

# **Pfenex Inc**

## **COMPANY AND PIPELINE OVERVIEW REPORT**

A comprehensive coverage of the company and a summary of the drug pipeline portfolio.

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## ABOUT COMPANY AND PIPELINE OVERVIEW REPORT

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## **GLOSSARY**

### **Number of Drugs in Active Development**

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

#### **Number of Inactive Drugs**

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

#### **Number of Patents as Owner**

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

### **Number of Patents as Third Party**

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

#### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

#### **Number of Deals**

A count of deals where the company or one of its subsidiaries is the primary company.

#### **Key Indications**

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

### **Key Target-based Actions**

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

#### **Key Technologies**

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

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**PLEASE NOTE:** the financials section where present in the report includes: Share Information, Stock Performance chart (including the consensus recommendation), and Major Shareholders. Financial Performance presents graphical and tabular data on Worldwide Sales, Operating Income and Net Income over time, together with a Quarterly earnings update. Balance Sheet lists Assets, Liabilities and Stockholders Equity, and Forecasts includes: EPS Forecast and Other Forecasts. The data reported in all sections (except share information and major stock holders) are correct as of the publication date of the report (and not the download date). For share information and major stock holders the data is correct for the date shown with these sections



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## Pfenex Inc

#### **COMPANY OVERVIEW**

Company Name	Pfenex Inc
Parent Company Name	Pfenex Inc
Website	http://www.pfenex.com/
Country	US
Number of Drugs in Active Development	17
Number of Inactive Drugs	3
Number of Patents as Owner	5
Number of Patents as Third Party	0
Number of Deals	17
Key Indications	Inflammatory disease, Neutropenia, Bacillus anthracis infection, Cancer, Growth hormone deficiency, Multiple sclerosis, Plasmodium falciparum infection, Age related macular degeneration, Metastatic breast cancer, Non-Hodgkin lymphoma, Plasmodium infection, Rheumatoid arthritis, Unidentified indication
Key Target-based Actions	Interferon beta ligand,GCSF receptor agonist,GCSF ligand,GP IIb IIIa antagonist,Growth hormone ligand,Interferon alpha 2 ligand modulator,Interferon receptor modulator,TNF alpha ligand inhibitor,TNF antagonist,VEGF-A ligand inhibitor
Key Technologies	Biological therapeutic,Protein recombinant,Biosimilar product,Parenteral formulation unspecified,Injectable formulation,Antibody fragment,PEGylated formulation,Subcutaneous formulation,Antigen,Infusion,Intravenous formulation,Monoclonal antibody humanized

## **COMPANY PROFILE**

#### **SUMMARY**

Pfenex Inc, headquartered in San Diego, CA is a leading biotechnology company focused on recombinant protein expression for a broad range of applications including therapeutic proteins, vaccines, research, reagents and biosimilars.

#### **ACQUISITIONS AND SPINOFFS**

In April 2013, Pfenex, established an unnamed joint venture with Strides Acrolab subsidiary, Agila Biotech, to develop biosimilar products at Agila's Malaysian manufacturing facility. In July 2014, Strides disclosed that R&D programs for the biosimilar products were on track but further delays were expected in the manufacturing facility setup in Malaysia.

## **FINANCIAL**

In September 2014, the shares began trading on the Russell Microcap and the Russell Global Indices.

In June 2014, Pfenex planned an IPO of common stock; in July 2014, the company priced its IPO of 8,333,333 common stock shares at a price of \$6.00 per share to the public and at that time, the underwriters were granted a 30-day option to purchase up to 1,250,000 additional common stock shares at the same price. The shares had begun trading under the symbol "PFNX" on the NYSE MKT; later that month, the offering was closed.

## **COMPANY FINANCIALS**

## **SHARE INFORMATION**

Close Price (USD)	15.80
Change (USD)	-0.20 (-1.25%)
Previous Close Price (USD)	16.00
Volume	748,049
52-Week High (USD)	19.95
52-Week Low (USD)	5.28
Date	24-Apr-2015
Exchange	NYSE AMEX(COMPOSITE)
Current Number of Shares Outstanding	20,376,974
Current Market Capitalization	310,301,062
EPS (Date Reported)	-0.47723

#### STOCK PERFORMANCE

## **Stock Performance**



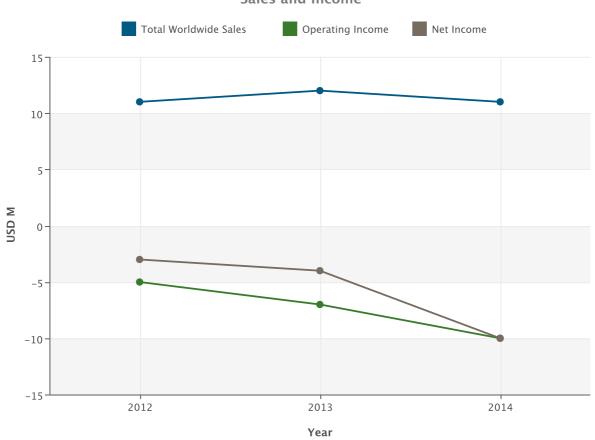
## **MAJOR SHAREHOLDERS**



Shareholder	Туре	Country	Shares held	% of shares held	Change in holding	% changes in shares held	Date
Dow Chemical Co	Corporati on	United States	5,053,661	24.62	0	0	17-Apr-2015
Signet Healthcare Partners L.L.C.	Private Equity	United States	4,319,084	21.05	0	0	17-Apr-2015
Liang (Bertrand C)	Individua I Investor	United States	561,980	2.74	-5,000	-0.01	17-Apr-2015
Lucy (Patrick K)	Individua I Investor	United States	116,290	0.57	-1,500	-0.01	02-Apr-2015
Wagner Paul A	Individua I Investor	United States	700	0	0	0	17-Apr-2015

## **FINANCIAL PERFORMANCE**

## Sales and Income



	2012	2013	2014	
Sales (USD M)	11.294	11.914	10.644	



	2012	2013	2014	
Operating Income (USD M)	-4.627	-6.697	-9.717	
Net Income (USD M)	-2.593	-4.062	-9.794	

## **Quarterly earnings update**

Period	Sales (USD M)	Operating Income (USD M)	Net Income (USD M)
2014 Q4	2.019	-3.556	-3.574
2014 Q3	2.801	-2.476	-2.495
2014 Q2	3.266	-2.162	-2.63
2014 Q1	2.558	-1.523	-1.977
2013 Q3	1.989	-2.799	-2.12
2013 Q2	2.309	-1.945	-1.596
2013 Q1	3.385	-1.207	-1.134

## **BALANCE SHEET**

## Assets (USD M)

	2012	2013	2014	
Cash & Short Term Investments	9.966	5.204	45.722	
Inventories - Total	0.754	0.026	0.023	
Current Assets - Total	15.579	12.854	52.765	
Property, Plant And Equipment - Net	2.681	2.329	2.31	
Other Assets - Total	13.078	12.506	11.993	
Total Assets	32.932	31.813	71.023	



## Liabilities (USD M)

	2012	2013	2014	
Accounts Payable	2.012	1.804	2.042	
Short Term Debt & Current Portion Of Long Term Debt	0	0	3.862	
<b>Current Liabilities - Total</b>	5.541	6.01	7.776	
Long Term Debt	1.14	3.59	0.097	
Deferred Taxes	3.602	3.481	3.281	
Other Liabilities	0.009	0.003	-0.005	
Total Liabilities	10.292	13.084	11.149	

## Stockholders Equity (USD M)

	2012	2013	2014	
Minority Interest	0	0	0	
Preferred Stock	42.5	113.18	0	
Common Stock	0.002	0.002	0.021	
Treasury Stock	0	0	0	
Total Liabilities & Shareholders' Equity	32.932	31.813	71.023	

## **FORECASTS**

## **EPS Forecast**

Year ending	Current Forecast	1 month ago	3 months ago
31-Dec-2015	-1.19	-1.23	-0.99
31-Dec-2016	-1.45	-1.45	-0.99
31-Dec-2017	-1.5	-1.5	-1

## **Other Forecasts**

Year ending	DPS	CPS	Pretax	Sales
31-Dec-2015	0	-1.1	-23.9	8.65
31-Dec-2016	0	-1.83	-36.78	8.17
31-Dec-2017	0	-1.64	-42.03	9.25



## **SUBSIDIARY COMPANIES**

#### **Names**

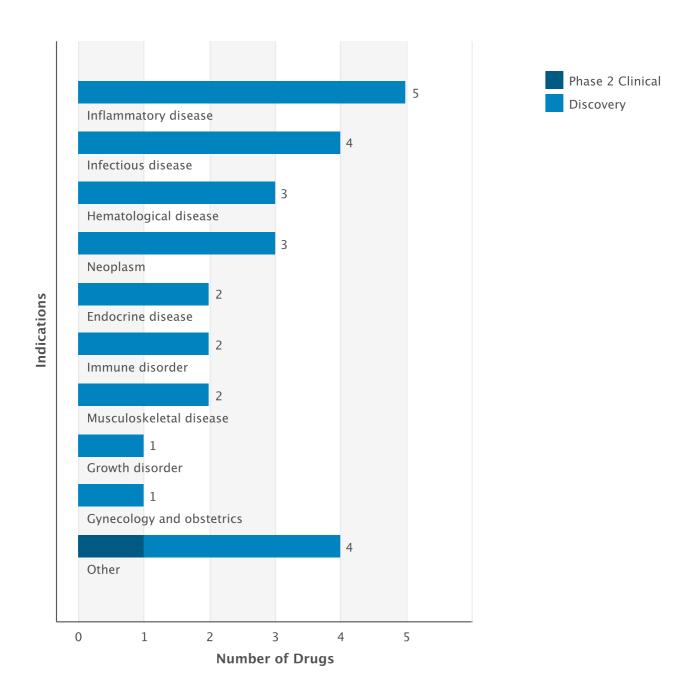
Pfenex/Stelis Joint Venture

#### PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart





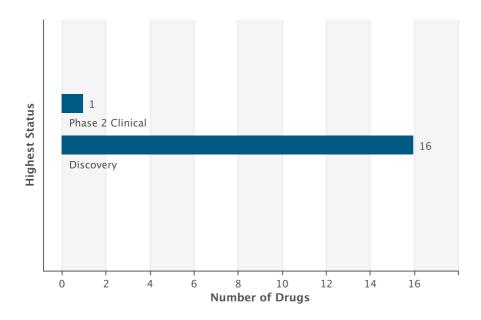
# Drugs by Indication Table

Indication	Active	Inactive	Total
Inflammatory disease	5	0	5
Infectious disease	4	1	5
Hematological disease	3	1	4
Neoplasm	3	1	4
Musculoskeletal disease	2	0	2
Immune disorder	2	0	2
Endocrine disease	2	0	2
Gynecology and obstetrics	1	0	1
Neurological disease	1	0	1
Ocular disease	1	0	1
Growth disorder	1	0	1
Metabolic disorder	1	0	1
Unidentified indication	1	0	1
Cardiovascular disease	0	1	1
Respiratory disease	0	1	1



## **Drugs by Highest Status**

Active Drugs by Highest Status Chart



## Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 2 Clinical	1
Discovery	16
No Development Reported	3

## **DEALS**

Deal Type	Prin	cipal	Par	tner	Total
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	7	0	0	0	7
Drug - Funding	4	0	1	0	5
Drug - Development/Commercialization License	1	0	0	0	1
Drug - Manufacturing/Supply	0	0	3	0	3

## **CLINICAL TRIALS**

Trials by Condition Studied

Condition Studied	Ongoing	All



## Trials by Condition Studied

Condition Studied	Ongoing	All
Ocular disease	1	2

## Trials by Phase

Phase	Ongoing	All
Phase 1	2	3

## **Phase Definitions**

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

## **PATENTS** \*

Indication	As Owner	As Third Party	Total
Cardiovascular disease	2	0	2
Endocrine disease	6	0	6
Gastrointestinal disease	4	0	4
Growth disorder	2	0	2
Hematological disease	2	0	2
Immune disorder	5	0	5
Musculoskeletal disease	1	0	1
Neoplasm	8	0	8
Genetic disorder	1	0	1
Metabolic disorder	3	0	3
Neurological disease	4	0	4
Respiratory disease	3	0	3
Infectious disease	13	0	13
Unidentified indication	2	0	2
Inflammatory disease	4	0	4



Gynecology and obstetrics	1	0	1
Dermatological disease	2	0	2

<sup>\*</sup> This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

## **PRODUCT PORTFOLIO DRUGS**

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

## PF-582

Drug Name	PF-582
Key Synonyms	ranibizumab
Originator Company	Pfenex Inc
Active Companies	Hospira Inc, Pfenex Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Age related macular degeneration
Target-based Actions	VEGF-A ligand inhibitor
Other Actions	Angiogenesis inhibitor, Ocular antineovascularisation agent
Technologies	Monoclonal antibody humanized, Antibody fragment, Injectable formulation, Ophthalmic formulation, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	17-Mar-2015

## Px-563L

Drug Name	Px-563L
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc, US Health and Human Services Department
Inactive Companies	
Highest Status	Discovery
Active Indications	Bacillus anthracis infection
Target-based Actions	
Other Actions	Antibacterial, Recombinant bacterial vector vaccine
Technologies	Injectable formulation, Quick release formulation, Antigen, Biological therapeutic, Parenteral formulation unspecified
Last Change Date	17-Mar-2015



## Px-533

Drug Name	Px-533
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	National Institutes of Health, Science Applications International Corp, Pfenex Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Plasmodium falciparum infection
Target-based Actions	
Other Actions	Antiparasitic, Protein subunit vaccine
Technologies	Injectable formulation, Biological therapeutic, Parenteral formulation unspecified, Peptide
Last Change Date	17-Mar-2015

# interferon beta-1b biosimilar, Pfenex

Drug Name	interferon beta-1b biosimilar, Pfenex
Key Synonyms	interferon beta-1b
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc
Inactive Companies	Pfenex/Stelis Joint Venture
Highest Status	Discovery
Active Indications	Multiple sclerosis
Target-based Actions	Interferon beta ligand, Interferon receptor modulator
Other Actions	Immunomodulator
Technologies	Subcutaneous formulation, Biological therapeutic, Protein recombinant, Biosimilar product
Last Change Date	18-Mar-2015

# GCSF biosimilar, Pfenex/Sun

Drug Name	GCSF biosimilar, Pfenex/Sun
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc, Sun Pharmaceutical Industries Ltd
Inactive Companies	Ranbaxy Laboratories Ltd
Highest Status	Discovery
Active Indications	Neutropenia
Target-based Actions	GCSF receptor agonist, GCSF ligand
Other Actions	Hematopoietic stimulant, Neutrophil stimulator
Technologies	Subcutaneous formulation, Intravenous formulation, Infusion, Biological therapeutic, Protein recombinant, Biosimilar product
Last Change Date	26-Mar-2015

## somatropin biosimilar, Pfenex/Sun

Drug Name	somatropin biosimilar, Pfenex/Sun
Key Synonyms	somatropin
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc, Sun Pharmaceutical Industries Ltd
Inactive Companies	Ranbaxy Laboratories Ltd
Highest Status	Discovery
Active Indications	Growth hormone deficiency
Target-based Actions	Growth hormone ligand
Other Actions	
Technologies	Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	26-Mar-2015

# pegfilgrastim biosimilar, Pfenex

Drug Name	pegfilgrastim biosimilar, Pfenex
Key Synonyms	pegfilgrastim
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc
Inactive Companies	Pfenex/Stelis Joint Venture
Highest Status	Discovery
Active Indications	Neutropenia
Target-based Actions	GCSF receptor agonist
Other Actions	Hematopoietic stimulant, Neutrophil stimulator
Technologies	PEGylated formulation, Subcutaneous formulation, Biological therapeutic, Protein recombinant, Biosimilar product
Last Change Date	17-Mar-2015

## undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Pfenex/Stelis

Drug Name	undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Pfenex/Stelis
Key Synonyms	
Originator Company	Inbiopro Solutions Pvt Ltd
Active Companies	Pfenex/Stelis Joint Venture
Inactive Companies	Inbiopro Solutions Pvt Ltd, Stelis Biopharma Pvt Ltd
Highest Status	Discovery
Active Indications	Rheumatoid arthritis, Non-Hodgkin lymphoma
Target-based Actions	B-lymphocyte antigen CD20 inhibitor
Other Actions	Anticancer monoclonal antibody, Anti-inflammatory
Technologies	Chimeric monoclonal antibody, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	20-Sep-2014

# undisclosed mAb biosimilar (cancer), Pfenex/Stelis

Drug Name	undisclosed mAb biosimilar (cancer), Pfenex/Stelis
Key Synonyms	
Originator Company	Inbiopro Solutions Pvt Ltd
Active Companies	Pfenex/Stelis Joint Venture
Inactive Companies	Inbiopro Solutions Pvt Ltd, Stelis Biopharma Pvt Ltd
Highest Status	Discovery
Active Indications	Cancer
Target-based Actions	Erbb2 tyrosine kinase receptor inhibitor
Other Actions	Anticancer monoclonal antibody, Anticancer protein kinase inhibitor
Technologies	Monoclonal antibody humanized, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	20-Sep-2014

## undisclosed humanized VmAb biosimilar (metastatic breast cancer), Pfenex/Stelis

Drug Name	undisclosed humanized VmAb biosimilar (metastatic breast cancer), Pfenex/Stelis
Key Synonyms	
Originator Company	Inbiopro Solutions Pvt Ltd
Active Companies	Pfenex/Stelis Joint Venture
Inactive Companies	Inbiopro Solutions Pvt Ltd, Stelis Biopharma Pvt Ltd
Highest Status	Discovery
Active Indications	Metastatic breast cancer
Target-based Actions	Erbb2 tyrosine kinase receptor inhibitor
Other Actions	Anticancer monoclonal antibody
Technologies	Monoclonal antibody humanized, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	20-Sep-2014

# undisclosed mAb biosimilar (inflammatory diseases), Pfenex/Stelis

Drug Name	undisclosed mAb biosimilar (inflammatory diseases), Pfenex/Stelis
Key Synonyms	
Originator Company	Inbiopro Solutions Pvt Ltd
Active Companies	Pfenex/Stelis Joint Venture
Inactive Companies	Inbiopro Solutions Pvt Ltd, Stelis Biopharma Pvt Ltd
Highest Status	Discovery
Active Indications	Inflammatory disease
Target-based Actions	TNF antagonist
Other Actions	Anti-inflammatory
Technologies	Monoclonal antibody human, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	20-Sep-2014

## undisclosed chimeric mAb biosimilar (inflammatory diseases), Pfenex/Stelis

Drug Name	undisclosed chimeric mAb biosimilar (inflammatory diseases), Pfenex/Stelis
Key Synonyms	
Originator Company	Inbiopro Solutions Pvt Ltd
Active Companies	Pfenex/Stelis Joint Venture
Inactive Companies	Inbiopro Solutions Pvt Ltd, Stelis Biopharma Pvt Ltd
Highest Status	Discovery
Active Indications	Inflammatory disease
Target-based Actions	TNF alpha ligand inhibitor
Other Actions	Anti-inflammatory
Technologies	Chimeric monoclonal antibody, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	20-Sep-2014

## **PRIMALVAC**

Drug Name	PRIMALVAC
Key Synonyms	
Originator Company	European Vaccine Initiative
Active Companies	INSERM, European Vaccine Initiative, Pfenex Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Plasmodium infection
Target-based Actions	
Other Actions	Prophylactic vaccine, Protein subunit vaccine
Technologies	Biological therapeutic, Protein recombinant
Last Change Date	20-Feb-2015

## PF-688

Drug Name	PF-688
Key Synonyms	certolizumab pegol
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Inflammatory disease
Target-based Actions	TNF alpha ligand inhibitor, TNF antagonist
Other Actions	Anti-inflammatory, TNF binding agent
Technologies	Monoclonal antibody humanized, Antibody fragment, PEGylated formulation, Injectable formulation, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant, Biosimilar product
Last Change Date	04-Dec-2013

# IFN alpha 2b biosimilar, Pfenex

Drug Name	IFN alpha 2b biosimilar, Pfenex
Key Synonyms	interferon alfa-2b
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Inflammatory disease
Target-based Actions	Interferon alpha 2 ligand modulator
Other Actions	Anti-inflammatory
Technologies	Biological therapeutic, Protein recombinant, Biosimilar product
Last Change Date	24-Jul-2014

## rPA vaccine (solid-dose injectable/ Glide SDI, anthrax), Pfenex / Glide

Drug Name	rPA vaccine (solid-dose injectable/ Glide SDI, anthrax), Pfenex / Glide
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc, Glide Pharmaceutical Technologies Ltd
Inactive Companies	
Highest Status	Discovery
Active Indications	Bacillus anthracis infection
Target-based Actions	
Other Actions	Antibacterial, Recombinant bacterial vector vaccine
Technologies	Injectable controlled release formulation, Antigen, Biological therapeutic, Parenteral formulation unspecified, Formulation solid
Last Change Date	10-Mar-2015

# peginterferon beta 1b, Pfenex

Drug Name	peginterferon beta 1b, Pfenex
Key Synonyms	
Originator Company	Pfenex/Stelis Joint Venture
Active Companies	Pfenex Inc
Inactive Companies	Pfenex/Stelis Joint Venture
Highest Status	Discovery
Active Indications	Unidentified indication
Target-based Actions	Interferon beta ligand
Other Actions	
Technologies	PEGylated formulation, Biological therapeutic, Parenteral formulation unspecified, Protein recombinant
Last Change Date	18-Mar-2015



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