Cotellic® (cobimetinib) – New orphan indication

- On October 28, 2022, the FDA approved Genentech's Cotellic (cobimetinib), as a single agent, for the treatment of adult patients with histiocytic neoplasms.

- Cotellic is also approved for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with Zelboraf® (vemurafenib).

- The approval of Cotellic for the new indication was based on a single-center, single-arm study in 26 adult patients with histologically confirmed histiocytic neoplasms of any mutational status. The major efficacy outcome was best overall response rate (ORR) using the PET Response Criteria (PRC).

    — The PRC-based ORR was 76.9% (95% CI: 56.4, 91).
    — The median PRC-based duration of response was 31 months (range: 2 to 31).

- The most common adverse reactions (≥ 20%) with Cotellic use for histiocytic neoplasms were acneiform dermatitis, diarrhea, infection, fatigue, nausea, edema, dry skin, maculopapular rash, pruritus, dyspepsia, vomiting, dyspnea, and urinary tract infections.
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- The most common (≥ 5%) grade 3-4 lab abnormalities with Cotellic use for histiocytic neoplasms were hyponatremia, increased blood creatine phosphokinase, hypokalemia, increased blood creatinine, increased aspartate aminotransferase, hypocalcemia, lymphopenia, leukopenia, and anemia.

- The recommended dosage regimen of Cotellic for both of its indications is 60 mg (three 20 mg tablets) orally taken once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.