Perseris™ (risperidone) – New drug approval

- On July 27, 2018, Indivior and Durect announced the FDA approval of Perseris (risperidone), for the treatment of schizophrenia in adults.

- Perseris is the first once monthly subcutaneous (SC) risperidone-containing, long-acting injectable.

    — Clinically relevant levels are reached after the first injection of Perseris without use of a loading dose or any supplemental oral risperidone.

- Risperidone is also available generically as an oral tablet, orally disintegrating tablet, and oral solution, as well as a branded long-acting intramuscular injection, Risperdal Consta®.

    — The oral formulations are all approved for schizophrenia, bipolar I disorder, and irritability associated with autistic disorder.
    — Risperdal Consta is approved for schizophrenia and bipolar I disorder and should be administered every 2 weeks by a healthcare professional.

- The safety and efficacy of Perseris were evaluated in an 8-week, placebo-controlled study of 354 adult patients experiencing acute exacerbations of schizophrenia. Patients were randomized to receive two doses of Perseris (90 mg or 120 mg) or placebo 28 days apart. The primary endpoint was the change in Positive and Negative Syndrome Scale (PANSS) total score from baseline to the end of the study (day 57).

    — Both doses of Perseris demonstrated a statistically significant improvement in the PANSS total score vs. placebo (Perseris 90 mg vs. placebo: difference = -6.50 [95% CI: -10.87, -2.13]; Perseris 120 mg vs. placebo: difference = -10.24 [95% CI: -14.64, -5.85]).

- Similar to other atypical antipsychotic agents, Perseris carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.

- Additional warnings and precautions of Perseris include cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; hyperprolactinemia; orthostatic hypotension; falls; leukopenia, neutropenia, and agranulocytosis; potential for cognitive and motor impairment; seizures; dysphagia; priapism; and body temperature regulation.

- The most common adverse reactions (≥ 5% and greater than twice placebo) with Perseris use were increased weight, sedation/somnolence, and musculoskeletal pain.

- The recommended dose of Perseris is 90 mg or 120 mg administered monthly by SC injection in the abdomen. Do not administer by any other route.

    — Each injection must be administered by a healthcare professional using the prepackaged injection syringe and enclosed safety needle.
    — For patients who have never taken risperidone, establish tolerability with oral risperidone prior to starting Perseris.
    — Do not administer more than one dose (90 mg or 120 mg total) per month.
    — Neither a loading dose nor any supplemental oral risperidone is recommended.

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- Indivior and Durect's launch plans for Perseris are pending. Perseris will be available as a 90 mg and 120 mg extended-release injectable suspension.