

Empliciti® (elotuzumab) - New indication

- On November 6, 2018, <u>Bristol-Myers Squibb announced</u> the FDA approval of <u>Empliciti (elotuzumab)</u>, in combination with <u>Pomalyst[®] (pomalidomide)</u> and <u>dexamethasone</u> for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including <u>Revlimid[®] (lenalidomide)</u> and a proteasome inhibitor.
 - Empliciti is also approved in combination with Revlimid and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies.
- Multiple myeloma is a blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow. The <u>National Cancer Institute</u> estimates there will be 30,770 new cases of multiple myeloma and 12,770 related deaths in the U.S. this year.
- The approval of Empliciti's new indication was based on a randomized, open-label study in 117
 patients with relapsed or refractory multiple myeloma. Patients were randomized to receive either
 Empliciti in combination with Pomalyst and low-dose dexamethasone or Pomalyst and low-dose
 dexamethasone. The efficacy of Empliciti was evaluated by progression-free survival (PFS) and
 overall response rate (ORR).
 - Median PFS was 10.25 months (95% CI: 5.59, not-estimable) and 4.67 (95% CI: 2.83, 7.16) for patients in the Empliciti and comparator arms, respectively (HR 0.54, 95% CI: 0.34, 0.86; p = 0.0078).
 - ORR was 53.3% (95% CI: 40.0, 66.3) and 26.3% (95% CI: 15.5, 39.7) for patients in the Empliciti and comparator arms, respectively (p = 0.0029).
- The most common adverse reactions (≥ 20%) with Empliciti in combination with Pomalyst and dexamethasone use were constipation and hyperglycemia.
- The recommended dose for Empliciti when used in combination with Pomalyst and dexamethasone is 10 mg/kg administered intravenously every week for the first two cycles and 20 mg/kg every 4 weeks thereafter until disease progression or unacceptable toxicity.
 - To reduce the risk of infusion reactions, patients should be premedicated with dexamethasone, <u>diphenhydramine</u>, <u>ranitidine</u>, and <u>acetaminophen</u>.
 - Refer to the Pomalyst and dexamethasone drug labels for additional dosing information.
- Refer to the Empliciti drug label for dosing recommendations when Empliciti is used in combination with Revlimid and dexamethasone.



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