Uzedy™ (risperidone) – New drug approval

- On April 28, 2023, Teva Neuroscience and MedinCell announced the FDA approval of Uzedy (risperidone) subcutaneous injection, for the treatment of schizophrenia in adults.

- Risperidone is available generically as an oral tablet, oral solution, and orally disintegrating tablets, and as a brand intramuscular injection (Risperdal Consta®) and a subcutaneous injection (Perseris®).

    - The tablet, oral solution and orally disintegrating tablets are indicated for treatment of schizophrenia, manic and mixed episodes of bipolar disorder and irritability associated with autistic disorder.
    - Risperdal Consta is indicated for the treatment of schizophrenia and bipolar disorder.
    - Perseris carries the same indication as Uzedy.

- The efficacy of Uzedy is based in part on the established effectiveness of oral risperidone as well as in a randomized withdrawal study. In the randomized withdrawal study, 543 patients with schizophrenia were enrolled to a 12- week open-label oral risperidone (2 mg to 5 mg) stabilization phase, followed by a placebo-controlled phase in which patients were randomized to Uzedy (once monthly or once every 2 months) or placebo for a variable time until impending relapse or study completion. The primary efficacy endpoint was time to impending relapse.

    - Time to relapse was statistically significantly longer in the Uzedy-treated groups vs. placebo.

- Uzedy carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.

- Uzedy is contraindicated in patients with a known hypersensitivity to risperidone, its metabolite, paliperidone, or to any of its components.

- Additional warnings and precautions for Uzedy include increased mortality in elderly patients with dementia-related psychosis; cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; hyperprolactinemia; orthostatic hypotension and syncope; 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 placebo) with Uzedy use were parkinsonism, akathisia, dystonia, tremor, sedation, dizziness, anxiety, blurred vision, nausea, vomiting, upper abdominal pain, stomach discomfort, dyspepsia, diarrhea, salivary hypersecretion, constipation, dry mouth, increased appetite, increased weight, fatigue, rash, nasal congestion, upper respiratory tract infection, nasopharyngitis, and pharyngolaryngeal pain.

- To start Uzedy, switch from oral daily risperidone. Initiate Uzedy, as either a once monthly subcutaneous (SC) injection or a once every 2 month injection, the day after the last dose of oral therapy.

    - Uzedy must be administered by a healthcare professional as an abdominal or upper arm SC injection.
    - Refer to Uzedy's drug label for additional dosing and administration guidelines.

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- Teva Neuroscience plans to launch Uzedy in the coming weeks. Uzedy will be available as 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL in single-dose prefilled-syringes.