Tafinlar® (dabrafenib) and Mekinist® (trametinib) – New orphan indication

- On May 4, 2018, the FDA announced the approval of Novartis' Tafinlar (dabrafenib) in combination with Mekinist (trametinib) for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

- Both Tafinlar and Mekinist are also approved for use alone, in combination, or as adjuvant therapy to treat certain BRAF mutation-positive melanomas. Additionally, Tafinlar and Mekinist are approved for use, in combination, to treat BRAF V600E mutation-positive, metastatic non-small cell lung cancer.

    — Refer to the drug labels for further indication information.

- ATC is a rare, aggressive type of thyroid cancer. The National Institutes of Health estimates there will be 53,990 new cases of thyroid cancer and an estimated 2,060 deaths from the disease in the U.S. in 2018. ATC accounts for about 1% to 2% of all thyroid cancers.

- The new indication is based on efficacy data of Tafinlar in combination with Mekinist in a clinical study of 23 patients with locally advanced, unresectable, or metastatic ATC with the BRAF V600E mutation. The major efficacy endpoints were overall response rate (ORR) and duration of response (DOR).

    — The ORR was 61% (95% CI: 39%, 80%) and 64% of patients had a DOR ≥ 6 months.
    — Fifty-seven percent of patients experienced a partial response and 4% experienced a complete response.

- The recommended doses of Tafinlar and Mekinist for all indications are as follows:

    — Tafinlar: 150 mg orally twice daily, approximately 12 hours apart as a single agent or with Mekinist.
    — Mekinist: 2 mg orally once daily at the same time each day as a single agent or with Tafinlar.
    — Treatment for the adjuvant indication should be continued until disease progression or unacceptable toxicity occurs for up to one year.
    — Treatment for all other indications should be continued until disease progression or unacceptable toxicity occurs.
    — Refer to the drug labels for additional dosing information.