**BLINCYTO™** (blinatumomab) Risk Evaluation and Mitigation Strategy (REMS)

**What is the BLINCYTO™ REMS?**

A Risk Evaluation and Mitigation Strategy (REMS) is a program to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

The purpose of the BLINCYTO REMS is to inform Healthcare Providers about the following serious risks:

**BOXED WARNING: Cytokine Release Syndrome**

- Serious adverse events that may be associated with CRS included **pyrexia, headache, nausea, asthenia, hypotension, increased alanine aminotransferase, increased aspartate aminotransferase, and increased total bilirubin.**
- The highest elevation of cytokines was observed in the first 2 days following start of BLINCYTO infusion

**BOXED WARNING: Neurological Toxicities**

- In patients receiving BLINCYTO in clinical trials, neurological toxicities have

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occurred in approximately 50% of patients.

- The median time to onset of any neurological toxicity was 7 days.

- Grade 3 or higher (severe, life-threatening or fatal) neurological toxicities following initiation of BLINCYTO administration occurred in approximately 15% of patients and included encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders. The majority of events resolved following interruption of BLINCYTO, but some resulted in treatment discontinuation.

Preparation and Administration Errors

- Preparation and administration errors have occurred with BLINCYTO treatment.

- It is very important that the instructions for preparation (including admixing) and administration are strictly followed to minimize medication errors (including underdose and overdose).

BLINCYTO Fact Sheet:

A non-promotional REMS Fact Sheet reviewed by the FDA, with more detailed information on the serious risks associated with BLINCYTO is available in the “Materials for Healthcare Providers” section above.

INDICATION:

BLINCYTO is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

You are encouraged to report negative side effects of BLINCYTO to Amgen at 1-800-77-AMGEN (1-800-772-6436) and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088

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