November 10, 2015

Cotellic Approved for Advanced Melanoma

On Nov. 10, 2015, Genentech and Exelixis received approval from the U.S. Food and Drug Administration (FDA) for Cotellic™ (cobimetinib) for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with Zelboraf® (vemurafenib – Genentech). The mutation should be detected by an FDA-approved test prior to initiating therapy. The recommended dose of Cotellic is 60mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity. The recommended dose of Zelboraf is 960mg every 12 hours. Genentech and Exelixis plan on launching Cotellic within two weeks. It will be available through a limited network of specialty pharmacies that includes Accredo. Full prescribing information is available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206192s000lbl.pdf

► At a Glance

- **Brand (Generic) Drug:** Cotellic™ (cobimetinib)
- **Manufacturer:** Genentech and Exelixis
- **Date Approved:** Nov. 10, 2015
- **Indications:** Treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib
- **Dosage Forms Available:** 20mg tablets
- **Specialty Status:** Cotellic will be added to Express Scripts’ specialty drug list.

Melanoma is a rare, but aggressive and deadly form of skin cancer. Each year in the United States, approximately 74,000 new cases of melanoma are diagnosed and nearly 10,000 patients will die from the disease. Approximately half of patients with melanoma skin cancer have a BRAF gene mutation.

Cotellic is a MEK inhibitor that works by slowing cancer cell growth. It is given in combination with Zelboraf (vemurafenib), an oral BRAF inhibitor that has been on the market since 2011 for certain patients with advanced melanoma.

The approval of Cotellic was based on a clinical study that showed patients with advanced BRAF V600 mutation-positive melanoma treated with the combination of Cotellic and Zelboraf experienced a delay in disease progression or death by approximately 12.3 months compared to approximately 7.2 months for those taking Zelboraf alone.

Cotellic / Zelboraf will compete with GlaxoSmithKline’s Mekinist® (trametinib), a MEK inhibitor, and Tafinlar® (dabrafenib), a BRAF inhibitor, that are approved for combination use to treat patients with advanced BRAF V600 mutation-positive melanoma.