Invega Hafyera™ (paliperidone palmitate) – New drug approval

- On September 1, 2021, Janssen announced the FDA approval of Invega Hafyera (paliperidone palmitate), an every-six-month injection, for the treatment of schizophrenia in adults after they have been adequately treated with:
  - A once-a-month paliperidone palmitate extended-release injectable suspension (eg, Invega Sustenna®) for at least four months, or
  - An every-three-month paliperidone palmitate extended-release injectable suspension (eg, Invega Trinza®) for at least one three-month cycle.
- Invega Hafyera is the first twice-yearly product approved for treatment of schizophrenia.
- The efficacy of Invega Hafyera was established in a randomized, double-blind, active-controlled, non-inferiority study designed to evaluate time to relapse in adults with diagnosis of schizophrenia who had previously been stably treated with either paliperidone palmitate once-a-month (PP1M) for at least 4 months or paliperidone palmitate every-three-month (PP3M) for at least one 3-month injection cycle. After establishing tolerability and clinical stability with the previous paliperidone formulations, patients were randomized to Invega Hafyera or PP3M. The primary efficacy variable was time to first relapse.
  - A relapse event was experienced by 7.5% and 4.9% of patients in the Invega Hafyera and PP3M treatment groups, respectively, with the Kaplan-Meier estimated difference of 2.9% (95% CI: -1.1, 6.8). The study demonstrated non-inferiority of Invega Hafyera to PP3M.
- Invega Hafyera carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.
- Warnings and precautions for Invega Hafyera include cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; QT prolongation; tardive dyskinesia; metabolic changes; orthostatic hypotension and syncope; falls; leukopenia, neutropenia, and agranulocytosis; hyperprolactinemia; potential for cognitive and motor impairment; seizures; dysphagia; priapism; and disruption of body temperature regulation.
- The most common adverse reactions with Invega Hafyera use were upper respiratory tract infection, injection site reaction, increased weight, headache, and parkinsonism.
- The recommended initial dose of Invega Hafyera is 1,092 mg to 1,560 mg, depending on the previous dose of paliperidone palmitate. If needed, dosage adjustment can be made every 6 months between the dose of 1,092 mg to 1,560 mg based on individual response and tolerability.
  - Invega Hafyera must be administered as a gluteal intramuscular injection by a healthcare professional once every 6 months.
- Janssen's launch plans for Invega Hafyera are pending. Invega Hafyera will be available as 1,092 mg/3.5 mL and 1,560 mg/5 mL single-dose prefilled syringes.