RJHealth

PIPELINE REVIEW

Riluzole

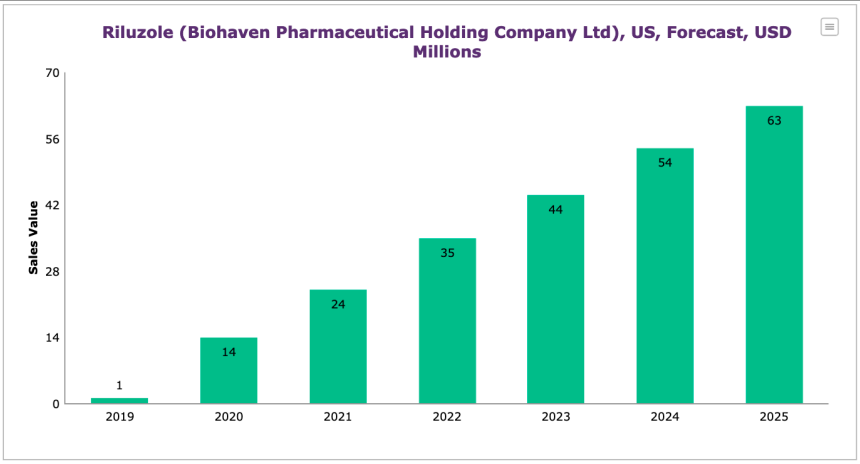
Page	Indication	Date Approved	Date Updated
Biohaven Pharmaceutical – Sublingual			
2	Amyotrophic Lateral Sclerosis	N/A	July 20, 2019
3	Social Anxiety Disorders (SAD)	N/A	June 21, 2019
Italfarmaco SpA – Oral Suspension			
4	Amyotrophic Lateral Sclerosis	Sep 5, 2018	June 21, 2019
Alkem Labs / Ascend Labs – Oral Tablet – Generic			
5	Amyotrophic Lateral Sclerosis	March 30, 2016	June 21, 2019
Mylan Pharmaceuticals Inc. – Oral Tablet – Generic			
6	Amyotrophic Lateral Sclerosis	July 1, 2013	June 21, 2019
Sun Pharmaceutical Industries Ltd. – Oral Tablet – Generic			
7	Amyotrophic Lateral Sclerosis	June 18, 2013	June 21, 2019
Glenmark Pharmaceuticals – Oral Tablet – Generic			
8	Amyotrophic Lateral Sclerosis	June 18, 2013	June 21, 2019
Apotex Corp. – Oral Tablet – Generic			
9	Amyotrophic Lateral Sclerosis	June 18, 2013	June 21, 2019
Impax Labs / Amneal Pharmaceuticals – Oral Tablet – Generic			
10	Amyotrophic Lateral Sclerosis	Jan 29, 2003	June 21, 2019
Covis Pharmaceuticals – Oral Tablet – RLD			
11	Amyotrophic Lateral Sclerosis	Dec 12, 1995	June 21, 2019

Drug Information		Regulatory Information	
Manufacturer:	Biohaven Pharmaceutical Holding Company Ltd.	**Application Type:**	NDA
Drug Brand Name:	Nurtec™	**Original Anticipated Approval (PDUFA):**	7/21/2019
		Regulatory Status:	Complete Response Letter
Drug Generic Name:	riluzole	**Regulatory Status Date:**	07/20/2019
		Regulatory Status Reason:	See Comments Section
Drug Type:	Small Molecule	**Orphan Drug Designation:**	11/30/2016
		FDA Fast Track Designation:	N/A
Route of Administration:	Sublingual	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Prevalence Type	Prevalence
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast



Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 18, 2019.

Comments Section

On July 20, 2019, the FDA identified in the CRL an issue relates to a concern regarding the use of an active pharmaceutical ingredient (API) that was manufactured by Apotex Pharmachem India Private Limited ("Apotex") between 2014 to 2016 and used in the drug product supplies for the bioequivalence study in 2017.

On November 26, 2018, FDA accepted for review the 505(b)(2) new drug application (NDA) for BHV-0223, the investigational sublingual form of riluzole for the treatment of people living with amyotrophic lateral sclerosis (ALS). The anticipated PDUFA date for approval is July 21, 2019.

More than 80% of people living with ALS experience dysphagia at some point during their disease course. If approved, this sublingual form of riluzole would be the only formulation that does not require swallowing of tablets or liquids, which would offer an important delivery alternative in ALS.

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

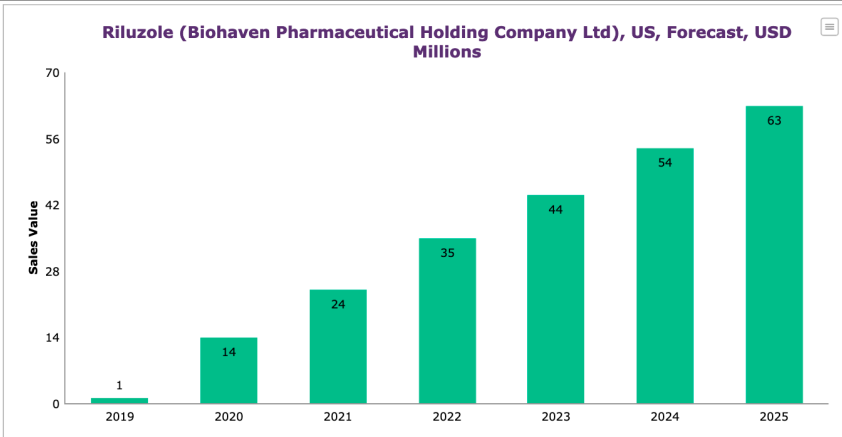
Sources:
"Biohaven Announces FDA Acceptance of 505(b)(2) NDA Filing for BHV-0223, a Novel Sublingual Delivery Form of Riluzole for the Treatment of Amyotrophic Lateral Sclerosis (ALS)." *Biohaven Pharmaceuticals*, 26 Nov. 2018, www.biohavenpharma.com/investors/news-events/press-releases/11-26-2018.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 21, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Biohaven Pharmaceutical Holding Company Ltd.	**Application Type:**	NDA
Drug Brand Name:	Nurtec	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Phase III
Drug Generic Name:	riluzole	**Regulatory Status Date:**	1/9/2017
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	N/A
		FDA Fast Track Designation:	N/A
Route of Administration:	Sublingual	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Prevalence Type	Prevalence
Social Anxiety Disorders (SAD)	U.S.	29,647,984
	Global	79,630,935

Sales Forecast



Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 18, 2019.

Comments Section

As of January 9, 2017, sublingual riluzole is currently being studied in Phase III trials for the treatment of patients diagnosed with social anxiety disorder and public speaking anxiety while performing an anxiety-provoking speech task.

NOTE: Likelihood of Approval is 100%.

Sources:
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Italfarmaco SpA	**Application Type:**	NDA
Drug Brand Name:	Tiglutik™	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	9/5/2018
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	9/15/2016
		FDA Fast Track Designation:	N/A
Route of Administration:	Oral Suspension	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Prevalence Type	Prevalence
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On September 5, 2018, FDA approved Tiglutik™ (riluzole) oral suspension for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:

"Drugs@FDA: FDA Approved Drug Products - Tiglutik." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209080. Accessed: June 20, 2019.

* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.

GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

"ITF Pharma Announces FDA Approval Of TIGLUTIK™ (Riluzole) Oral Suspension For The Treatment Of Amyotrophic Lateral Sclerosis (ALS)." *ITF Pharma*, 6 Sept. 2018, itfpharma.com/wp-content/uploads/2018/09/FINAL-FOR-FDA-FILING_US-FDA-Approves-TIGLUTIK-Press-Release_TIGLPA092018.pdf.

TIGLUTIK™ (riluzole) [Package Insert]. Berwyn, PA: ITF Pharma, Inc.; 2018.

Drug Information		Regulatory Information	
Manufacturer:	Alkem Labs / Ascend Labs	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	3/30/2016
		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		
Indication	**Prevalence Type**	**Prevalence**
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On March 30, 2016, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204048. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Mylan Pharmaceuticals Inc.	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	7/1/2013
		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

Indication	Prevalence Type	Prevalence
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On July 1, 2013, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203042. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Sun Pharmaceutical Industries Ltd.	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	6/18/2013
		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		
Indication	**Prevalence Type**	**Prevalence**
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On June 18, 2013, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=091417. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Glenmark Pharmaceuticals	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	6/18/2013
		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		
Indication	**Prevalence Type**	**Prevalence**
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On June 18, 2013, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=091394. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Apotex Corp.	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	6/18/2013
		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		
Indication	**Prevalence Type**	**Prevalence**
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On June 18, 2013, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=091300. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Impax Labs / Amneal Pharmaceuticals	**Application Type:**	ANDA
Drug Brand Name:	Riluzole	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	1/29/2003
		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		
Indication	**Prevalence Type**	**Prevalence**
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast

Sales forecast data not available.

Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On January 29, 2003, FDA approved riluzole (generic Rilutek®) for the treatment of amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

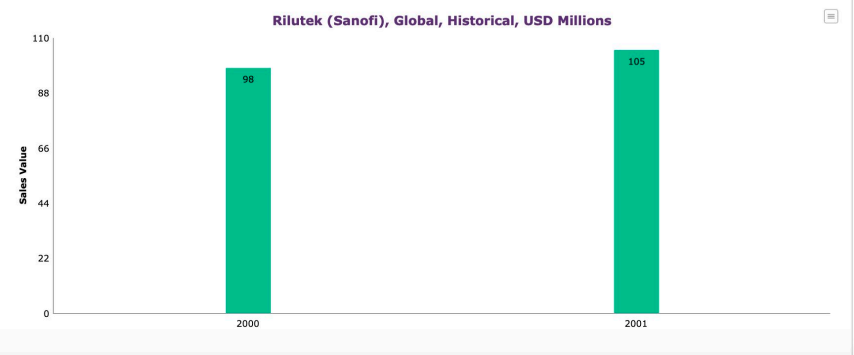
Sources:
"Drugs@FDA: FDA Approved Drug Products - Riluzole." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=076173. Accessed: June 20, 2019.
* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.
GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Drug Information		Regulatory Information	
Manufacturer:	Covis Pharmaceuticals Inc.	**Application Type:**	NDA
Drug Brand Name:	Rilutek®	**Original Anticipated Approval (PDUFA):**	N/A
		Regulatory Status:	Approved
Drug Generic Name:	riluzole	**Regulatory Status Date:**	12/12/1995
		Regulatory Status Reason:	N/A
Drug Type:	Small Molecule	**Orphan Drug Designation:**	3/16/1993
		FDA Fast Track Designation:	N/A
Route of Administration:	Oral	**Breakthrough Therapy Designation**	N/A
		Priority Review Designation:	N/A

Indication Details

Indication	Prevalence Type	Prevalence
Amyotrophic Lateral Sclerosis	U.S.	19,947
	Global	55,191

Sales Forecast



Source: GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

Comments Section

On December 12, 1995, FDA approved Rilutek® (riluzole) for the treatment of patients with amyotrophic lateral sclerosis (ALS).

ALS Incidence: 2 new cases per 100,000 people each year.*
ALS Prevalence: 5-7 cases per 100,000 people, which is estimated to be 15,000-21,000 people living with ALS in the United States.*

Sources:

"Drugs@FDA: FDA Approved Drug Products - Rilutek." *U.S. Food and Drug Administration*, www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020599. Accessed: June 20, 2019.

* "Epidemiology of ALS and Suspected Clusters." *The ALS Association*, www.alsa.org/als-care/resources/publications-videos/factsheets/epidemiology.html. Accessed: June 21, 2019.

GlobalData, Pharma Intelligence Center. https://pharma.globaldata.com, Accessed: June 20, 2019.

RILUTEK® (riluzole) [Package Insert]. Cary, NC: Covis Pharmaceuticals, Inc.; 2016.