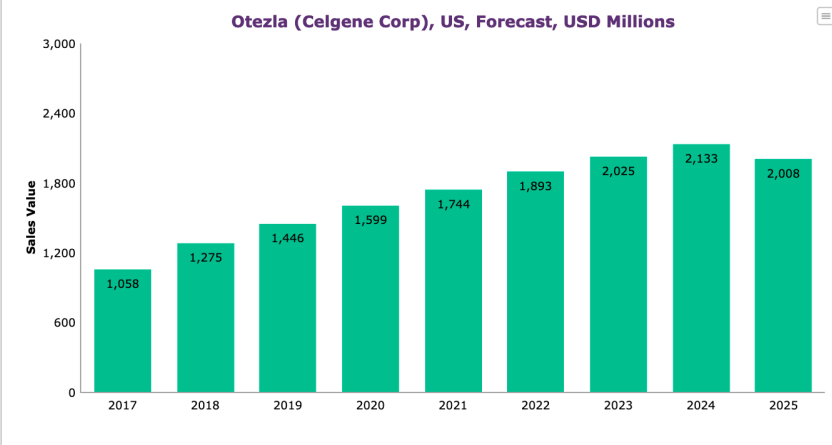


PIPELINE REVIEW

Otezla® (apremilast)

Page	Indication	Date Approved	Date Updated
2	Behcet Disease	July 19, 2019	July 23, 2019
3	Plaque Psoriasis (Psoriasis Vulgaris)	Sep 23, 2014	July 11, 2019
4	Psoriatic Arthritis	March 21, 2014	July 11, 2019

Drug Information			Regulatory Information																					
Manufacturer:	Celgene		Application Type:	Supplemental NDA																				
Drug Brand Name:	Otezla®		Original Anticipated Approval (PDUFA):	7/21/2019																				
			Regulatory Status:	Approved																				
Drug Generic Name:	apremilast		Regulatory Status Date:	7/19/2019																				
			Regulatory Status Reason:	N/A																				
Drug Type:	Small Molecule		Orphan Drug Designation:	1/17/2013																				
			FDA Fast Track Designation:	N/A																				
Route of Administration:	Oral		Breakthrough Therapy Designation	N/A																				
			Priority Review Designation:	N/A																				
Indication Details			Sales Forecast																					
Indication	Prevalence Type	Prevalence	Otezla (Celgene Corp), US, Forecast, USD Millions <table><thead><tr><th>Year</th><th>Sales Value</th></tr></thead><tbody><tr><td>2017</td><td>1,058</td></tr><tr><td>2018</td><td>1,275</td></tr><tr><td>2019</td><td>1,446</td></tr><tr><td>2020</td><td>1,599</td></tr><tr><td>2021</td><td>1,744</td></tr><tr><td>2022</td><td>1,893</td></tr><tr><td>2023</td><td>2,025</td></tr><tr><td>2024</td><td>2,133</td></tr><tr><td>2025</td><td>2,008</td></tr></tbody></table> Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: July 9, 2019.		Year	Sales Value	2017	1,058	2018	1,275	2019	1,446	2020	1,599	2021	1,744	2022	1,893	2023	2,025	2024	2,133	2025	2,008
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2025	2,008																							
Behcet Disease	U.S.	14,397																						
	Global	28,931																						

Comments Section

UPDATE: On July 19, 2019, FDA approved Otezla® (apremilast) for the treatment of adult patients with oral ulcers associated with Behcet’s Disease.

Behcet Disease is estimated to affect fewer than 1 in 100,000 people in the United States.*

Sources:

* “Behçet Disease - Genetics Home Reference.” *U.S. National Library of Medicine*, National Institutes of Health, ghr.nlm.nih.gov/condition/behcet-disease#statistics. Accessed: July 10, 2019.

“FDA Approves OTEZLA® (Apremilast) for the Treatment of Oral Ulcers Associated with Behçet's Disease.” *Celgene*, 19 July 2019, ir.celgene.com/press-releases/press-release-details/2019/FDA-Approves-OTEZLA-apremilast-for-the-Treatment-of-Oral-Ulcers-Associated-with-Behets-Disease/default.aspx.

GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>. Accessed: July 23, 2019.

Drug Information			Regulatory Information	
Manufacturer:	Celgene		Application Type:	NDA
Drug Brand Name:	Otezla®		Original Anticipated Approval (PDUFA):	N/A
			Regulatory Status:	Approved
Drug Generic Name:	apremilast		Regulatory Status Date:	9/23/2014
			Regulatory Status Reason:	N/A
Drug Type:	Small Molecule		Orphan Drug Designation:	N/A
			FDA Fast Track Designation:	N/A
Route of Administration:	Oral		Breakthrough Therapy Designation	N/A
			Priority Review Designation:	N/A
Indication Details			Sales Forecast	
Indication	Prevalence Type	Prevalence	Otezla (Celgene Corp), US, Forecast, USD Millions Sales Value 3,000 2,400 1,800 1,200 600 0 2017 2018 2019 2020 2021 2022 2023 2024 2025 1,058 1,275 1,446 1,599 1,744 1,893 2,025 2,133 2,008	
Plaque Psoriasis (Psoriasis Vulgaris)	U.S.	8,054,716		
	Global	16,465,044		
			Otezla (Celgene Corp), US, Historical, USD Millions Sales Value 1,000 800 600 400 200 0 2014 2015 2016 70 440 904	

Source: GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

Source: GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

Comments Section

On September 23, 2014, FDA approved Otezla® (apremilast) for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Plaque psoriasis is the most common form of psoriasis, affecting about 80-90% of psoriasis patients.*

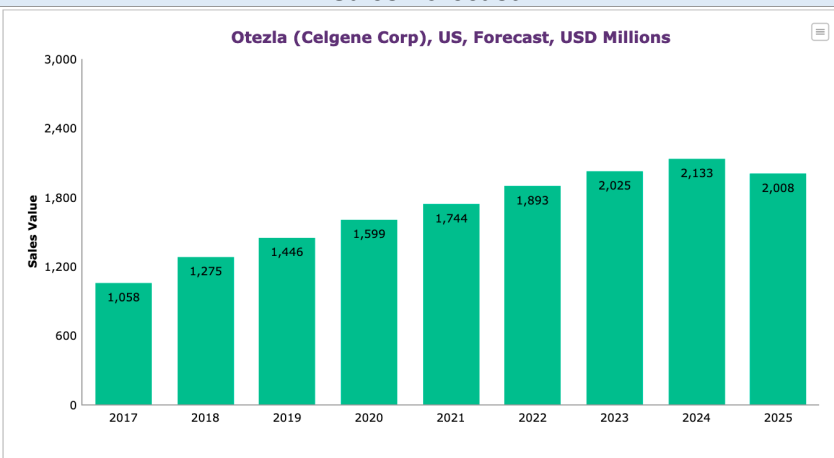
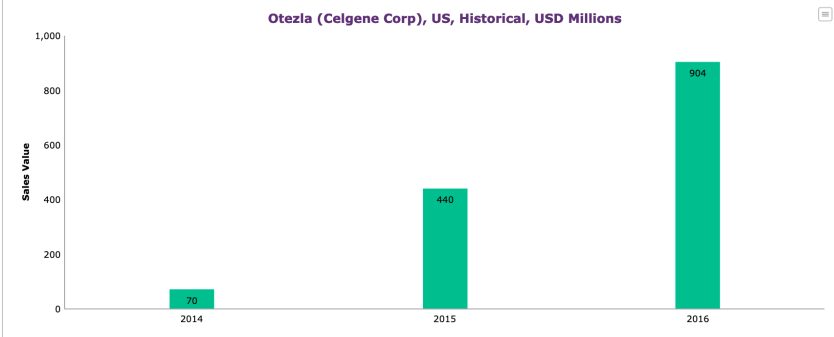
Sources:

GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

"Oral OTEZLA® (Apremilast) Approved by the U.S. Food and Drug Administration for the Treatment of Patients with Moderate to Severe Plaque Psoriasis." *Celgene*, 23 Sept. 2014, ir.celgene.com/press-releases/press-release-details/2014/Oral-OTEZLA-apremilast-Approved-by-the-US-Food-and-Drug-Administration-for-the-Treatment-of-Patients-with-Moderate-to-Severe-Plaque-Psoriasis/default.aspx.

OTEZLA® (apremilast) [Package Insert]. Summit, NJ: Celgene Corporation; 2017.

* "Skin Conditions by the Numbers." *American Academy of Dermatology*, www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed: July 10, 2019.

Drug Information			Regulatory Information	
Manufacturer:	Celgene		Application Type:	NDA
Drug Brand Name:	Otezla®		Original Anticipated Approval (PDUFA):	N/A
			Regulatory Status:	Approved
Drug Generic Name:	apremilast		Regulatory Status Date:	3/21/2014
			Regulatory Status Reason:	N/A
Drug Type:	Small Molecule		Orphan Drug Designation:	N/A
			FDA Fast Track Designation:	N/A
Route of Administration:	Oral		Breakthrough Therapy Designation	N/A
			Priority Review Designation:	N/A
Indication Details			Sales Forecast	
Indication	Prevalence Type	Prevalence	Otezla (Celgene Corp), US, Forecast, USD Millions  Otezla (Celgene Corp), US, Historical, USD Millions 	
Psoriatic Arthritis	U.S.	922,449		
	Global	2,222,569		

Source: GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

Source: GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

Comments Section

On March 21, 2014, FDA approved Otezla® (apremilast) for the treatment of adult patients with active psoriatic arthritis (PsA).

Psoriatic arthritis is estimated to occur in about 10-20% of people with psoriasis.*

Approximately 7.5 million people in the United States have psoriasis.**

Sources:

GlobalData, Pharma Intelligence Center. <https://pharma.globaldata.com>, Accessed: July 9, 2019.

"OTEZLA® (Apremilast) - First Oral Therapy Approved by the U.S. Food and Drug Administration for the Treatment of Adults with Active Psoriatic Arthritis." *Celgene*, 21 Mar. 2014, ir.celgene.com/press-releases/press-release-details/2014/OTEZLA-apremilast---First-Oral-Therapy-Approved-by-the-US-Food-and-Drug-Administration-for-the-Treatment-of-Adults-with-Active-Psoriatic-Arthritis/default.aspx.

OTEZLA® (apremilast) [Package Insert]. Summit, NJ: Celgene Corporation; 2017.

* "Psoriasis." *Centers for Disease Control and Prevention*, 25 Oct. 2018, www.cdc.gov/psoriasis/index.htm. Accessed: July 9, 2019.

** "Skin Conditions by the Numbers." *American Academy of Dermatology*, www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed: July 10, 2019.