Lartruvo

(olaratumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Lartruvo
- **Generic name:** Olaratumab
- **Pharmacological class:** PDGFR-alpha inhibitor
- **Strength and Formulation:** 500mg/50mL; solution for IV infusion; preservative-free
- **Manufacturer:** Eli Lilly
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

Indications

- In combination with doxorubicin, for the treatment of adults with **soft tissue sarcoma** with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery

Dosage & Administration

- **Premedicate** with IV diphenhydramine and IV dexamethasone prior to infusion on Day 1 of cycle 1
- Give with doxorubicin for the first 8 cycles: refer to doxorubicin PI for dosing and modifications
- Give by IV infusion over 60 minutes
- **15mg/kg** on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity
- Dose modifications: see full labeling

Considerations for Special Populations

- **Pregnancy:** Can cause fetal harm
- **Nursing mothers:** Not recommended during and for 3 months after last dose
- **Pediatric:** Not established
- **Geriatric:** Insufficient number studied

Warnings/Precautions

- Have resuscitative equipment available
- **Monitor** for signs/symptoms of infusion-related reactions during and post-infusion
- **Permanently discontinue** for Grade 3/4 infusion-related reactions; interrupt for Grade 1/2 infusion-related reactions; resume at 50% of initial rate after resolution

Warnings/Precautions

- If neutropenic fever/infection or Grade 4 neutropenia lasts >1 week, **discontinue** until ANC ≥1,000µL then permanently reduce dose to 12mg/kg
- Embryo-fetal toxicity
- Females of reproductive potential should use effective contraception during and for 3 months after last dose

Adverse Reactions

- With doxorubicin:
  - Nausea
  - Fatigue
  - Musculoskeletal pain
  - Mucositis
  - Alopecia
  - Vomiting
  - Diarrhea
  - Decreased appetite
  - Abdominal pain
  - Neuropathy
  - Headache
  - Anxiety
  - Dry eyes
  - Lymphopenia
  - Neutropenia
  - Thrombocytopenia
  - Hyperglycemia
  - Elevated aPTT
  - Hypokalemia
  - Hypophosphatemia
  - Increased ALP

Mechanism of Action

- Olaratumab is a **human IgG1 antibody** that binds PDGFR-alpha, a receptor involved in cell growth, chemotaxis, and mesenchymal stem cell differentiation
- The receptor has also been detected on some tumor and stromal cells, including sarcomas, where signaling can contribute to cancer cell proliferation, metastasis, and maintenance of the tumor microenvironment

Clinical Trials

- The efficacy of Lartruvo was seen in **Trial 1**, an open-label, randomized, active-controlled study (n=133)

- Patients were randomized (1:1) to receive Lartruvo in combination with doxorubicin or doxorubicin alone

Clinical Trials

- Lartruvo 15mg/kg was given as an IV infusion on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity

- All patients received doxorubicin 75mg/m^2 as an IV infusion on Day 1 of each 21-day cycle for a maximum of 8 cycles and were permitted to receive dexrazoxane prior to doxorubicin in Cycles 5 to 8

Clinical Trials

- The efficacy outcome measures were overall survival (OS), progression-free survival (PFS), and objective response rate (ORR) as assessed by an investigator and by independent review

Clinical Trials

- Patients in the Lartruvo plus doxorubicin group had a **significant improvement in OS** as compared to the doxorubicin alone group (26.5 months vs. 14.7 months, hazard ratio [HR] 0.52, 95% CI: 0.34, 0.79; *P*<0.05)

- Patients in the Lartruvo plus doxorubicin group had a **longer PFS** as compared to the doxorubicin alone group (8.2 months vs. 4.4 months, HR 0.74, 95% CI: 0.46, 1.19)

Clinical Trials

- Also, patients in the Lartruvo plus doxorubicin group had a **higher ORR** (complete response + partial response) as compared to the doxorubicin alone group (18.2% vs. 7.5%)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/lartruvo/drug/34624/