Tafinlar® (dabrafenib), Mekinist® (trametinib) – New indication

- On June 23, 2022, Novartis announced the FDA approval of Tafinlar (dabrafenib) plus Mekinist (trametinib), for the treatment of adult and pediatric patients 6 years 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.
    - 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 and Tafinlar are not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.

- Tafinlar plus Mekinist 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; and BRAF V600E mutation-positive locally advanced or metastatic anaplastic thyroid cancer.

- Additionally, Tafinlar is approved as a single-agent for BRAF V600E mutation-positive unresectable or metastatic melanoma and Mekinist is approved as a single-agent for BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma.

- The approval of Tafinlar plus Mekinist for the new indication was based on Trials BRF117019, NCI-MATCH, and CTMT212X2101 and supported by results in COMBI-d, COMBI-v, and BRF113928. Refer to the Tafinlar and Mekinist drug labels for complete efficacy results by solid tumor type.

- The most common adverse reactions (≥ 20%) for Tafinlar and Mekinist use in adult patients with solid tumors were pyrexia, fatigue, nausea, rash, chills, headache, hemorrhage, cough, vomiting, constipation, diarrhea, myalgia, arthralgia, and edema.

- The most common adverse reactions (≥ 20%) for Tafinlar and Mekinist use in pediatric patients with solid tumors were pyrexia, rash, vomiting, fatigue, dry skin, cough, diarrhea, dermatitis acneiform, headache, abdominal pain, nausea, hemorrhage, constipation, and paronychia.

- The recommended dosage for Tafinlar in adult patients is 150 mg orally taken twice. The recommended dosage for Tafinlar in pediatric patients who weigh at least 26 kg is based on body weight. The recommended duration of treatment for patients with solid tumors is until disease progression or unacceptable toxicity.

- The recommended dosage for Mekinist in adult patients is 2 mg orally taken once daily. The recommended dosage for Mekinist in pediatric patients who weigh at least 26 kg is based on body weight. The recommended duration of treatment for patients with solid tumors is until disease progression or unacceptable toxicity.

- Refer to the Tafinlar and Mekinist drug labels for complete pediatric dosing for solid tumors and for complete dosing information for all their other indications.