## Erzofri®™ (paliperidone palmitate) – New drug approval

- On July 28, 2024, Luye Pharma announced the FDA approval of Erzofri (paliperidone palmitate), for the treatment of schizophrenia in adults; and for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.

- The efficacy of Erzofri was established in an open-label, randomized, multiple-dose, parallel-group study that enrolled 281 patients (ages 18 - 65) with schizophrenia or schizoaffective disorder, designed to evaluate the pharmacokinetic profile of Erzofri and its relative bioavailability compared with the listed drug Invega Sustenna® (paliperidone palmitate).

    - Erzofri was demonstrated to be bioequivalent to Invega Sustenna at steady state after multiple injections.
    - Compared with Invega Sustenna, the initial dosing was optimized for Erzofri by omitting the injection on day 8 after the first injection, resulting in a comparable total drug exposure.

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

- Warnings and precautions for Erzofri 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 (≥ 5% and occurring at least twice as often as placebo) with Erzofri use were injection site reactions, somnolence/sedation, dizziness, akathisia, and extrapyramidal disorder.

- The recommended dose of Erzofri is as follows:

| Indication | Initial Dose Day 1 | Monthly Dosage[a] | Maximum Monthly Dose |
|---|---|---|---|
| Schizophrenia | 351 mg | 39 mg to 234 mg[b] | 234 mg |
| Schizoaffective disorder | 351 mg | 78 mg to 234 mg[c] | 234 mg |

[a] Administered 4 weeks after the first injection.
[b] The recommended monthly dosage for treatment of schizophrenia is 117 mg. Some patients may benefit from lower or higher monthly doses within the additional available strengths (39 mg, 78 mg, 156 mg, and 234 mg).
[c] Adjust dose based on tolerability and/or efficacy using available strengths. The 39 mg strength was not studied in the long-term schizoaffective disorder study.

    - The initial dosage of Erzofri is administered in the deltoid muscle.
    - Following the initial dose, monthly doses can be administered in either the deltoid or gluteal muscle.

- Erzofri must be administered by a healthcare professional as an intramuscular injection.

- For patients who have never taken oral or injectable paliperidone, or oral or injectable risperidone, tolerability with oral paliperidone or oral risperidone should be established prior to initiating treatment with Erzofri.

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- Luye Pharma launch plans for Erzofri are pending. Erzofri will be available as 39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL, 234 mg/1.5 mL, and 351 mg/2.25 mL extended-release suspension in single-dose prefilled syringes.