Mezofy™ (aripiprazole) – New drug approval

- On April 15, 2025, the FDA approved CMG Pharmaceutical's Mezofy (aripiprazole) oral film, for the **treatment of schizophrenia in adult and pediatric patients 13 years and older**.
- Aripiprazole is also available across different oral and injectable formulations for schizophrenia.
- The efficacy of Mezofy oral film has been established based on adequate and well-controlled studies of oral aripiprazole in the treatment of schizophrenia in adult and pediatric patients ages 13 to 17 years.
- Mezofy carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.
- Additional warnings and precautions for Mezofy include cerebrovascular adverse events, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; pathological gambling and other compulsive behaviors; orthostatic hypotension and syncope; falls; leukopenia, neutropenia, and agranulocytosis; seizures; potential for cognitive and motor impairment; body temperature dysregulation; and dysphagia.
- The most common adverse reactions (≥ 5% and at least twice that for placebo) with aripiprazole use are:
    - Adult patients with schizophrenia: akathisia
    - Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder, somnolence, and tremor.
- The recommended starting dosage in adults is 10 mg or 15 mg taken orally once daily.
    - Aripiprazole has been shown to be effective in a dosage range of 10 mg to 30 mg daily; however, dosages higher than 10 mg or 15 mg daily were not more effective. Dosage increases should generally not be made before 2 weeks, the time needed to achieve steady-state.
- In pediatric patients 13 to 17 years of age, the recommended starting dosage of oral aripiprazole is 2 mg once daily. Because Mezofy is not available in dosage strengths below 5 mg, patients should initiate aripiprazole treatment at the 2 mg daily dosage with another aripiprazole product. After two days, the dose can be titrated to 5 mg of Mezofy once daily, and after an additional two days, the dose can be titrated to 10 mg Mezofy once daily. Subsequent dose titrations should be made in 5 mg increments according to patient tolerability.
    - The 30 mg daily dosage was not shown to be more efficacious than 10 mg once daily.
- CMG Pharmaceutical's launch plans for Mezofy are pending. Mezofy will be available as a 5 mg, 10 mg, and 15 mg oral film.