Braftovi® (encorafenib) plus Mektovi® (binimetinib) – New indication

- On October 12, 2023, Pfizer announced the FDA approval of Braftovi (encorafenib) plus Mektovi (binimetinib), for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test.

- Braftovi plus Mektovi combination therapy is also approved for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

- Additionally, Braftovi is approved in combination with Erbitux® (cetuximab), for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

- The approval of Braftovi plus Mektovi for the new indication was based on an open-label, single-arm study in patients with BRAFV600E mutation-positive metastatic NSCLC. Patients received Braftovi plus Mektovi until disease progression or unacceptable toxicity. The efficacy population included 59 treatment-naïve patients and 39 previously-treated patients. The major outcome measures were objective response rate (ORR) and duration of response (DOR).

    — In treatment-naïve patients, the ORR was 75% (95% CI: 62, 85). The median DOR was not estimable (NE) (95% CI: 23.1, NE).
    — In previously treated patients, the ORR was 46% (95% CI: 30, 63). The median DOR was 16.7 months (7.4, NE).

- The most common adverse reactions (≥ 25%) with Braftovi plus Mektovi use for NSCLC were fatigue, nausea, diarrhea, musculoskeletal pain, vomiting, abdominal pain, visual impairment, constipation, dyspnea, rash, and cough.

- The recommended dosage of Braftovi for NSCLC is 450 mg (six 75 mg capsules) orally once daily until disease progression or unacceptable toxicity. The recommended dose of Mektovi for NSCLC is 45 mg orally taken twice daily until disease progression or unacceptable toxicity.

    — Confirm the presence of a BRAF V600E mutation in tumor or plasma specimens prior to initiating treatment with Braftovi plus Mektovi. If no mutation is detected in a plasma specimen, test tumor tissue. Information on FDA-approved tests for the detection of BRAF V600E mutations in NSCLC is available at: http://www.fda.gov/CompanionDiagnostics.
    — Refer to the Braftovi and Mektovi drug labels for dosing for their other indications.