Mekinist® (trametinib) plus Tafinlar® (dabrafenib) – Expanded indication

- On August 31, 2023, the FDA approved Novartis' Mekinist (trametinib) plus Tafinlar (dabrafenib), for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
    - Mekinist plus Tafinlar was previously approved for this indication in patients 6 years of age and older.
    - This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Mekinist plus Tafinlar are also approved for:
    - BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma
    - Adjuvant treatment of BRAF V600E or V600K mutation-positive melanoma
    - BRAF V600E mutation-positive metastatic non-small cell lung cancer
    - BRAF V600E mutation-positive locally advanced or metastatic anaplastic thyroid cancer
    - BRAF V600E mutation-positive low-grade glioma
- Mekinist is also approved as a single-agent for BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma and Tafinlar is approved as a single-agent for BRAF V600E mutation-positive unresectable or metastatic melanoma.
- The recommended oral doses of Mekinist and Tafinlar for pediatric patients is based on body weight. Refer to the drug labels for each for complete dosing and administration recommendations.