RJHealth

PIPELINE REVIEW

Revlimid® (lenalidomide)

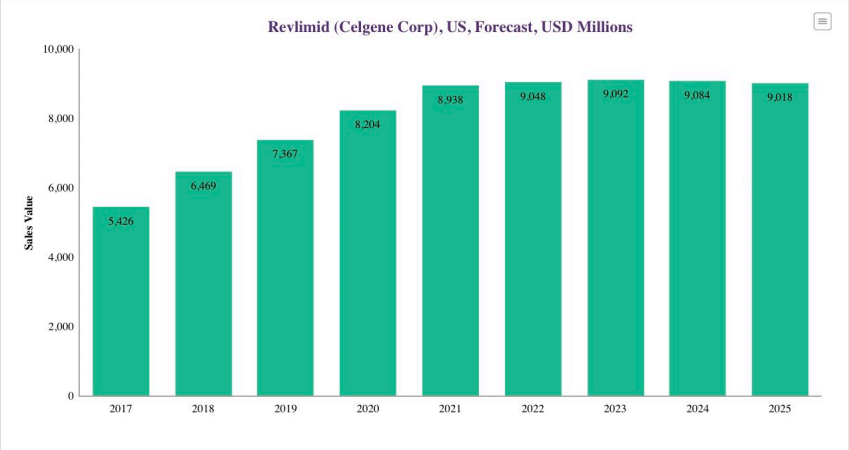
Page	Indication	Date Approved	Date Updated
2	Follicular Lymphoma	May 28, 2019	May 28, 2019
3	Marginal Zone B-cell Lymphoma	May 28, 2019	May 28, 2019
4	Mantle Cell Lymphoma	June 5, 2013	May 22, 2019
5	Multiple Myeloma (Kahler Disease)	Feb 22, 2017 Feb 17, 2015 June 29, 2006	May 22, 2019
6	Myelodysplastic Syndrome	Dec 27, 2005	May 22, 2019

Drug Information		Regulatory Information	
Manufacturer:	Celgene Corp.	**Application Type:**	Supplemental NDA
Drug Brand Name:	Revlimid®	**Original Anticipated Approval (PDUFA):**	6/27/2019
		Regulatory Status:	Approved
Drug Generic Name:	lenalidomide	**Regulatory Status Date:**	5/28/2019
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	9/17/2013
		FDA Fast Track Designation:	N/A
Route of Administration:	Oral	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	2/26/2019

Indication Details

Indication	Incidence Type	Incidence
Follicular Lymphoma	U.S.	2.7 / 100,000 / yr
	Global	N/A

Sales Forecast



Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

Comments Section

On February 26, 2019, FDA granted Priority Review to the supplemental NDA for Revlimid® (lenalidomide) in combination with rituximab for the treatment of patients with previously treated follicular lymphoma and marginal zone lymphoma. FDA granted a PDUFA date of June 27, 2019.

UPDATE: On May 28, 2019, FDA approved Revlimid® (lenalidomide) in combination with a rituximab product for previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).

An estimated 74,200 cases of non-Hodgkin lymphoma (NHL) are expected to be diagnosed in the U.S. in 2019. Follicular lymphoma comprises approximately 20% of all NHL cases.

Sources:

Adult Non-Hodgkin Lymphoma Treatment (PDQ®) – Health Professional Version. *National Cancer Institute*. Available at: https://www.cancer.gov/types/lymphoma/hp/adult-nhl-treatment-pdq#link/_552_toc. Accessed: May 21, 2019.

American Cancer Society. Cancer Facts & Figures 2019. Atlanta: *American Cancer Society*; 2019. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf. Accessed: May 22, 2019.

"Celgene Corporation Announces Key Regulatory Updates for REVLIMID® in Lymphoma and Luspatercept in MDS and Beta-Thalassemia." *Celgene*, 26 Feb. 2019, ir.celgene.com/press-releases/press-release-details/2019/Celgene-Corporation-Announces-Key-Regulatory-Updates-for-REVLIMID-in-Lymphoma-and-Luspatercept-in-MDS-and-Beta-Thalassemia/default.aspx.

"FDA Approves Lenalidomide for Follicular and Marginal Zone Lymphoma." *U.S. Food and Drug Administration*, 28 May 2019, www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lenalidomide-follicular-and-marginal-zone-lymphoma.

GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 22, 2019.

REVLIMID® (lenalidomide) [Package Insert]. Summit, NJ: Celgene Corporation; 2019.

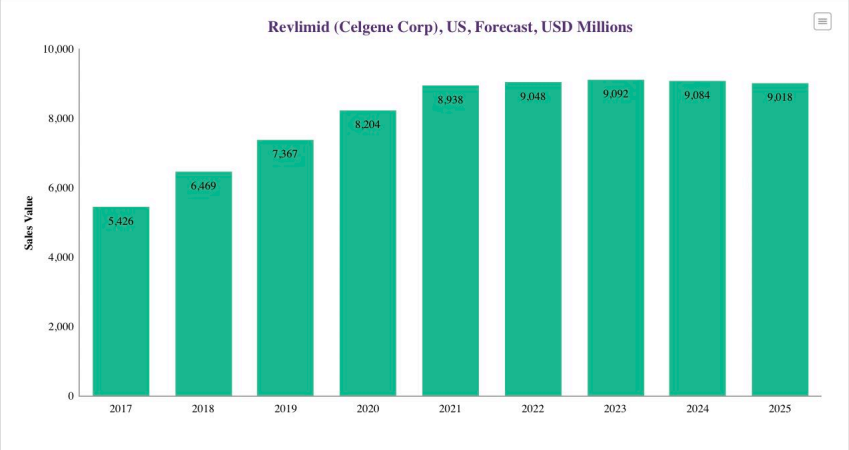
SEER Cancer Stat Facts: Follicular Lymphoma. *National Cancer Institute*. Bethesda, MD, https://seer.cancer.gov/statfacts/html/follicular.html. Accessed: May 21, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Celgene Corp.	**Application Type:**	Supplemental NDA
Drug Brand Name:	Revlimid®	**Original Anticipated Approval (PDUFA):**	6/27/2019
		Regulatory Status:	Approved
Drug Generic Name:	lenalidomide	**Regulatory Status Date:**	5/28/2019
		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:	2/26/2019

Indication Details

Indication	Incidence Type	Incidence
Marginal Zone B-cell Lymphoma	U.S.	~8% of all NHL cases; 74,200 NHL cases
	Global	N/A

Sales Forecast



Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

Comments Section

On February 26, 2019, FDA granted Priority Review to the supplemental NDA for Revlimid® (lenalidomide) in combination with rituximab for the treatment of patients with previously treated follicular lymphoma and marginal zone lymphoma. FDA granted a PDUFA date of June 27, 2019.

UPDATE: On May 28, 2019, FDA approved Revlimid® (lenalidomide) in combination with a rituximab product for previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).

An estimated 74,200 cases of non-Hodgkin lymphoma (NHL) are expected to be diagnosed in the U.S. in 2019.
Marginal zone lymphomas account for approximately 8% of all NHL cases.

Sources:

American Cancer Society. Cancer Facts & Figures 2019. Atlanta: *American Cancer Society*; 2019. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf. Accessed: May 22, 2019.

"Celgene Corporation Announces Key Regulatory Updates for REVLIMID® in Lymphoma and Luspatercept in MDS and Beta-Thalassemia." *Celgene*, 26 Feb. 2019, ir.celgene.com/press-releases/press-release-details/2019/Celgene-Corporation-Announces-Key-Regulatory-Updates-for-REVLIMID-in-Lymphoma-and-Luspatercept-in-MDS-and-Beta-Thalassemia/default.aspx.

"FDA Approves Lenalidomide for Follicular and Marginal Zone Lymphoma." *U.S. Food and Drug Administration*, 28 May 2019, www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lenalidomide-follicular-and-marginal-zone-lymphoma.

GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 22, 2019.

"Marginal Zone Lymphoma." Lymphoma Research Foundation, www.lymphoma.org/aboutlymphoma/nhl/mzl/. Accessed: May 21, 2019.

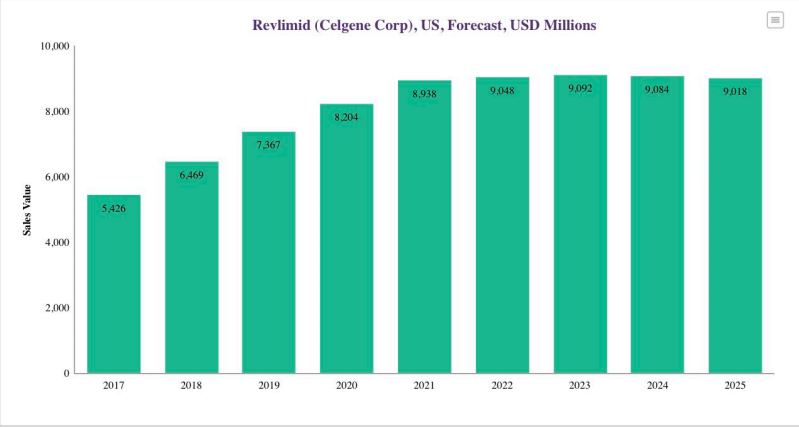
REVLIMID® (lenalidomide) [Package Insert]. Summit, NJ: Celgene Corporation; 2019.

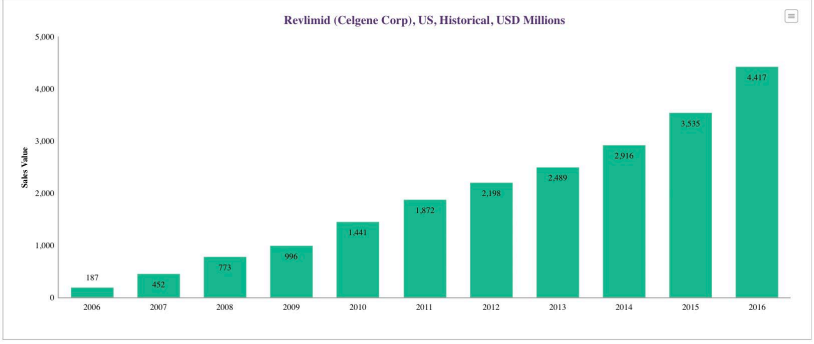
Drug Information		Regulatory Information	
Manufacturer:	Celgene Corp.	**Application Type:**	Supplemental NDA
Drug Brand Name:	Revlimid®	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	lenalidomide	**Regulatory Status Date:**	6/5/2013
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	4/27/2009
		FDA Fast Track Designation:	N/A
Route of Administration:	Oral	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Incidence Type	Incidence
Mantle Cell Lymphoma	U.S.	~6% of all NHL cases; 74,200 NHL cases
	Global	N/A

Sales Forecast





Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

Comments Section

On June 5, 2013, FDA approved Revlimid® (lenalidomide) for the treatment of patients with Mantle Cell Lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

An estimated 74,200 cases of non-Hodgkin lymphoma (NHL) are expected to be diagnosed in the U.S. in 2019.
Mantle cell lymphoma (MCL) represents about 6% of all cases of NHL in the U.S.

Sources:

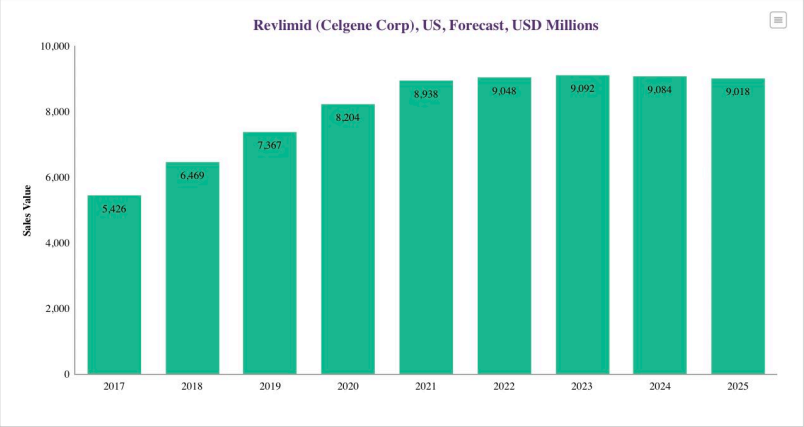
American Cancer Society. Cancer Facts & Figures 2019. Atlanta: *American Cancer Society*; 2019. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf. Accessed: May 21, 2019.
"Drugs@FDA: FDA Approved Drug Products - Revlimid." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed: May 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.
"Mantle Cell Lymphoma." *Lymphoma Research Foundation*, www.lymphoma.org/aboutlymphoma/nhl/mcl/. Accessed: May 22, 2019.
REVLIMID® (lenalidomide) [Package Insert]. Summit, NJ: Celgene Corporation; 2019.

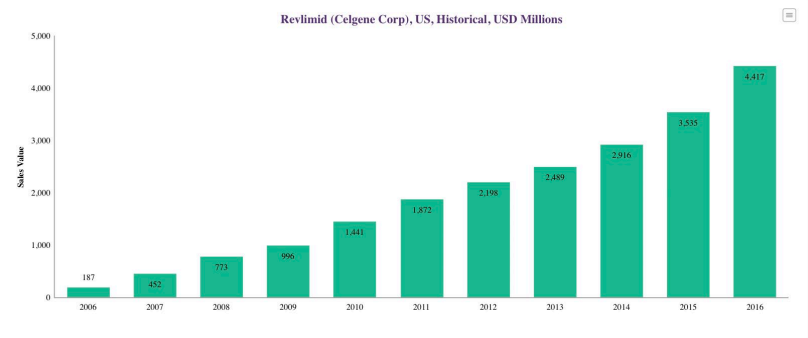
Drug Information		Regulatory Information	
Manufacturer:	Celgene Corp.	**Application Type:**	Supplemental NDA
Drug Brand Name:	Revlimid®	**Original Anticipated Approval (PDUFA):**	6/30/2006
		Regulatory Status:	Approved
Drug Generic Name:	lenalidomide	**Regulatory Status Date:**	6/29/2006, 2/17/2015, 2/22/2017
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	9/20/2001
		FDA Fast Track Designation:	N/A
Route of Administration:	Oral	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	3/3/2006

Indication Details

Indication	Prevalence Type	Prevalence
Multiple Myeloma (Kahler Disease)	U.S.	155,337
	Global	482,031

Sales Forecast





Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

Comments Section

On June 29, 2006, FDA approved Revlimid® (lenalidomide) in combination with dexamethasone for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy.

On February 17, 2015, FDA expanded the indication for Revlimid® (lenalidomide) to include the treatment of patients with newly diagnosed multiple myeloma (MM), in combination with dexamethasone.

On February 22, 2017, FDA expanded the indication for Revlimid® (lenalidomide) to include the treatment of multiple myeloma (MM), as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

Sources:

"Drugs@FDA: FDA Approved Drug Products - Revlimid." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed: May 21, 2019.

GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

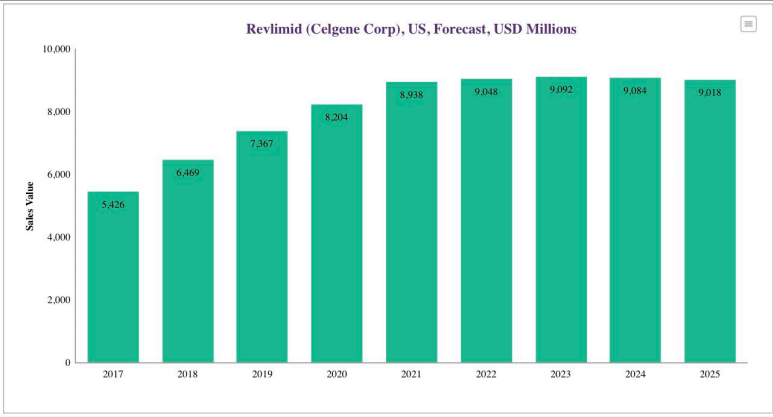
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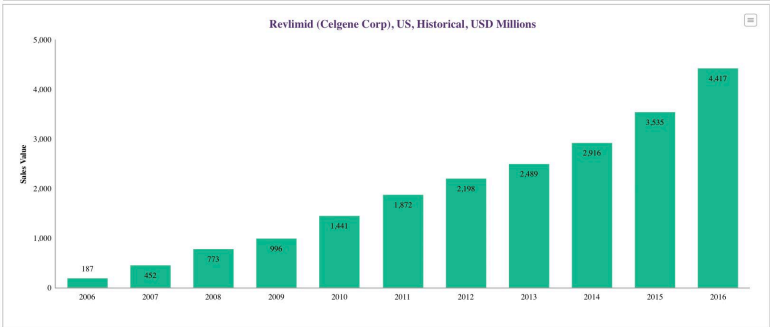
Drug Information		Regulatory Information	
Manufacturer:	Celgene Corp.	**Application Type:**	NDA
Drug Brand Name:	Revlimid®	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	lenalidomide	**Regulatory Status Date:**	12/27/2005
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	1/29/2004
		FDA Fast Track Designation:	4/15/2003
Route of Administration:	Oral	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Incidence Type	Incidence
Myelodysplastic Syndrome	U.S.	> 10,000
	Global	N/A

Sales Forecast





Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.

Comments Section

On December 27, 2005, FDA approved Revlimid® (lenalidomide) for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
Revlimid® was approved under the provisions of the RevAssist℠ Risk Minimization Action Plan (RiskMAP), a part of the postmarketing risk management for Revlimid®. The primary goal of the RevAssist℠ program is to prevent fetal exposures, pending complete and adequate characterization of the teratogenic potential of lenalidomide.
The REVLIMID REMS® program was later introduced in 2010, in which Revlimid® is available only through a restricted distribution program. The REMS® program consists of a Medication Guide, elements to assure safe use, and an implementation system.

Myelodysplastic Syndrome (MDS) Prevalence: It has been estimated that 22 to 45 per 100,000 people over the age of 70 have MDS.

Sources:

"Drugs@FDA: FDA Approved Drug Products - Revlimid." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed: May 22, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: May 21, 2019.
"Key Statistics for Myelodysplastic Syndromes." *American Cancer Society*, 22 Jan. 2018, www.cancer.org/cancer/myelodysplastic-syndrome/about/key-statistics.html. Accessed: May 22, 2019.
"Myelodysplastic Syndromes." *NORD - National Organization for Rare Disorders*, rarediseases.org/rare-diseases/myelodysplastic-syndromes/. Accessed: May 22, 2019.
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