Empliciti is the first immunostimulatory monoclonal antibody approved by the US Food and Drug Administration (FDA) for the treatment of multiple myeloma. It was approved in November 2015, in combination with Revlimid® (lenalidomide) + dexamethasone, because clinical trials demonstrated that the combination is more effective than Empliciti by itself. Because Empliciti stimulates the immune system cells to attack myeloma cells, it not only helps to cause myeloma cell death, it also appears to stimulate an ongoing immune response against myeloma.

Who is a candidate for Empliciti?
Empliciti is approved in the United States, in all countries of the European Union, and in Norway, Iceland, and Liechtenstein in combination with Revlimid + dexamethasone for the treatment of myeloma patients who have received 1 to 3 prior therapies.

How is Empliciti given?
Empliciti is given as an intravenous (IV, or into the vein) infusion. Dosing is determined by a patient’s weight. To ensure tolerance, Empliciti is infused very slowly at first at a rate of 0.5 mg/minute, and subsequently can be given at 2 mg/minute. By the third cycle of treatment, at the doctor’s discretion, the rate of infusion may increase to 5 mg/minute. Medication is given before the infusion to help prevent an infusion reaction.

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Each dosing cycle of Empliciti + Revlimid + dexamethasone (ERd) therapy is 28 days long. For the first two cycles, patients receive Empliciti at a dose of 10 milligrams (mg) for every kilogram (kg) of body weight once weekly (on Days 1, 8, 15, and 22 of each cycle). After the first two cycles, patients receive Empliciti every other week (on Days 1 and 15), repeated every 28 days. Revlimid is given orally at a dose of 25 mg (on Days 1–21 of each cycle) and dexamethasone is given orally at a dose of 40 mg (on Days 1, 8, 15, and 22 of each cycle).

For the first two cycles of Empliciti + Pomalyst® (pomalidomide) + dexamethasone (EPd) therapy, Empliciti is given at a dose of 10 mg/kg every week. Thereafter, it is given at a dose of 20 mg/kg every 4 weeks until disease progression or unacceptable toxicity.

What are the possible side effects of Empliciti?

- Infusion reactions
- Lymphocytopenia and neutropenia
- Anemia
- Thrombocytopenia
- Fatigue
- Diarrhea
- Fever
- Constipation
- Infections
- Muscle spasms
- Decreased appetite

As always, the IMF urges you to discuss all medical issues with your doctor, and to contact the IMF with your myeloma questions and concerns.