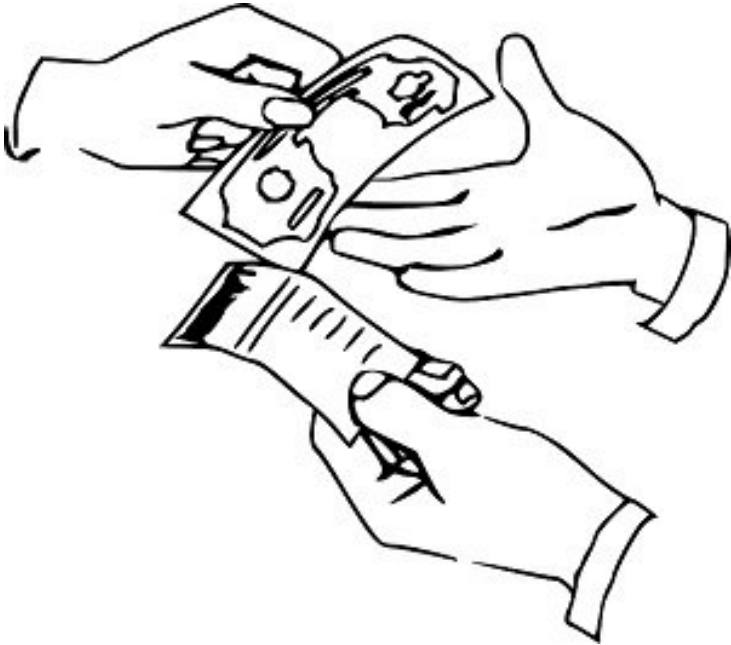


## FDA nod for BMS/AbbVie's multiple myeloma drug

01 December 2015 | News | By BioSpectrum Bureau

### FDA nod for BMS/AbbVie's multiple myeloma drug



Bristol-Myers Squibb Company and AbbVie has announced the US Food and Drug Administration (US FDA) has approved Empliciti (elotuzumab) for the treatment of multiple myeloma as combination therapy with Revlimid (lenalidomide) and dexamethasone (ERd) in patients who have received one to three prior therapies. The approval of this first and only immunostimulatory antibody for multiple myeloma is based on data from the randomized, open-label, Phase 3, ELOQUENT-2 study, which demonstrated that the ERd regimen resulted in a 30 percent reduction in the risk of disease progression or death compared to Rd alone.

"At Bristol-Myers Squibb, we are leading a revolution in cancer treatment that is changing expectations for patients with some of the hardest-to-treat cancers. With today's approval of Empliciti, we are pleased to now bring the promise of our Immuno-Oncology research to patients with multiple myeloma," said Dr Francis Cuss, chief scientific officer, Bristol-Myers Squibb. "Empliciti represents a fundamentally different approach of directly activating the immune system in patients with relapsed or refractory multiple myeloma, delivering improved outcomes for those in need."

Empliciti is available for injection for intravenous use in 300 mg and 400 mg vials. The company expects to begin shipping Empliciti within the next 48 hours. Empliciti is also under review by the European Medicines Agency and has been granted accelerated assessment.

Discontinuation rates due to adverse reactions were similar across the ERd and Rd control arms (6.0 vs. 6.3 percent). ERd is associated with the following Warnings and Precautions: Infusion Reactions, Infections, Second Primary Malignancies, Hepatotoxicity, Interference with Determination of Complete Response, Pregnancy/Females and Males of Reproductive

Potential, and Adverse Reactions. Please see the detailed Important Safety Information and a link to the Prescribing Information below.

"Empliciti in combination with lenalidomide and dexamethasone is an important new option for patients with multiple myeloma and healthcare providers who are treating this cancer," said Dr Michael Severino, executive vice president of research and development and chief scientific officer, AbbVie. "AbbVie is pleased to have partnered with Bristol-Myers Squibb in making this new treatment available for patients with relapsed or refractory multiple myeloma."