November 25, 2015

Portrazza Approved for Lung Cancer

On Nov. 24, 2015, Lilly received approval from the U.S. Food and Drug Administration (FDA) for Portrazza™ (necitumumab) for the first-line treatment of patients with metastatic squamous non-small cell lung cancer in combination with gemcitabine and cisplatin. The recommended dose of Portrazza is 800mg, given as a 60-minute intravenous infusion, on Days 1 and 8 of each 21-day cycle. Lilly plans on launching Portrazza within the next few weeks. Full prescribing information is available at: http://pi.lilly.com/us/portrazza-uspi.pdf

At a Glance

- **Brand (Generic) Drug:** Portrazza™ (necitumumab)
- **Manufacturer:** Lilly
- **Date Approved:** Nov. 24, 2015
- **Indications:** First-line treatment of patients with metastatic squamous non-small cell lung cancer in combination with gemcitabine and cisplatin
- **Launch Date:** December 2015
- **Estimated Annual Cost:** Pricing information is not yet available.
- **Dosage Forms Available:** 800mg/50mL solution in single-dose vials
- **Specialty Status:** Portrazza will be added to Express Scripts’ specialty drug list
- More than 220,000 Americans are diagnosed with lung cancer each year. Non-small cell lung cancer accounts for 85% of cases; of which, about 30% are squamous cell carcinomas and 70% are non-squamous cell carcinomas.
- Portrazza is an epidermal growth factor receptor (EGFR) antagonist. Activation of EGFR is linked to the growth and spread of tumors.
- FDA approval of Portrazza was based on a clinical trial that showed that it improved overall survival by 1.6 months when added to gemcitabine and cisplatin compared gemcitabine and cisplatin alone (11.5 months versus 9.9 months).
- The labeling for Portrazza contains a boxed warning concerning the risks of cardiac arrest and sudden death, as well as hypomagnesemia (low levels of magnesium in the blood). Patients’ electrolytes (e.g., magnesium, calcium, potassium) should be closely monitored during and after treatment with Portrazza.