BRAND NAME: Tecentriq

COMMON NAME: Atezolizumab

REGULATORY MILESTONES:

US pre-IND	May 12, 2015
US Approval	October 18, 2016
EU Approval	September 20, 2017
Health Canada Approval	August 13, 2019
Japan Approval	December 25, 2020
TGA	June 4, 2020

MANUFACTURING:

PARAMETER	DATA	REFERENCE
Manufacturer	Genentech, Inc.	
Indication	treatment of patients with locally advanced or metastatic urothelial carcinoma who: • Have disease progression during or following platinum-containing chemotherapy • Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	1
Cell Substrate	Chinese hamster ovary (CHO) cells	3
Manufacturing platform	humanized monoclonal antibody based on an IgG1 (kappa) framework containing humanized heavy chain VHIII and light chain V kappa I subgroup sequences. Atezolizumab is produced using a stably transfected Chinese hamster ovary (CHO) cell line. One of the clones resulting from this transfection was selected as the host cell for production cell-line construction. A two-tier cell banking system of master cell bank and working	3

	cell bank was developed and characterized in accordance with ICH guidelines.	
Dose in vial/final container	1200 mg/20 mL (60 mg/mL)	1
Dose to patient	Initial infusion over 60 minutes through an intravenous line with or without a sterile, non-pyrogenic, low-protein binding in-line filter (pore size of 0.2–0.22 micron)	1

1. Package insert - Labeling
2. EPAR full - Tecentriq : EPAR
3. EPAR quality - Tecentriq : EPAR - Public assessment report (page 17)
4. FDA Review - Tecentriq (atezolizumab) Injection

CLINICAL TRIALS SUPPORTING BLA 761041[1]

NCT	TITLE	COUNTRIES
NCT01903993	A Randomized Phase 2 Study of Atezolizumab (an Engineered Anti-PDL1 Antibody) Compared with Docetaxel in Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum Therapy - "POPLAR"	United States, Belgium, Canada, France, Germany, Italy, Korea, Republic of, Poland, Spain, Sweden, Thailand, Turkey, United Kingdom
NCT02031458	A Study of Atezolizumab in Participants with Programmed Death - Ligand 1 (PD-L1) Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer	United States, Australia, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, France, Georgia, Germany, Hong Kong, Italy, Japan, Netherlands, Singapore, Slovenia, Spain, Switzerland, Turkey, United Kingdom
NCT01846416	A Study of Atezolizumab in Participants with Programmed Death-Ligand 1 (PD-L1) Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) [FIR]	United States, Belgium, France, Netherlands, United Kingdom

[1] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761041Orig1s000MedR.pdf

NCT01375842	A Study of Atezolizumab (an Engineered Anti-Programmed Death-Ligand 1 [PDL1] Antibody) to Evaluate Safety, Tolerability, and Pharmacokinetics in Participants with Locally Advanced or Metastatic Solid Tumors	United States, France, Spain, United Kingdom
NCT02008227	A Study of Atezolizumab Compared with Docetaxel in Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Failed Platinum-Containing Therapy	United States, Argentina, Austria, Brazil, Canada, Chile, Finland, France, Germany, Greece, Guatemala, Hungary, Italy, Japan, Korea, Republic of, Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Russian Federation, Serbia, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Kingdom

POST APPROVAL CHANGES

DATE	TYPE OF CHANGE	DESCRIPTION	LINK
03/08/2019	New dosage form	provides for a new 840 mg/14 mL single-dose vial presentation	Approval letter