Fanapt® (iloperidone) – New indication

- On April 2, 2024, Vanda Pharmaceuticals announced the FDA approval of Fanapt (iloperidone), for acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
- Fanapt is also approved for the treatment of schizophrenia in adults.
- The approval of Fanapt for the new indication was based on a randomized, double-blind, placebo-controlled study in 392 patients with bipolar I disorder, manic or mixed type. The primary endpoint was change in Young Mania Rating Scale (YMRS) total score from baseline to day 28. The YMRS is an 11-item clinician rated scale traditionally used to assess the degree of manic symptomatology. YMRS total scores may range from 0 to 60 with a higher score reflecting greater severity.
    - The least squares mean change from baseline in YMRS score was -14.0 and -10.0 with Fanapt and placebo, respectively (difference -4.0, 95% CI: -5.70, -2.25).
- Fanapt carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.
- The most common adverse reactions (≥ 5% and 2-fold greater than placebo) with Fanapt use for bipolar mania were tachycardia, dizziness, dry mouth, increased hepatic enzymes, nasal congestion, increased weight, hypotension, and somnolence.
- The recommended dose of Fanapt for acute treatment of manic or mixed episodes associated with bipolar I disorder is 12 mg orally twice daily. The dose should be titrated from 1 mg (see details below).

Titration schedule					Recommended dosage
Day 1	Day 2	Day 3	Day 4	Day 5	
1 mg twice daily	3 mg twice daily	6 mg twice daily	9 mg twice daily	12 mg twice daily	12 mg twice daily

    - Refer to the Fanapt drug label for dosing for schizophrenia.