialist clinical supervision to ensure that the medication is correctly administered and the safety of the patient considered first.[9]

Depression is the leading cause of disability worldwide and is forecast to be the leading cause of global disease burden by 2030.[2] Sadly, about one-third of people with major depressive disorder (MDD) do not respond to traditional antidepressant treatments.[10] This is set to increase with the prevalence of MDD and depressive symptoms rising worldwide as a consequence of COVID-19.[4,7]

People living with MDD can experience a depressed mood and/or loss of interest or pleasure in almost all activities. One-third of people living with MDD experience TRD, where there is a lack of improvement in MDD symptoms following adequate trials of two or more antidepressants.[10,11] Compared to other forms of MDD, depressive episodes for people living with TRD are twice as long, with significantly higher rates of co-morbidities.[12,13]

"For people living with treatment resistant depression, the lack of response to existing treatments not only prolongs suffering but reduces their expectations of future treatment success and perpetuates the negative thoughts that are associated with TRD," [6] said Professor Ian Hickie, Brain and Mind Centre at the University of Sydney.

When people fail to recover, their depression can be defined as treatment resistant. Treatment-resistant is a lack of improvement following adequate trials of two or more antidepressants.[11]

"Until now, treatments have focused on the same monoaminergic pathway – with some options being lengthy and ineffective for a number of people with MDD. Many patients cycled through treatments with no resolve, feeling desperate for options that worked for them," said Prof Hickie. *"We now have the potential to change the way we treat depression and offer another option for Australians living with this debilitating illness".*

"Despite there being greater awareness of mental health, depression is a largely misunderstood and stigmatised disease. Many do not know that there is more than one type of depression – it's a spectrum and every experience is different," said Tony Stevenson, Chief Executive Officer, Mental Illness Fellowship of Australia. *"Living with depression has a profound impact on quality of life and function, which not only affects the individual, but also the network of friends and family around them. There remains a need to look differently at how we manage MDD. The availability of another treatment option is welcomed news for people living with MDD, who have previously felt desperate for anything to work."*

To receive SPRAVATO®, patients should discuss with their treating doctors to learn more about their eligibility and access to treatment. Eligible patients will be referred to a trained site for administration.[1,9] Janssen is now working with over 20 centres across Australia to ensure eligible patients can access SPRAVATO® from a range of locations including in some regional areas. Each centre will have its own independent referral criteria and can advise their GP networks of this criteria.

"Janssen has a strong heritage in helping to reduce the burden, disability and devastation caused by mental illness and is committed to transforming individual lives. With the listing of SPRAVATO®, we are proud to have introduced the first new class of treatment for treatment resistant depression in over a decade. We recognise the need for a holistic approach to treatment resistant depression and know medicines are only part of the solution. We are committed to continuing our work, in partnership with Australia's mental health community, to re-define the course of MDD and transform the mental health space for good," said Biljana Naumovic, Managing Director, Janssen Australia and New Zealand.

Janssen is planning a second submission to the Pharmaceutical Benefits Advisory Committee (PBAC) to ensure that eligible patients will be able to access the treatment via the Pharmaceutical Benefits Scheme (PBS) in the future.

Like all medicines, SPRAVATO® can cause side effects. When used along with an antidepressant taken by mouth included, SPRAVATO may cause: dissociation, dizziness, nausea, sedation, spinning sensation, reduced sense of touch and sensation, anxiety, lack of energy, increased blood pressure, vomiting, and feeling drunk.[9] The adverse events were mild to moderate, transient and resolved within 2 hours of dosing.[14,15,16,17,18]

SPRAVATO® (esketamine hydrochloride) Consumer Medicines Information is available at: www.janssen.com.au/SPRAVATO_cmi

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

SPRAVATO® esketamine hydrochloride MINIMUM PRODUCT INFORMATION
WARNING: During and after SPRAVATO administration patients must be monitored for blood pressure, sedation and dissociation until clinically stable. SPRAVATO is to be provided by the Healthcare Professional for patients to administer under their direct supervision. Patients should be instructed not to drive or operate machinery until next day (see full Product Information, 4.2 DOSE AND METHOD OF ADMINISTRATION). There is no safety and efficacy data for the use of SPRAVATO in patients under 18 years old.[1]

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Issued by WE Communications on behalf of Janssen Australia.

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Additional notes for media

About SPRAVATO® (esketamine hydrochloride)
SPRAVATO is the first and only approved antagonist of the N-methyl-D-aspartate (NMDA) glutamate receptor.[9] The precise mechanism of action for SPRAVATO® is unknown.[19] It is proposed that SPRAVATO® exerts its antidepressant effects through modulating glutamatergic neurotransmission.[20,21,22,23,24] With the approval of SPRAVATO comes the first new mechanism of action for MDD in decades.

SPRAVATO is administered via a non-invasive nasal spray under specialist clinical supervision, allowing it to be absorbed by the lining of the nasal passages and move into the blood stream.[9] As SPRAVATO is a Schedule 8 medicine, too receive it, eligible patients with TRD will

be referred to a trained SPRAVATO® site for administration, supervised by a specialist healthcare provider.

About Major Depressive Disorder & Treatment-Resistant Depression
Major Depressive Disorder (MDD) is also known as 'depression' or 'clinical depression', and is characterised by a persistently depressed mood that affects quality of life.[7] People living with MDD experience a depressed mood and/or loss of interest or pleasure in almost all activities. Their symptoms are present nearly every single day for at least two weeks and can often be long-lasting and recurrent.[3,25]

MDD, like other leading health conditions, is a spectrum – every experience with MDD is different. For some it may be a lifelong chronic condition, for others, their experience may be more severely acute.[7] Individuals with depression, including major depressive disorder, experience continuous suffering from a serious, biologically based disease which has a significant negative impact on all aspects of life, including quality of life and function.

Although currently available antidepressants are effective for many patients, about one-third of patients do not respond to treatment and are thought to have treatment resistant depression (TRD).[10] TRD is defined as a lack of improvement in MDD symptoms following adequate trials of two or more antidepressants.[3] TRD is a devastating chronic condition that has a profound lifelong impact, placing ongoing emotional, functional, and economic burden on the individual, their loved ones, and society.[26]

To learn more, visit https://www.janssen.com/australia/stories/breaking-depression

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Janssen Australia and New Zealand (Janssen-Cilag Pty Ltd.) is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Learn more at www.janssen.com.au. Follow us on Twitter @JanssenANZ.

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