Caplyta® (lumateperone) – New dosage strengths

- On April 25, 2022, Intra-Cellular Therapies announced the FDA approval of new dosage strengths of Caplyta (lumateperone), 10.5 mg and 21 mg capsules, for specific patient populations.
    - Caplyta was previously only available as 42 mg capsules.
- Caplyta is approved for the treatment of schizophrenia in adults as well as bipolar depression in adults (as monotherapy and as adjunctive therapy with lithium or valproate).
- The recommended dosage for patients receiving strong CYP3A4 inhibitors is Caplyta 10.5 mg orally once daily. The recommended dosage for patients receiving moderate CYP3A4 inhibitors or for patients with moderate or severe hepatic impairment (Child-Pugh class B or C) is Caplyta 21 mg orally once daily.
- Intra-Cellular Therapies plans to launch the new dosage strengths of Caplyta in mid-2022.