

## **Pfenex Inc**

## **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

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## ABOUT CORTELLIS COMPANY DETAILED PIPELINE 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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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## **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	15
Number of Inactive Drugs	4
Number of Patents as Owner	5
Number of Patents as Third Party	0
Number of Deals	16
Key Indications	Inflammatory disease,Bacillus anthracis infection,Neutropenia,Cancer,Multiple sclerosis,Plasmodium falciparum infection,Age related macular degeneration,Growth hormone deficiency,Metastatic breast cancer,Non-Hodgkin lymphoma,Plasmodium infection,Rheumatoid arthritis
Key Target-based Actions	GCSF receptor agonist,GCSF ligand,Interferon beta 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,Subcutaneous formulation,Antigen,Infusion,Intravenous formulation,Monoclonal antibody humanized,PEGylated formulation

#### **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.

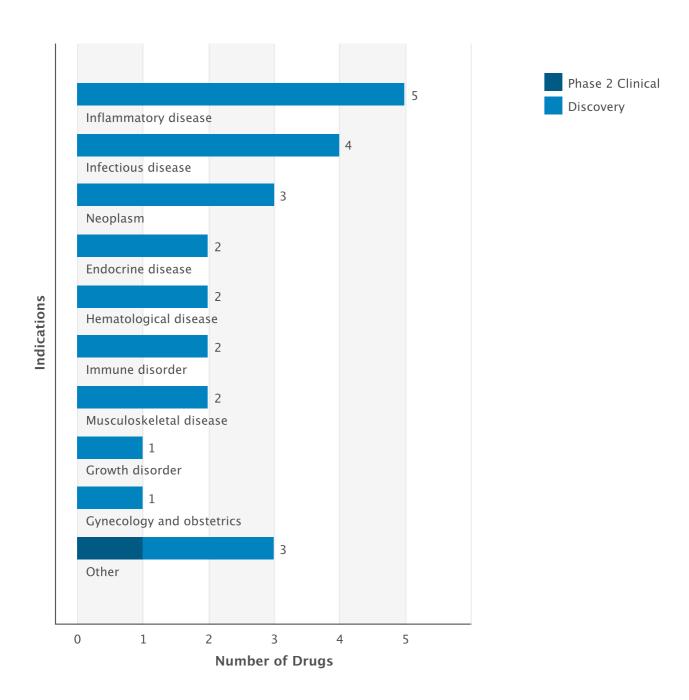
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## PRODUCT PORTFOLIO SUMMARY

#### **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart



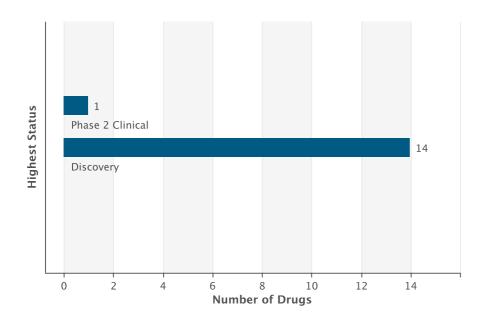


## Drugs by Indication Table

Indication	Active	Inactive	Total
Inflammatory disease	5	0	5
Infectious disease	4	1	5
Hematological disease	2	2	4
Neoplasm	3	1	4
Immune disorder	2	0	2
Endocrine disease	2	0	2
Musculoskeletal disease	2	0	2
Gynecology and obstetrics	1	0	1
Ocular disease	1	0	1
Metabolic disorder	1	0	1
Neurological disease	1	0	1
Growth disorder	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	14
No Development Reported	4

#### **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 - Manufacturing/Supply	0	0	3	0	3

#### **CLINICAL TRIALS**

#### Trials by Condition Studied

Condition Studied	Ongoing	All
Ocular disease	1	2

#### Trials by Phase

Phase	Ongoing	All
Phase 1	1	2

#### **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 1, 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 DRUG PIPELINE DETAIL

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

#### **PF-582**

#### **PF-582 SNAPSHOT**

Drug Name	PF-582
Key Synonyms	ranibizumab
Originator Company	Pfenex Inc
Active Companies	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	01-Sep-2014

#### **PF-582 DEVELOPMENT PROFILE**

#### **SUMMARY**

Pfenex is investigating a PF-582, biosimilar version of ranibizumab, a humanized anti-VEGF-A mAb fragment, as an injectable formulation, for the potential treatment of age-related macular degeneration (AMD). In November 2013, a pilot, phase I/II study in AMD was initiated. In August 2014, a phase III trial was planned for mid 2015. In February 2013, the company was seeking to outlicense the biosimilar in Western markets.

#### **PF-582 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex Inc	Age related macular degeneration	New Zealand	Phase 2 Clinical	30-Nov-2013
Pfenex Inc	Age related macular degeneration	US	Discovery	21-Jun-2012



#### **PF-582 DRUG NAMES**

Names	Туре
PF-582	Research Code
ranibizumab biosimilar (age related macular degeneration), Pfenex	
ranibizumab biosimilar, Pfenex	
ranibizumab	USAN, INN

#### **PF-582 CLINICAL TRIALS**

## Trials by Phase and Condition Studied

	se 4 nical		ise 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Age related macular degeneration											
0	0	0	0	0	0	0	1	0	0	0	1

## Total Trials by Phase and Status

	ise 4 nical		ise 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Total by	Total by Phase and Status										
0	0	0	0	0	0	0	1	0	0	0	1

#### **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)

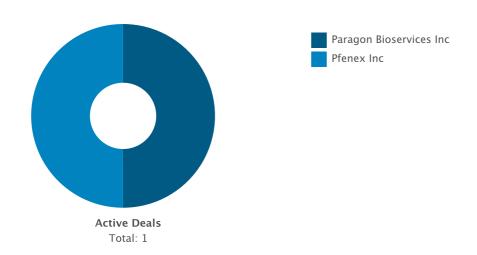
#### Phase 1 Clinical

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

## **PF-582 DEALS AND PATENTS**

DEALS

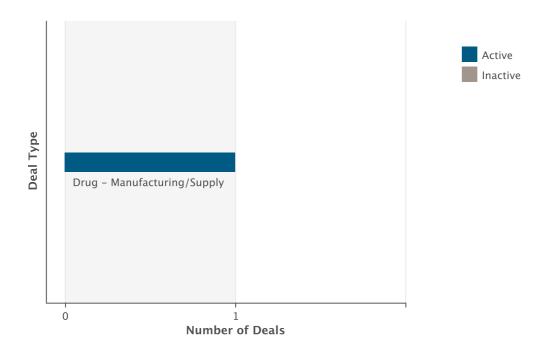
Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Pfenex Inc	0	0	1	0	1
Paragon Bioservices Inc	1	0	0	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Drug - Manufacturing/Supply	1	0	1

## Px-533

#### Px-533 SNAPSHOT

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	04-Dec-2013

#### Px-533 DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex in collaboration with NIH and SAIC is investigating Px-533, a Plasmodium falciparum antigen vaccine comprising recombinant circumsporozoite protein (CSP) antigens, using Pfenex's Expression technology which is a Pseudomonas fluorescens-based platform technology, as an injectable formulation, for the potential prevention or treatment of malaria,. In November 2011, the vaccine was listed as being in the preclinical development. By November 2013, preclinical studies had been completed and at that time, the company was seeking to outlicense the vaccine.

#### **Px-533 DEVELOPMENT STATUS**

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
National Institutes of Health	Plasmodium falciparum infection	US	Discovery	26-Jan-2011
Pfenex Inc	Plasmodium falciparum infection	US	Discovery	26-Jan-2011
Science Applications International Corp	Plasmodium falciparum infection	US	Discovery	26-Jan-2011

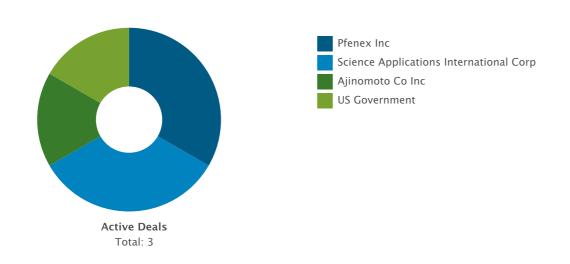


#### **Px-533 DRUG NAMES**

Names	Туре
recombinant circumsporozoite protein antigen vaccine (malaria), Pfenex/SAIC	
Px-533	Research Code
Plasmodium falciparum antigen (circumsporozoite protein, malaria), Pfenex	
Plasmodium falciparum antigen vaccine (malaria), Pfenex/SAIC	

#### **Px-533 DEALS AND PATENTS**

# DEALS Deals by Parent Company Chart

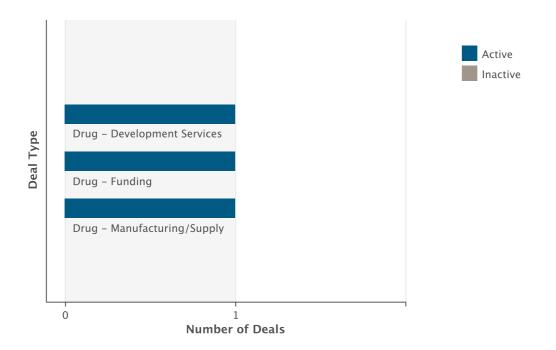


## **Deals by Parent Company Table**

Company Name	Prin Active	<b>cipal</b> Inactive	Par Active	tner Inactive	Total
Science Applications International Corp	1	0	1	0	2
Pfenex Inc	1	0	1	0	2
US Government	0	0	1	0	1
Ajinomoto Co Inc	1	0	0	0	1



## **Deals by Type Chart**



## **Deals by Type Table**

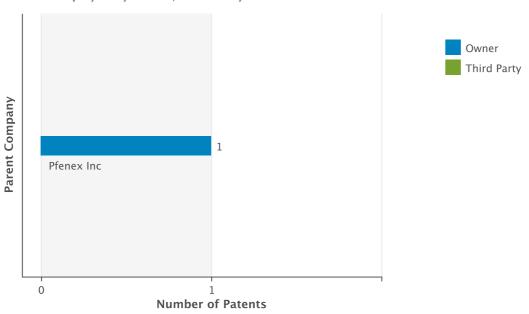
Deal Type	Active	Inactive	Total
Drug - Manufacturing/Supply	1	0	1
Drug - Funding	1	0	1
Drug - Development Services	1	0	1



#### **PATENTS**

## **Patents by Parent Company Chart**

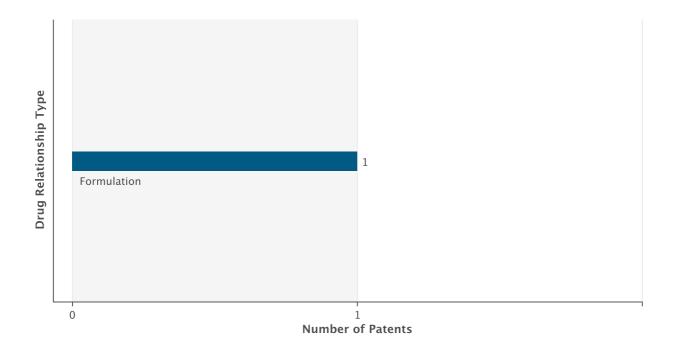
Chart displayed by Owner/Third Party



## **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Pfenex Inc	1	0	1

## **Patents by Drug Relationship Type Chart**





## **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Formulation	1



## GCSF biosimilar, Pfenex/Ranbaxy

#### GCSF biosimilar, Pfenex/Ranbaxy SNAPSHOT

Drug Name	GCSF biosimilar, Pfenex/Ranbaxy
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc;Ranbaxy Laboratories Ltd
Inactive Companies	
Highest Status	Discovery
Active Indications	Neutropenia
Target-based Actions	GCSF ligand;GCSF receptor agonist
Other Actions	Hematopoietic stimulant;Neutrophil stimulator
Technologies	Subcutaneous formulation;Intravenous formulation;Infusion;Biological therapeutic;Protein recombinant;Biosimilar product
Last Change Date	04-Dec-2013

#### GCSF biosimilar, Pfenex/Ranbaxy DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex, presumed to be in collaboration with Ranbaxy, is investigating a biosimilar version of a recombinant methionyl, non-glycosylated form GCSF, for the potential treatment of neutropenia. In June 2012, the biosimilar was in preclinical development; in September 2013, development was ongoing. In July 2012, Pfenex was seeking to outlicense the biosimilar.

#### GCSF biosimilar, Pfenex/Ranbaxy DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex Inc	Neutropenia	US	Discovery	29-Mar-2010
Ranbaxy Laboratories Ltd	Neutropenia	India	Discovery	29-Mar-2010

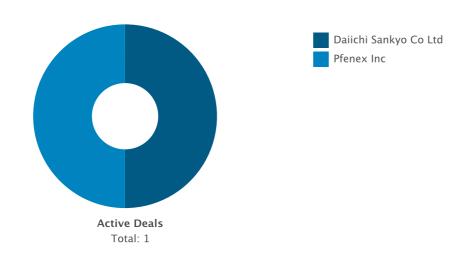
#### **GCSF** biosimilar, Pfenex/Ranbaxy DRUG NAMES

Names	Туре
G-CSF	
granulocyte colony-stimulating factor	
GCSF biosimilar, Pfenex/Ranbaxy	



## **GCSF** biosimilar, Pfenex/Ranbaxy DEALS AND PATENTS

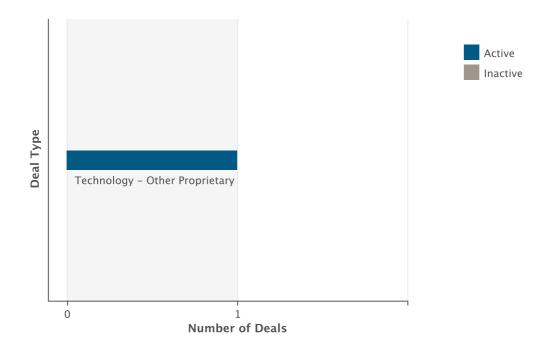
# DEALS Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		i <b>cipal</b> Inactive		tner Inactive	Total
Daiichi Sankyo Co Ltd	0	0	1	0	1
Pfenex Inc	1	0	0	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Technology - Other Proprietary	1	0	1

## Px-563L

#### Px-563L SNAPSHOT

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	Recombinant bacterial vector vaccine;Antibacterial
Technologies	Injectable formulation;Quick release formulation;Antigen;Biological therapeutic;Parenteral formulation unspecified
Last Change Date	09-Apr-2014

#### **Px-563L DEVELOPMENT PROFILE**

#### **SUMMARY**

Pfenex, in collaboration with BARDA, is investigating Px-563L, a stable, fast acting, dose sparing vaccine containing an anthrax antigen, mutant recombinant protective antigen (mrPA)formulated in Immunovaccine's DepoVax liposome delivery platform, as a single dose vaccine, using Pfenex's Expression technology, which is a Pseudomonas fluorescens-based platform technology, as an injectable formulation, for the potential prevention or treatment of anthrax infection,,. In September 2013, the vaccine was listed as being in preclinical development. In April 2014, positive data were reported.

#### **Px-563L DEVELOPMENT STATUS**

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	Development Status	Date
Pfenex Inc	Bacillus anthracis infection	US	Discovery	03-Aug-2010
US Health and Human Services Department	Bacillus anthracis infection	US	Discovery	03-Aug-2010

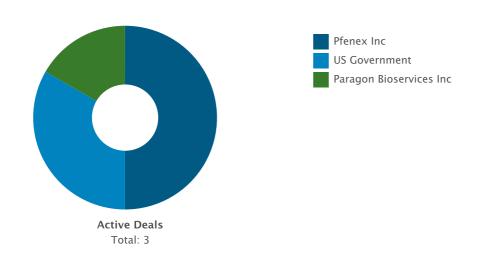
#### **Px-563L DRUG NAMES**

Names	Туре
Px-563L	Research Code
rPA vaccine (anthrax), Pfenex/BARDA	
recombinant protective antigen vaccine (anthrax infection), Pfenex/BARDA	
mrPA vaccine (DepoVax, anthrax), Pfenex	

#### **Px-563L DEALS AND PATENTS**

DEALS

Deals by Parent Company Chart

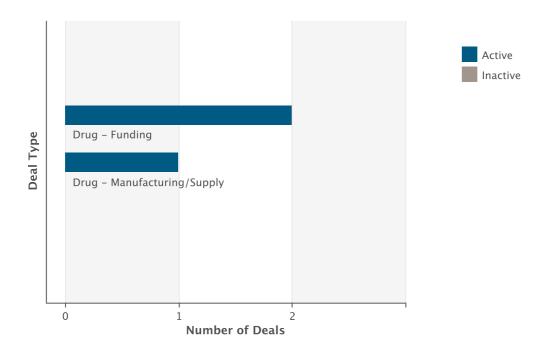


## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Pfenex Inc	2	0	1	0	3
US Government	0	0	2	0	2
Paragon Bioservices Inc	1	0	0	0	1



## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Drug - Funding	2	0	2
Drug - Manufacturing/Supply	1	0	1



## PF-530

#### **PF-530 SNAPSHOT**

Drug Name	PF-530
Key Synonyms	interferon beta-1b
Originator Company	Pfenex Inc
Active Companies	Stelis Biopharma Pvt Ltd;Pfenex/Stelis Joint Venture
Inactive Companies	Pfenex Inc
Highest Status	Discovery
Active Indications	Multiple sclerosis
Target-based Actions	Interferon receptor modulator;Interferon beta ligand
Other Actions	Immunomodulator
Technologies	Subcutaneous formulation;Biological therapeutic;Protein recombinant;Biosimilar product
Last Change Date	22-Jan-2014

#### PF-530 DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), is investigating PF-530, a biosimilar version of Betaseron, an IFN beta-1b, for the potential treatment of multiple sclerosis,. In June 2012, the biosimilar was in preclinical development. In April 2013, phase I trials were expected to begin by Q4 2013.

#### **PF-530 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Multiple sclerosis	Malaysia	Discovery	16-Apr-2013
Stelis Biopharma Pvt Ltd	Multiple sclerosis	Malaysia	Discovery	16-Apr-2013
Pfenex Inc	Multiple sclerosis	US	Discontinued	16-Apr-2013

#### **PF-530 DRUG NAMES**

Names	Туре
PF-530	Research Code
interferon beta-1b biosimilar, Pfenex/Agila Joint Venture	
interferon beta-1b biosimilar, Pfenex	
interferon beta-1b biosimilar, Pfenex/Stelis Joint Venture	
interferon beta-1b	USAN, BANN, INN



## somatropin biosimilar, Pfenex/Ranbaxy

#### somatropin biosimilar, Pfenex/Ranbaxy SNAPSHOT

Drug Name	somatropin biosimilar, Pfenex/Ranbaxy
Key Synonyms	somatropin
Originator Company	Pfenex Inc
Active Companies	Ranbaxy Laboratories Ltd;Pfenex Inc
Inactive Companies	
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	04-Dec-2013

#### somatropin biosimilar, Pfenex/Ranbaxy DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex, presumed to be in collaboration with Ranbaxy, is investigating a biosimilar version of the human growth hormone (HGH) ligand somatropin, presumably for the potential treatment of growth disorder. In September 2013, development was ongoing. In July 2012, the company was seeking to outlicense the biosimilar.

#### somatropin biosimilar, Pfenex/Ranbaxy DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex Inc	Growth hormone deficiency	US	Discovery	29-Mar-2010
Ranbaxy Laboratories Ltd	Growth hormone deficiency	India	Discovery	29-Mar-2010

#### somatropin biosimilar, Pfenex/Ranbaxy DRUG NAMES

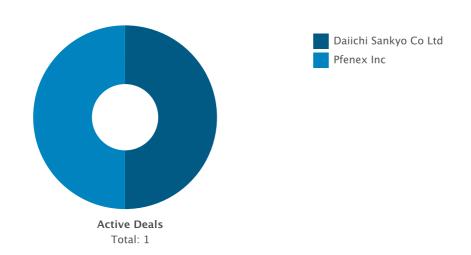
Names	Туре
somatropin	USAN, BAN, INN
human growth hormone biosimilar, Pfenex/Ranbaxy	
somatropin biosimilar, Pfenex/Ranbaxy	



## somatropin biosimilar, Pfenex/Ranbaxy DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Pfenex Inc	1	0	0	0	1
Daiichi Sankyo Co Ltd	0	0	1	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Technology - Other Proprietary	1	0	1

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

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

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 (non-Hodgkin's lymphoma/rheumatoid arthritis), Pfenex/Stelis DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), following the acquisition of Inbiopro, is investigating IBPM-001RX, a chimeric IgG1 kappa mAb targeting CD20 antigen and a biosimilar version of an undisclosed drug, for the potential treatment of non-Hodgkin's lymphoma and rheumatoid arthritis,,. By 2010, process development and toxicology studies had been completed. In August 2012, the drug was listed on Inbiopro's development pipeline ; in January 2014, this was still the case.

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

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Non-Hodgkin lymphoma	India	Discovery	16-Apr-2013
Pfenex/Stelis Joint Venture	Rheumatoid arthritis	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Non-Hodgkin lymphoma	India	Discontinued	09-Dec-2010
Inbiopro Solutions Pvt Ltd	Rheumatoid arthritis	India	Discontinued	09-Dec-2010



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

Names	Туре
IBPM-001RX	Research Code
undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Inbiopro	
undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Pfenex/Stelis	
undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Stelis	
undisclosed mAb biosimilar (non-Hodgkin's lymphoma/rheumatoid arthritis), Agila	
unspecified biological active substance	



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

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

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 mAb biosimilar (inflammatory diseases), Pfenex/Stelis DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), following the acquisition of Inbiopro, is investigating IBPM-004AM, a fully human mAb targeting TNF and a biosimilar version of an undisclosed drug, for the potential treatment of inflammatory diseases including rheumatoid arthritis, juvenile arthritis, ankylosing spondylitis, Crohn's disease and psoriatic arthritis,.. In 2010, process development and toxicology studies had begun. In January 2014, IBPM-004AM was listed on the Inbiopro company's pipeline.

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

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Inflammatory disease	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Inflammatory disease	India	Discontinued	09-Dec-2010

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

Names	Туре
undisclosed mAb biosimilar (inflammatory diseases), Stelis	
undisclosed mAb biosimilar (inflammatory diseases), Pfenex/Stelis	
unspecified biological active substance	
IBPM-004AM	Research Code
undisclosed mAb biosimilar (inflammatory diseases), Agila	
undisclosed mAb biosimilar (inflammatory diseases), Inbiopro	



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

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

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 humanized VmAb biosimilar (metastatic breast cancer), Pfenex/Stelis DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), following the acquisition of Inbiopro, is investigating an angiogenesis inhibitor and Her-2/neu receptor expression down-regulator, IBPM-003TZ, a humanized anti-VmAb and a biosimilar version of an undisclosed drug, for the potential treatment of metastatic breast cancer ,.. In 2011, process development and toxicology studies had begun ; in January 2014, IBPM-003TZ was listed on the Inbiopro company's pipeline.

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

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Metastatic breast cancer	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Metastatic breast cancer	India	Discontinued	09-Dec-2010

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

Names	Туре
undisclosed humanized VmAb biosimilar (metastatic breast cancer), Pfenex/Stelis	
undisclosed humanized VmAb biosimilar (metastatic breast cancer), Agila	
IBPM-003TZ	Research Code
undisclosed humanized VmAb biosimilar (metastatic breast cancer), Inbiopro	
unspecified biological active substance	
undisclosed humanized VmAb biosimilar (metastatic breast cancer), Stelis	



## undisclosed mAb biosimilar (cancer), Pfenex/Stelis

#### undisclosed mAb biosimilar (cancer), Pfenex/Stelis SNAPSHOT

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 protein kinase inhibitor;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 (cancer), Pfenex/Stelis DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), following the acquisition of Inbiopro, is investigating IBPM-002BZ, a humanized anti-Her-2/neu mAb and a biosimilar version of an undisclosed drug, for the potential treatment of cancer including metastatic colorectal cancer, small cell lung cancer and metastatic renal cell carcinoma ,.. In 2010, process development and toxicology studies had begun ; in 2012, development was ongoing . In January 2013, IBPM-002BZ was listed on the Inbiopro's company pipeline.

#### undisclosed mAb biosimilar (cancer), Pfenex/Stelis DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Cancer	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Cancer	India	Discontinued	09-Dec-2010

## undisclosed mAb biosimilar (cancer), Pfenex/Stelis DRUG NAMES

Names	Туре
undisclosed mAb biosimilar (cancer), Stelis	
undisclosed mAb biosimilar (cancer), Inbiopro	
undisclosed mAb biosimilar (cancer), Pfenex/Stelis	
IBPM-002BZ	Research Code
undisclosed mAb biosimilar (cancer), Agila	
unspecified biological active substance	



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

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

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

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

#### **SUMMARY**

Pfenex/Stelis (following Agila's name change), an unnamed joint venture created by Pfenex and Stelis (formerly Agila Biotech (Agila Specialties)), following the acquisition of Inbiopro, is investigating IBPM-005IX, a chimeric mAb targeting TNF-alpha and a biosimilar version of an undisclosed drug, for the potential treatment of inflammatory diseases including rheumatoid arthritis, juvenile arthritis, ankylosing spondylitis, Crohn's disease and psoriatic arthritis,.. In 2011, process development and toxicology studies had begun. In January 2013, IBPM-005IX was listed on the Inbiopro company's pipeline.

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

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex/Stelis Joint Venture	Inflammatory disease	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Inflammatory disease	India	Discontinued	09-Dec-2010

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

Names	Туре
undisclosed chimeric mAb biosimilar (inflammatory diseases), Pfenex/Stelis	
IBPM-005IX	Research Code
unspecified biological active substance	
undisclosed chimeric mAb biosimilar (inflammatory diseases), Inbiopro	
undisclosed chimeric mAb biosimilar (inflammatory diseases), Stelis	
undisclosed chimeric mAb biosimilar (inflammatory diseases), Agila	



## **PRIMALVAC**

#### **PRIMALVAC SNAPSHOT**

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	Protein subunit vaccine;Prophylactic vaccine
Technologies	Biological therapeutic;Protein recombinant
Last Change Date	06-Feb-2013

#### PRIMALVAC DEVELOPMENT PROFILE

#### **SUMMARY**

European Vaccine Initiative, INSERM and Pfenex are investigating PRIMALVAC, a vaccine comprised of var2 chondroitin sulfate A (var2CSA), for the potential prevention of pregnancy related malaria. In January 2013, toxicity studies data were expected in the second quarter of 2014. At that time, a phase I trial was expected to begin in fourth quarter of 2014.

## PRIMALVAC DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
European Vaccine Initiative	Plasmodium infection	Germany	Discovery	30-Sep-2011
INSERM	Plasmodium infection	France	Discovery	30-Sep-2011
Pfenex Inc	Plasmodium infection	US	Discovery	30-Sep-2011

#### **PRIMALVAC DRUG NAMES**

Names	Type
PRIMALVAC	



## rPA vaccine (solid, anthrax), Pfenex / Glide

#### rPA vaccine (solid, anthrax), Pfenex / Glide SNAPSHOT

Drug Name	rPA vaccine (solid, anthrax), Pfenex / Glide
Key Synonyms	
Originator Company	Pfenex Inc
Active Companies	Pfenex Inc;Glide Pharma
Inactive Companies	
Highest Status	Discovery
Active Indications	Bacillus anthracis infection
Target-based Actions	
Other Actions	Recombinant bacterial vector vaccine;Antibacterial
Technologies	Antigen;Biological therapeutic;Parenteral formulation unspecified;Formulation solid
Last Change Date	01-May-2013

#### rPA vaccine (solid, anthrax), Pfenex / Glide DEVELOPMENT PROFILE

#### **SUMMARY**

Pfenex and Glide Pharma are investigating a solid formulation of Pfenex's recombinant protective antigen (rPA) vaccine, using Pfenex's Expression technology, which is a Pseudomonas fluorescence-based platform technology, for the potential prevention or treatment of anthrax infection.

## rPA vaccine (solid, anthrax), Pfenex / Glide DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Glide Pharma	Bacillus anthracis infection	UK	Discovery	30-Apr-2013
Pfenex Inc	Bacillus anthracis infection	US	Discovery	30-Apr-2013

#### rPA vaccine (solid, anthrax), Pfenex / Glide DRUG NAMES

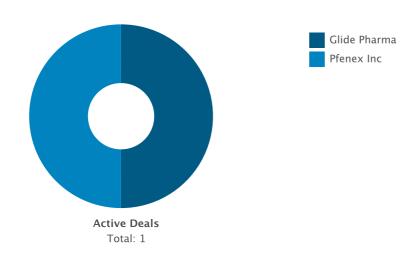
Names	Туре
recombinant protective antigen vaccine (solid, anthrax infection), Pfenex / Glide	
rPA vaccine (solid, anthrax), Pfenex / Glide	



## rPA vaccine (solid, anthrax), Pfenex / Glide DEALS AND PATENTS

DEALS

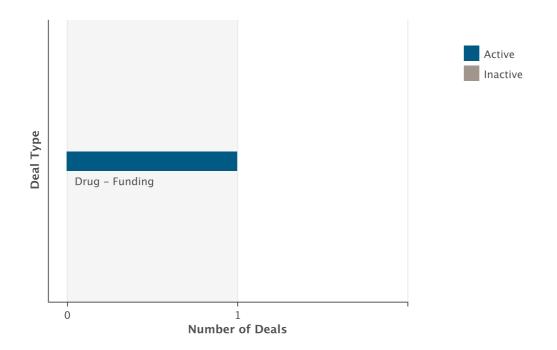
Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Glide Pharma	1	0	0	0	1
Pfenex Inc	0	0	1	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Drug - Funding	1	0	1

## IFN alpha 2b biosimilar, Pfenex

#### IFN alpha 2b biosimilar, Pfenex SNAPSHOT

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

## IFN alpha 2b biosimilar, Pfenex DEVELOPMENT PROFILE

## **SUMMARY**

Pfenex is investigating a biosimilar version of IFN alpha 2b for the potential treatment of inflammatory diseases. By February 2013, investigations were ongoing.

## IFN alpha 2b biosimilar, Pfenex DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex Inc	Inflammatory disease	US	Discovery	26-Feb-2013

## IFN alpha 2b biosimilar, Pfenex DRUG NAMES

Names	Туре
IFN alpha 2b biosimilar, Pfenex	
interferon alfa-2b	USAN, INN



## **PF-688**

#### **PF-688 SNAPSHOT**

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 antagonist;TNF alpha ligand inhibitor
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

#### **PF-688 DEVELOPMENT PROFILE**

#### **SUMMARY**

Pfenex is investigating PF-688, a biosimilar version of certolizumab pegol, an anti-TNF-alpha humanized monoclonal antibody fragment, as an injectable formulation, for the potential use in the treatment of inflammatory diseases including Crohn's disease. In November 2013, the biosimilar was listed as being in preclinical development and at that time, the company was seeking to outlicense the biosimilar.

#### **PF-688 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Pfenex Inc	Inflammatory disease	US	Discovery	26-Mar-2013

#### **PF-688 DRUG NAMES**

Names	Туре
certolizumab pegol	INN
certolizumab pegol biosimilar, Pfenex	
PF-688	Research Code



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