Empliciti

(elotuzumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Empliciti
- **Generic name:** Elotuzumab
- **Pharmacological class:** SLAMF7-directed immunostimulatory antibody
- **Strength and Formulation:** 300mg, 400mg; per vial; lyophilized powder for IV infusion after reconstitution; preservative-free
- **Manufacturer:** Bristol-Myers Squibb
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

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NDC 0003-2291-11
Rx only
Empliciti™
(elotuzumab)
for Injection
300 mg per vial
For Intravenous Infusion Only
Reconstitute and Further Dilute Prior to Use
Single-Dose Vial. Discard Unused Portion.
Bristol-Myers Squibb
NDC 0003-2291-11
Empliciti
(elotuzumab)
for Injection
300 mg per vial
For Intravenous Infusion Only

Indications

- In combination with lenalidomide and dexamethasone, for the treatment of patients with **multiple myeloma** who have received 1–3 prior therapies

Dosage & Administration

- Give by IV infusion at initial rate of 0.5mL/min; may increase stepwise if no reactions develop; max rate 2mL/min
- After 4 cycles, infusion rate may be increased up to max 5mL/min
- Administer with **lenalidomide** and **dexamethasone** (see full labeling for dosing schedule)

Dosage & Administration

- 10mg/kg every week for the first 2 cycles then every 2 weeks thereafter; continue until disease progression or unacceptable toxicity
- **Premedicate** with dexamethasone, H_1 blocker, H_2 blocker, and acetaminophen before each infusion
- Dose modifications: see full labeling

Considerations for Special Populations

- **Pregnancy:** Not studied; lenalidomide is contraindicated in pregnancy
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** No overall differences in efficacy or safety

Contraindications

- Consult **lenalidomide** and **dexamethasone** prescribing information for contraindications before starting therapy

Warnings/Precautions

- Interrupt infusion if Grade ≥2 infusion reactions occur and manage appropriately
- Monitor for development of infections and treat promptly
- Monitor for second primary malignancies
- Monitor liver function periodically; **discontinue** if Grade ≥3 elevation of liver enzymes occur; consider resuming after return to baseline values

Interactions

- May interfere with correct response classification in SPEP and serum immunofixation assays

Adverse Reactions

- Fatigue
- Diarrhea
- Pyrexia
- Constipation
- Cough
- Peripheral neuropathy
- Nasopharyngitis
- Upper respiratory tract infection
- Decreased appetite
- Pneumonia

Mechanism of Action

- Elotuzumab is a humanized IgG1 monoclonal antibody that specifically targets the SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) protein
- It directly activates Natural Killer cells through both the SLAMF7 pathway and Fc receptors
- It also targets SLAMF7 on myeloma cells and facilitates the interaction with Natural Killer cells to mediate the killing of myeloma cells through antibody-dependent cellular cytotoxicity

Clinical Trials

- The efficacy and safety of Empliciti in combination with lenalidomide and dexamethasone were evaluated in a randomized, open-label trial in 646 patients with multiple myeloma who had received 1–3 prior therapies and had documented progression after most recent therapy

Clinical Trials

- Patients were randomized 1:1 to receive either Empliciti (10mg/kg IV each week for the first 2 cycles and every 2 weeks thereafter) in combination with lenalidomide/low-dose dexamethasone or lenalidomide/low-dose dexamethasone alone in 4-week cycles until disease progression or unacceptable toxicity
- Tumor response assessment was conducted every 4 weeks

Clinical Trials

- The primary efficacy endpoints were progression-free survival (PFS) as assessed by hazard ratio (HR), and overall response rate (ORR) using the EBMT response criteria
- After a median follow-up of 24.5 months, study results showed that Empliciti + lenalidomide/low-dose dexamethasone led to a 30% reduction in the risk of disease progression or death vs. lenalidomide/low-dose dexamethasone alone (HR 0.7, [95% CI: 0.57, 0.85]; *P*=0.0004)

Clinical Trials

- The 1- and 2-year rates of PFS for the Empliciti combination therapy were 68% and 41%, respectively, compared with 57% and 27%, respectively, for lenalidomide/dexamethasone treatment

Clinical Trials

- Results also showed greater ORR in the Empliciti + lenalidomide/low-dose dexamethasone arm vs. the lenalidomide/ low-dose dexamethasone arm (78.5%, [95% CI: 73.6, 82.9] vs. 65.5%, [95% CI: 60.1, 70.7] respectively, P=0.0002)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/empliciti/drugproduct/403/