BRAND NAME: COSENTYX

PROPER NAME: Secukinumab

MANUFACTURER: NOVARTIS PHARMS CORP

INDICATION: COSENTYX is a human interleukin-IL-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

DESCRIPTION: Secukinumab is a recombinant human monoclonal IgG1/k antibody that binds tp IL-17A. It is expressed in a recombinant Chinese Hamster Ovary (CHO) cell line. Secukinumab has a molecular mass of approximately 151 kDa; both heavy chains of secukinumab contain oligosaccharide chains.

BLA: 125504

REGULATORY MILESTONES:

US Approval	January 21, 2015
EU Approval	January 14, 2015
Health Canada Approval	April 10, 2015
Japan Approval	May 11, 2016
TGA	December 26, 2014

ADVISORY COMMITTEE:

A Dermatologic and Ophthalmologic Drugs Advisory Committee meeting was convened on October 20, 2014 to discuss the safety and efficacy results for this application.

MANUFACTURING:

PARAMETER	DATA	REFERENCE
Manufacturer	Novartis Pharmaceuticals Corporation	
Indication	COSENTYX is a human interleukin-IL-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	1
Cell Substrate	CHO (Chinese Hamster Ovary) cells MCB 060428 (CHO-HPT1 cell line)	3
Manufacturing platform	The cell culture process is conventional, expanding the culture via T-flasks and roller bottles to a fed batch bioreactor. The cell culture media used for inoculum preparation, for seed expansion, and for the production stage are serum-free, with low protein content and do not contain animal- or human-derived raw materials. The cell culture fluid is harvested as a single-harvest batch which is subsequently purified as a single active substance batch. The purification process consists of 9 steps including harvest, chromatography and filtration with final freezing and storage at ≤- 60℃.	3
Dose in vial/final container	• Injection: 150 mg/mL solution in a single-use Sensoready® pen • Injection: 150 mg/mL solution in a single-use prefilled syringe • For Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution.	1
Dose to patient	300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg.	1

1. Package insert - COSENTYX
2. EPAR full – Cosentyx
3. EPAR quality - Cosentyx : EPAR - Public assessment report
4. FDA Review - COSENTYX (secukinumab)

CLINICAL TRIALS:

NCT	TRIAL PHASE	NO OF PATIENTS ENROLLED	TITLE	COUNTRIES
Placebo-controlled, active-controlled trials				
NCT01365455	3	738	Efficacy and Safety of Subcutaneous Secukinumab for Moderate to Severe Chronic Plaque-type Psoriasis for up to 1 Year	United States, Canada, Estonia, Colombia, Japan, Iceland, Israel, Latvia, Argentina, Lithuania, Taiwan, Mexico
NCT01358578	3	1306	Safety and Efficacy of Secukinumab Compared to Etanercept in Subjects with Moderate to Severe, Chronic Plaque-Type Psoriasis	United States, Argentina, Italy, Australia, Belgium, Canada, Colombia, Egypt, Finland, France, Germany, Guatemala, India, Hungary, Iceland, Korea Republic of, Philippines, Spain, Poland, Romania, Singapore, Sweden, United Kingdom
NCT01555125	3	177	First Study of Secukinumab in Pre-filled Syringes in Subjects With Chronic Plaque-type Psoriasis: Response at 12 Weeks	United States, Canada, Estonia, France, Germany
NCT01636687	3	182	Judging the Efficacy of Secukinumab in Patients With Psoriasis Using AutoiNjector: a Clinical Trial Evaluating Treatment Results (JUNCTURE)	United States, Canada, Estonia, France, Germany
NCT01406938	3	967	Efficacy and Safety of Subcutaneous Secukinumab (AIN457) for Moderate to Severe Chronic Plaque-type	United States, Austria, Bulgaria, Canada, Czech Republic, France, Germany, India,

			Psoriasis Assessing Different Doses and Dose Regimens	Italy, Japan, Poland, Singapore, Slovakia, Vietnam, Switzerland, United Kingdom
NCT01412944	3	43	Efficacy and Safety of Intravenous and Subcutaneous Secukinumab in Moderate to Severe Chronic Plaque-type Psoriasis	United States, Austria, Canada, Czech Republic, France, Germany, India, Japan, Slovakia
Phase 2 studies in psoriasis				
NCT01412944	2	404	AIN457 Regimen Finding Study in Patients with Moderate to Severe Psoriasis	United States, France, Germany, Iceland, Israel, Japan, Norway
NCT00805480	2	130	Multiple-loading Dose Regimen Study in Patients with Chronic Plaque-type Psoriasis	

POST APPROVAL CHANGES

DATE	TYPE OF CHANGE	DESCRIPTION	LINK