

## BLINCYTO<sup>®</sup> (blinatumomab) REMS

### FDA-REQUIRED UPDATED REMS SAFETY INFORMATION

#### Risk of:

- Cytokine Release Syndrome (CRS), which may be life-threatening or fatal
- Neurological Toxicities, which may be severe, life-threatening or fatal
- Preparation and Administration Errors

March 2018

Dear Healthcare Provider:

The Food and Drug Administration (FDA) has required this safety notice as part of the BLINCYTO<sup>®</sup> REMS (Risk Evaluation and Mitigation Strategy) to highlight new risk information about cytokine release syndrome and neurological toxicities for BLINCYTO.

#### BOXED WARNING: Cytokine Release Syndrome

- Monitor patients for signs or symptoms of CRS.
- BLINCYTO has been recently approved for the treatment of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.
  - **In patients treated for MRD-positive B-cell precursor ALL, hospitalization is recommended for the first 3 days of the first cycle and the first 2 days of the second cycle.**
  - In patients treated for relapsed or refractory B-cell precursor ALL, hospitalization is recommended for the first 9 days of the first cycle and the first 2 days of the second cycle.

New



#### BOXED WARNING: Neurological Toxicities

- In patients with ALL receiving BLINCYTO in clinical studies, neurological toxicities have occurred in approximately 65% of patients.
  - **Manifestations of neurological toxicity included cranial nerve disorders.**

New



#### OTHER SERIOUS RISKS: Preparation and Administration Errors

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

Please see the enclosed non-promotional REMS Fact Sheet, reviewed by the FDA, and the full Prescribing Information for more detailed safety information. Additional copies of the Fact Sheet and other important information are available at: [www.blincytoREMS.com](http://www.blincytoREMS.com).

BLINCYTO is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with 1) B-cell precursor ALL in first or second complete remission with MRD greater than or equal to 0.1% and 2) relapsed or refractory B-cell precursor ALL.

## REPORTING ADVERSE EVENTS

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. Healthcare Providers should report all suspected adverse events associated with BLINCYTO to the FDA or to Amgen at 1-800-77-AMGEN (1-800-772-6436).

Sincerely,

A handwritten signature in black ink that reads "Isma Benattia". The signature is written in a cursive, flowing style.

Isma Benattia, MD, MBE  
Vice President, Global Patient Safety & Labeling