Johnson&Johnson

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ABOUT BIPOLAR MANIA
Bipolar disorder affects an estimated 37 million people worldwide—approximately 1 in 200 individuals—with 4.4% of U.S. adults experiencing the condition in their lifetime. Mania, a key feature of Bipolar I disorder, is characterized by at least a week-long period of elevated or irritable mood and/or increased energy, as well as symptoms including grandiosity, decreased need for sleep, racing thoughts, distractibility, and risk-taking behavior. These noticeable behavioral changes often differ markedly from an individual's baseline and are frequently first recognized by those close to them. In severe cases, manic episodes may require hospitalization for safety and treatment.

ABOUT MAJOR DEPRESSIVE DISORDER (MDD)
MDD is one of the most common psychiatric disorders and a leading cause of disability worldwide, impacting an estimated 332 million people—or about 4 percent of the population. In 2023, approximately 22 million adults in the U.S. had at least one major depressive episode. While depression is typically treated with a “one-size-fits-all” approach, no two cases are the same. MDD is a complex, heterogeneous disorder involving multiple regions of the brain and presenting with as many as 256 unique symptom combinations. As a result, responses to treatment vary widely. Only 1 in 3 patients reach remission with their first antidepressant—and rates continue to decline further with each subsequent treatment, leaving many to spend years cycling through multiple treatments trying to find complete, sustained symptom relief. Moreover, MDD is a risk factor for the development and worsening of a range of comorbidities, illustrating the importance of integrating mental and general health care.

Anhedonia, a loss of interest or pleasure in previously enjoyed activities, is one of two defining symptoms of a major depressive episode. Anhedonia is associated with poorer treatment outcomes, including lower remission rates, greater functional impairment, and higher suicide risk. Notably, 40-70% of people with MDD experience anhedonia.

MDD often includes sleep disturbances such as insomnia or hypersomnia, with approximately 60 percent of MDD patients experiencing clinically relevant insomnia symptoms despite being on an SSRI/SNRI. Disturbed sleep and insomnia symptoms have a significant impact on a patient’s quality of life and exacerbate the risk of depressive relapse and suicide.

Approximately one-third of adults with MDD will not respond to oral antidepressants alone and are considered to have treatment-resistant depression (TRD), which is often defined as inadequate response to two or more oral antidepressants that were administered at an adequate dose for an adequate duration. TRD has a significant negative impact on the lives of those affected and has one of the highest economic burdens of all psychiatric disorders. Patients often cycle through multiple oral medications, waiting 4-6 weeks for potential relief. Based on the STAR*D study, after their third line of treatment, approximately 86 percent of patients do not achieve remission.

ABOUT SCHIZOPHRENIA
Schizophrenia is a complex, chronic brain disorder that affects how people think, feel, speak, and act. It affects up to an estimated 2.8 million adults in the United States yet remains widely misunderstood and insufficiently treated. Symptoms vary by person, but confusion and distortions in perceptions, emotions, and behavior are common. Evidence shows that the first three to five years after diagnosis — “the critical period” — from symptom onset are key for a patient’s treatment, as this is when the condition progresses most rapidly. A comprehensive treatment plan, which may include medication, therapy, and psychosocial services, is critical in delaying the time to relapse for adults with schizophrenia.

ABOUT CAPLYTA® (lumateperone)
CAPLYTA® 42 mg is an oral, once daily atypical antipsychotic approved in adults as an adjunctive therapy with antidepressants for major depressive disorder (MDD), schizophrenia, and depressive episodes associated with bipolar I or II disorder (bipolar depression), as monotherapy, or as adjunctive therapy with lithium or valproate.

While the mechanism of action of CAPLYTA® is unknown, the efficacy of CAPLYTA® could be mediated through a combination of antagonist activity at central serotonin 5-HT_{2A} receptors and partial agonist activity at central dopamine D_2 receptors.

A supplemental New Drug Application (sNDA) for CAPLYTA® with long-term data evaluating the safety and efficacy of the medication for delayed time to relapse in schizophrenia was recently approved by the U.S. Food and Drug Administration. The medication is also being studied for other neuropsychiatric disorders. CAPLYTA® is not FDA-approved for these disorders.

ABOUT SPRAVATO® (esketamine) CIII NASAL SPRAY
SPRAVATO® is approved by the U.S. Food and Drug Administration as monotherapy or in conjunction with an oral antidepressant for adults with MDD when they have inadequate response to at least two oral antidepressants (TRD) and depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior in conjunction with an oral antidepressant. It is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor and is believed to work differently than traditional antidepressants by acting on a pathway in the brain that affects

glutamate. The mechanism by which esketamine exerts its antidepressant effect is unknown. To date, SPRAVATO® has been approved in over 70 markets and administered to more than 250,000 patients worldwide.

ABOUT J&J'S SCHIZOPHRENIA LONG-ACTING INJECTABLE (LAI) PORTFOLIO
Johnson & Johnson's portfolio of long-acting injectable (LAI) offerings for schizophrenia offers a varied range of dosing options and the longest-lasting schizophrenia treatments with each dose available, including INVEGA SUSTENNA® (1-month paliperidone palmitate), INVEGA TRINZA® (3-month paliperidone palmitate), and INVEGA HAFYERA® (6-month paliperidone palmitate), all of which are administered in a clinical setting by a medical professional.

ABOUT SELTOREXANT
Seltorexant, an investigational first-in-class therapy, is a selective antagonist of the human orexin-2 receptor currently being developed as an adjunctive treatment for adults with MDD with insomnia symptoms. Seltorexant selectively antagonizes the orexin-2 receptors, potentially improving mood symptoms associated with depression and restoring sleep without next-day sedation. When orexin-2 receptors are stimulated for too long or at inappropriate times, their activation can cause hyperarousal manifestations, including insomnia and excessive cortisol release, which may contribute to depression. Seltorexant is the only investigational therapy under study for the treatment of MDD that is believed to work by normalizing the overactivation of the orexin-2 receptors, thereby targeting the underlying biology that contributes to depression and insomnia symptoms.

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity.

Learn more at https://www.jnj.com/ or at www.innovativemedicine.jnj.com. Follow us at @JNJInnovMed.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to product development and the potential benefits and treatment impact of CAPLYTA® (lumateperone), SPRAVATO® (esketamine) CIII nasal spray, and seltorexant. 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 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; manufacturing difficulties and delays; 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; 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 most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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