BRAND NAME: Darzalex

COMMON NAME: Daratumumab

REGULATORY MILESTONES:

US pre-IND	July 2007
US Approval	November 16, 2015
EU Approval	May 20, 2016
Health Canada Approval	June 30, 2016
Japan Approval	August 22, 2019
TGA Approval	July 17, 2017

MANUFACTURING:

PARAMETER	DATA	REFERENCE
Manufacturer	Janssen Biotech, Inc.	
Indication	DARZALEX is a human CD38-directed monoclonal antibody indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.	1
Cell Substrate	Mammalian Chinese Hamster Ovary (CHO) cell line	3
Manufacturing platform	Daratumumab active substance is manufactured in an 11-stage process consisting of fed batch cell culture followed by purification with a series of chromatography, viral inactivation, and filtration steps. Formulation also takes place at the active substance level. The concentrated viral inactivation and neutralization (VIN) intermediate is obtained at Stage 5b. The CMC strategy for comparability included an evaluation of QC batch release results and additional biochemical, biophysical, and biological	3

	characterization data according to the guidance provided in ICH Q5E.	
Dose in vial/final container	100 mg/5 mL solution in a single-dose vial 400 mg/20 mL solution in a single-dose vial	1
Dose to patient	16 mg/kg body weight: • Weekly - Weeks 1 to 8 • Every two weeks - Weeks 9 to 24 • Every four weeks - Week 25 onwards until disease progression	1

1. Package insert – Darzalex
2. EPAR full – Darzalex
3. EPAR quality - DARZALEX: EPAR – Public assessment report
4. FDA Review - Darzalex Daratumumab injection

CLINICAL TRIALS:

NCT	TITLE	COUNTRIES
NCT01985126	An Efficacy and Safety Study of Daratumumab in Patients with Multiple Myeloma Who Have Received at Least 3 Prior Lines of Therapy (Including a Proteasome Inhibitor [PI] and Immunomodulatory Drug [IMiD]) or Are Double Refractory to a PI and an IMiD	United States, Canada, Spain
NCT00574288	Daratumumab (HuMax®-CD38) Safety Study in Multiple Myeloma	United States, Denmark, Netherlands, Sweden
NCT01615029	Daratumumab in Combination with Lenalidomide and Dexamethasone in Relapsed and Relapsed-refractory Multiple Myeloma	United States, Denmark, France, Netherlands, United Kingdom
NCT01998971	A Study of JNJ-54767414 (HuMax CD38) (Anti-CD38 Monoclonal Antibody) in Combination with Backbone Treatments for the Treatment of Patients with Multiple Myeloma	United States, France, Spain
NCT02116569	A Study of Daratumumab in Japanese Participants with Relapsed or Refractory Multiple Myeloma	Japan

POST APPROVAL CHANGES

DATE	TYPE OF CHANGE	DESCRIPTION	LINK
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