

**Media Contact:**

Greg Panico
908-240-2011 (mobile)
gpanico1@its.jnj.com

Investor Contacts:

Christopher DelOrefice
732-524-2955 (office)

Lesley Fishman
732-524-3922 (office)

FDA Advisory Committee Recommends Approval of SPRAVATO™ (esketamine) Nasal Spray CIII for Adults with Treatment-Resistant Depression

If approved, SPRAVATO™ will offer the first new mechanism of action in 30 years to treat this debilitating disease, continuing Janssen's 60-plus-year history and commitment to research that make a difference for people living with mental illnesses, including severe mood disorders

TITUSVILLE, N.J., February 12, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee jointly voted (14 yes, 2 no, 1 abstain) that data support the favorable benefit-risk profile of SPRAVATO™ (esketamine) nasal spray CIII for adults living with treatment-resistant depression. SPRAVATO™ is an investigational prescription treatment that is thought to work differently than currently approved therapies for major depressive disorder (MDD). Janssen announced on September 4, 2018 that it submitted a New Drug Application (NDA) to the FDA for the approval of SPRAVATO™.¹ If approved, SPRAVATO™ would provide the first new mechanism of action in 30 years to treat this debilitating mental illness.^{2,3}

"We are pleased with the advisory committees' vote and their recommendation to approve SPRAVATO™ as a potential therapy for adults living with treatment-resistant depression," said Husseini K. Manji, M.D., Global Head, Neuroscience Therapeutic Area, Janssen Research & Development, LLC. "Our comprehensive research program for esketamine nasal spray supports a positive benefit-risk profile for adults with treatment-resistant depression."

The committees based their support on the safety and efficacy data from five Phase 3 studies in patients with treatment-resistant depression: three short-term studies; one maintenance of effect study; and one long-term safety study. In addition, the SPRAVATO™ research program provided supportive data from three Phase 2 studies and 19 Phase 1 studies in patients with treatment-resistant depression and healthy volunteers. Data from both a short-term Phase 3 study and a long-term Phase 3 study demonstrated that esketamine nasal spray plus a newly initiated oral antidepressant provided statistically significant, clinically meaningful, rapid, and sustained improvement of depressive symptoms in this difficult-to-treat population.^{4,5} All the patients who participated in the Phase 3 studies

received esketamine or placebo in addition to a newly initiated oral antidepressant at the start of the treatment phase.

The long-term safety study showed that esketamine was generally tolerable, with no new safety signals with dosing up to 52 weeks compared to data from short-term (4-week) studies.⁶ Discontinuation rates due to esketamine-related adverse events were low and occurred typically in the first weeks. Most treatment-emergent adverse events, including dissociative symptoms, dizziness/vertigo, increased blood pressure, and sedation, occurred shortly after dosing while patients were under the supervision of a health care professional, were transient, and resolved the same day. In addition to the comprehensive clinical research program, the company proposed a robust Risk Evaluation and Mitigation Strategy (REMS).

While the FDA is not bound by the committees' recommendation, it does take its advice into consideration. The Prescription Drug User Fee Act (PDUFA) date for SPRAVATO™ is March 4, 2019.

About SPRAVATO™

SPRAVATO™ (esketamine) nasal spray is an investigational product being studied by Janssen Research & Development, LLC as part of a global development program. Esketamine is a glutamate receptor modulator, thought to help restore synaptic connections in brain cells in people with major depressive disorder. It is believed to have a novel mechanism of action, meaning it is thought to work differently than currently available therapies for major depressive disorder.

The U.S. FDA has granted Breakthrough Therapy Designations for esketamine for treatment-resistant depression and for a second indication, major depressive disorder with imminent risk for suicide.⁷

About Treatment-Resistant Depression

Major depressive disorder affects nearly 300 million people of all ages globally and is the leading cause of disability worldwide. 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.⁸ 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.⁹

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits of

esketamine. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; manufacturing difficulties and delays; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

#

References

1. Johnson & Johnson Press Release. Janssen Submits Esketamine Nasal Spray New Drug Application to U.S. FDA for Treatment-Resistant Depression. Available at: <https://www.jnj.com/janssen-submits-esketamine-nasal-spray-new-drug-application-to-u-s-fda-for-treatment-resistant-depression>. Accessed September 2018.
2. Duman RS. Ketamine and rapid-acting antidepressants: a new era in the battle against depression and suicide. F1000Research. 2018;7:F1000 Faculty Rev-659. doi:10.12688/f1000research.14344.1.
3. Dubovsky SL. What Is New about New Antidepressants? Psychotherapy and Psychosomatics. 2018;87(3):129-139. doi:10.1159/000488945.
4. V Popova, EJ Daly, M Trivedi, K Cooper, R Lane, P Lim, C Mazzucco, D Hough, ME Thase, RC Shelton, P Molero, E Vieta, M Bajbouj, H Manji, WC Drevets, JB Singh. Randomized, Double-Blind Study of Flexibly Dosed Intranasal Esketamine Plus Oral Antidepressant Versus Active Control in Treatment-Resistant Depression. Poster presented at: 2018 Annual Meeting of the American Psychiatric Association (APA); May 2018; New York, New York.
5. EJ Daly, M Trivedi, A Janik, H Li, Y Zhang, X Li, R Lane, P Lim, AR Duca, D Hough, ME Thase, J Zajecka, A Winokur, I Divacka, A Fagiolini, WJ Cubala, I Bitter, P Blier, RC Shelton, P Molero, H Manji, WC Drevets, JB Singh. A Randomized Withdrawal, Double-blind, Multicenter Study of Esketamine Nasal Spray Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression. Poster presented at: American Society of Clinical Psychopharmacology; May 2018; Miami, Florida.

6. E Wajs, L Aluisio, R Morrison, EJ Daly, R Lane, P Lim, R Holder, G Sanacora, AH Young, S Kasper, AH Sulaiman, C Li, J Paik, H Manji, D Hough, WC Drevets, JB Singh. Long-Term Safety of Esketamine Nasal Spray Plus an Oral Antidepressant in Patients with Treatment-Resistant Depression: Phase 3, Open Label Safety and Efficacy Study (SUSTAIN-2). Poster presented at: The American Society of Clinical Psychopharmacology Meeting; May 2018; Miami, Florida.
7. Johnson & Johnson Press Release. Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Major Depressive Disorder with Imminent Risk for Suicide. Available at: <https://www.jnj.com/media-center/press-releases/esketamine-recieves-breakthrough-therapy-designation-from-us-food-and-drug-administration-for-major-depressive-disorder-with-imminent-risk-of-suicide>. Accessed September 2018.
8. World Health Organization. Depression. Available at: <http://www.who.int/mediacentre/factsheets/fs369/en/>. Accessed September 2018.
9. National Institute of Mental Health. Questions and Answers about the NIMH Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study — Background. Available at: <https://www.nimh.nih.gov/funding/clinical-research/practical/stard/backgroundstudy.shtml>. Accessed September 2018.