BRAND NAME: BLINCYTO

COMMON NAME: Blinatumomab

REGULATORY MILESTONES:

US pre-IND	June 16, 2006
US Approval	December 3, 2014
EU Approval	November 23, 2015
Health Canada Approval	January 12, 2016
Japan Approval	September 24, 2018
TGA Approval	September 30, 2019

MANUFACTURING:

PARAMETER	DATA	REFERENCE
Manufacturer	Amgen, Inc.	
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)	1
Cell Substrate	Chinese hamster ovary (CHO) cell line	3
Manufacturing platform	The description of the active substance manufacturing process and process controls/tests is appropriately detailed and starts with the expansion (into flasks, roller bottles and bag bioreactors) of 1 vial of working cell bank (WCB) of the Chinese hamster ovary (CHO) cell line, which is used to inoculate the main fermenter. One vial of working cell bank leads to a single batch of active substance, without cycling or generation of sub-lots. The harvest is collected by centrifugation followed by filtration steps to remove cells and cellular debris. The purification process includes three chromatography steps, two concentration/diafiltration steps and two virus	3

	removal/inactivation steps. The active substance is filtered, dispensed and stored at 2-8°C. No reprocessing is claimed.	
Dose in vial/final container	38.5 mcg blinatumomab per 4mL vial	1
Dose to patient	For patients at least 45 kg in weight: t 9 mcg/day on Days 1–7 and at 28 mcg/day on Days 8–28. For subsequent cycles, administer BLINCYTO at 28 mcg/day on Days 1–28	1

1. Package insert - BLINCYTO
2. EPAR full - Blincyto
3. EPAR quality - Blincyto: EPAR – Public assessment report
4. FDA Review - Blincyto (blinatumomab) Injection

CLINICAL TRIALS:

NCT	TITLE	COUNTRIES
NCT00274742	Safety Study of the Bispecific T-cell Engager Blinatumomab (MT103) in Patients with Relapsed NHL	Germany
NCT01466179	Clinical Study with Blinatumomab in Patients With Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (ALL)	United States, France, Germany, Italy, Spain, United Kingdom
NCT01471782	Clinical Study with Blinatumomab in Pediatric and Adolescent Patients with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia	United States, Austria, Canada, France, Germany, Italy, Netherlands
NCT02187354	Expanded Access Protocol - Blinatumomab in Pediatric & Adolescent Subjects with Relapsed/Refractory B-precursor ALL	United States, Austria, France, Germany, Italy, Switzerland, United Kingdom
NCT02101853	Blinatumomab in Treating Younger Patients with Relapsed B-cell Acute Lymphoblastic Leukemia	United States, Australia, Canada, New Zealand, Puerto Rico
NCT01209286	Study of the BiTE® Blinatumomab (MT103) in Adult Patients with Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia (ALL)	Germany

POST APPROVAL CHANGES

DATE	TYPE OF CHANGE	DESCRIPTION	LINK
03/20/2020	Dosage and Administration	changes to the reconstitution and preparation procedures based on the results of the label comprehension validation study.	Supplement Approval