Zykadia® (ceritinib) – New formulation approval

- On March 18, 2019, the FDA approved Novartis' Zykadia (ceritinib) tablets, for the treatment of adults with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase-positive as detected by an FDA-approved test.
    - Zykadia is also available as capsules for the same indication.
- The approval of Zykadia tablets was based on studies conducted with Zykadia capsules.
- Warnings and precautions of Zykadia include gastrointestinal adverse reactions, hepatotoxicity, interstitial lung disease/pneumonitis, QT interval prolongation, hyperglycemia, bradycardia, pancreatitis, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 25%) with the use of Zykadia 450 mg with food were diarrhea, nausea, abdominal pain vomiting, and fatigue; and with Zykadia 750 mg under fasted conditions were diarrhea, nausea, vomiting, fatigue, abdominal pain, decreased appetite, and weight loss.
- The recommended dose of Zykadia tablets or capsules is 450 mg orally once daily with food until disease progression or unacceptable toxicity.
- Novartis' launch plans for Zykadia tablets are pending. Zykadia tablets will be available in a strength of 150 mg.