NEWS RELEASE

Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Major Depressive Disorder with Imminent Risk for Suicide

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TITUSVILLE, N.J., Aug. 16, 2016 /PRNewswire/ -- Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today that the U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy Designation for esketamine, an investigational antidepressant medication, for the indication of major depressive disorder with imminent risk for suicide. If approved by the FDA, esketamine would be one of the first new approaches to treat major depressive disorder available to patients in the last 50 years.

This also marks the second time esketamine has received a Breakthrough Therapy Designation from the U.S. regulatory authority. Esketamine was first granted this designation for treatment-resistant depression in November 2013. Breakthrough Therapy Designation is intended to expedite development and review timelines when preliminary clinical evidence indicates the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies for serious or life-threatening conditions.[1]

The esketamine Phase 2 clinical trial data presented by Janssen in May 2016 at the Society of Biological Psychiatry 71st Annual Scientific Meeting in Atlanta, Georgia, provided preliminary clinical evidence to support the Breakthrough Therapy Designation for major depressive disorder with imminent risk for suicide.[2]

"In the U.S. alone, there are more than 41,000 suicides each year,[3] many of which result from untreated or poorly treated major depression," said Husseini K. Manji, MD, Global Head, Neuroscience Therapeutic Area, Janssen. "This designation reinforces the potential of esketamine as a novel treatment for patients with major depressive disorder

who are at imminent risk for suicide, a condition for which there currently is no approved treatment and which represents a major public health challenge. We are currently conducting clinical trials to further evaluate the clinical benefit of esketamine and look forward to working closely with the FDA throughout the development and review process to bring this important potential new therapy to patients in critical need."

About Esketamine

Esketamine for intranasal administration is an investigational compound being studied by Janssen as part of a global development program. Esketamine is a non-competitive and subtype non-selective activity-dependent N-methyl-D-aspartate (NMDA) receptor antagonist, which has a novel mechanism of action, meaning it works differently than currently available therapies for depression. The program in treatment-resistant depression is currently in Phase 3, with six ongoing clinical trials.

About Major Depressive Disorder

Major depressive disorder affects approximately 16 million people in the U.S.[4] and 121 million people worldwide. Individuals with depression, including major depressive disorder, experience continuous suffering from a serious, biologically based disease which can prevent them from enjoying life and functioning normally.[5] Depression is the psychiatric disorder most commonly associated with suicide.[6] In the U.S. alone, there are more than 41,000 suicides each year,[3] many of which result from untreated or poorly treated major depression. Only 30 percent of patients on currently available antidepressants achieve remission.[7] While conventional antidepressants can be effective in treating major depressive disorder, and thereby suicidal ideation, they are not FDA-approved for this use, and their delayed onset of effect, which takes three to six weeks, limits their value in treating acutely suicidal patients.

About the Janssen Pharmaceutical Companies

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**.

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 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; manufacturing difficulties and delays; changes in behavior and spending patterns or financial distress 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 description 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 January 3, 2016, including in Exhibit 99 thereto, 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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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Canuso C, et al. "Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide." Society of Biological Psychiatry 71st Annual Scientific Meeting. May 12-14, 2016.

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