Zykadia® (ceritinib) – Expanded indication

- On May 26, 2017, Novartis announced the FDA approval of Zykadia (ceritinib) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
    - Previously, Zykadia was approved for the treatment of patients with ALK-positive metastatic NSCLC who have progressed on or are intolerant to Xalkori® (crizotinib).
- The expanded indication for Zykadia was approved based on the open-label ASCEND-4 study that enrolled 376 patients with ALK-positive NSCLC who had not received prior systemic therapy for metastatic disease. Patients were randomized to Zykadia or chemotherapy plus maintenance chemotherapy. The major efficacy outcome measure was progression-free survival (PFS).
    - The PFS was 16.6 months for Zykadia patients vs. 8.1 months for chemotherapy treated patients (Hazard ratio = 0.55; 95% CI: 0.42, 0.73; $p < 0.001$).
    - The overall response rate was 73% (95% CI: 66, 79) for Zykadia patients vs. 27% (95% CI: 21, 34) for chemotherapy treated patients.
    - The duration of response was 23.9 months (95% CI: 16.6, not estimable) for Zykadia patients vs. 11.1 months (95% CI: 7.8, 16.4) for chemotherapy treated patients.
- The recommended dose of Zykadia is 750 mg orally once daily until disease progression or unacceptable toxicity.