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Janssen Pharmaceuticals (a pharmaceutical subsidiary of Johnson & Johnson) has announced that the US Food and Drug Administration (US FDA) approved under priority review the New Drug Application (NDA) for the three-month long-acting atypical antipsychotic INVEGA TRINZA. INVEGA TRINZA, a three-month injection, is an atypical antipsychotic indicated to treat schizophrenia. Before starting INVEGA TRINZA, patients must be adequately treated with INVEGA SUSTENNA (one-month paliperidone palmitate) for at least four months.

In a long-term maintenance trial, 93 percent of patients treated with INVEGA TRINZA did not experience a significant return of schizophrenia symptoms. The results of the phase III study were published in March by JAMA Psychiatry, a peer-reviewed medical journal published by the American Medical Association. Based on positive efficacy, Janssen concluded this study early following the recommendation of an Independent Data Monitoring Committee (IDMC).

"With a dosing interval that can be measured in seasons, not days, people living with schizophrenia and their treatment teams can focus on recovery goals beyond short-term symptom control," said trial investigator Dr Joseph Kwentus, Precise Research Centers. He added, "Recovery looks different for everyone, and the long-term symptom control offered by INVEGA TRINZA can help patients work toward their own personal goals."

"Building on Janssen's more than 50 years of leadership in developing innovative mental health therapies and helpful programs, this medication offers a new paradigm for treating people living with schizophrenia. After at least four months on INVEGA SUSTENNA, patients and their doctors can seamlessly transition to INVEGA TRINZA for sustained symptom control with a single dose every three months," said Dr Husseini Manji, Global head, Neuroscience Therapeutic Area, Janssen Research and Development.

Janssen anticipates that INVEGA TRINZA will be commercially available by mid-June.

Based on the phase III study, the safety and tolerability profile of INVEGA TRINZA is consistent with that of INVEGA SUSTENNA. No new benefit-risk concerns emerged from studies of INVEGA TRINZA.