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FDA advisory committee proposes approval of SPRAVATOTM Nasal Spray CIII

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If approved, SPRAVATOTM would provide the first new mechanism of action in 30 years to treat debilitating mental illness

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced that the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee jointly voted 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™. If approved, SPRAVATO™ would provide the first new mechanism of action in 30 years to treat this debilitating mental illness.

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. 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. 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.