Xospata® (gilteritinib) – New boxed warning

- On May 29, 2019, a new *Boxed Warning* was added to the Xospata (gilteritinib) drug label regarding differentiation syndrome.
- Xospata is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia with a FMS-like tyrosine kinase 3 mutation as detected by an FDA-approved test.
- Patients treated with Xospata have experienced symptoms of differentiation syndrome, which can be fatal or life-threatening if not treated. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells.
- Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, or renal dysfunction. If differentiation syndrome is suspected, corticosteroid therapy should be initiated and hemodynamic monitoring until symptom resolution. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, Xospata should be interrupted until signs and symptoms are no longer severe.
- Of 319 patients treated with Xospata in the clinical trials, 3% experienced differentiation syndrome. Some cases had concomitant acute febrile neutrophilic dermatosis. Differentiation syndrome occurred as early as 2 days and up to 75 days after Xospata initiation and has been observed with or without concomitant leukocytosis. Of the 11 patients who experienced differentiation syndrome, 9 (82%) recovered after treatment or after dose interruption of Xospata.