Mekinist® (trametinib) – New warning

- On February 24, 2017, the FDA approved a new warning to the *Warnings and Precautions* section of the Mekinist (trametinib) drug label regarding colitis and gastrointestinal perforation.
- Mekinist is indicated, as a single agent or in combination with Tafinlar® (dabrafenib), for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
    - Mekinist is not indicated for treatment of patients who have received prior BRAF-inhibitor therapy.
- Colitis and gastrointestinal perforation, including fatal outcomes, have been reported in patients taking Mekinist as a single-agent and when administered with dabrafenib.
    - In clinical trials of Mekinist administered as a single agent (n = 329) and Mekinist administered with dabrafenib (n = 559), colitis occurred in 0.6% of patients and gastrointestinal perforation occurred in 0.3% of patients.
    - Patients should be monitored closely for colitis and gastrointestinal perforations.