Caplyta® (lumateperone) – New indication

- On December 20, 2021, Intra-Cellular Therapies announced the FDA approval of Caplyta (lumateperone), for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

- Caplyta is also approved for the treatment of schizophrenia in adults.

- The approval of Caplyta, as monotherapy, for the new indication was based on a randomized, double-blind, placebo-controlled study in 381 adult patients with depressive episodes associated with bipolar I or bipolar II disorder. The primary endpoint was the change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at week 6. The MADRS is a 10-item clinician-rated scale with total scores ranging from 0 (no depressive features) to 60 (maximum score).

    — The least squares mean change from baseline in the MADRS total score was -16.7 with Caplyta vs. -12.1 with placebo (difference -4.6, 95% CI: -6.3, -2.8).

- The approval of Caplyta, as adjunctive therapy with lithium or valproate, for the new indication was based on a randomized, double-blind, placebo-controlled study in 529 adult patients with depressive episodes associated with bipolar I or bipolar II disorder. The primary endpoint was the change from baseline in MADRS total score at week 6.

    — The least squares mean change from baseline in the MADRS total score was -16.9 with Caplyta plus lithium or valproate vs. -14.5 with placebo plus lithium or valproate (difference -2.4, 95% CI: -4.4, -0.4).

- Caplyta carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.

- The most common adverse reactions (≥ 5% and greater than twice placebo) with Caplyta use for bipolar depression were somnolence/sedation, dizziness, nausea, and dry mouth.

- The recommended dose of Caplyta for the treatment of schizophrenia and bipolar depression is 42 mg administered orally once daily. Dose titration is not required.