

Pfenex Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

Publication Date: 19-Nov-2014

THOMSON REUTERS

3 Times Square
New York, New York 10036
United States

Tel: +1 646 223 4000

thomsonreuters.com

[Return to Table of Contents](#)

ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

Thomson Reuters provides the knowledge, tools, and expertise to help support drug discovery and development activities, IP portfolio optimization, identification of licensing and partnering opportunities, delivery of successful regulatory submissions, and the ability to keep current with the rapidly-changing pharmaceutical and chemical markets, supporting informed, early decisions.

This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis™ for Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information. From drug discovery and development activities to patent reports, the latest deals, and partnering opportunities, *Cortellis* can provide the confidence to make the most informed business decisions, faster. *Cortellis for Competitive Intelligence* provides accurate and validated information on pharmaceutical and biotechnology companies globally, their drug pipelines, deals, patents, and clinical trials, plus breaking industry news and conference coverage. All contained in one simple, highly intuitive research platform.

Cortellis Company Detailed Pipeline reports are the second in a series of that track pharmaceutical and biotechnology companies worldwide. All *Cortellis for Competitive Intelligence* content is subject to the most comprehensive editorial review process available, conducted by scientists, pharma professionals, regulatory experts, and generics specialists. Featuring timely drug pipeline information expertly uncovered and integrated from over 400 global meetings each year, you'll always be on top of the latest developments.

Chosen by leading life sciences companies, their executives and investors, *Cortellis for Competitive Intelligence* accelerates your deal-making and gives you timely insights on the development landscape.

Discover undiscovered opportunities in drug development and licensing faster with *Thomson Reuters Cortellis™ for Competitive Intelligence*

DISCLAIMER

The information contained in this report is based on sources believed to be correct but Thomson Reuters does not guarantee the accuracy, timeliness, or completeness of this information. Opinions, if any, are those held by the author of any individual report or article at the time of initial publication and do not necessarily reflect the views of Thomson Reuters.

Information in this report on companies is intended for reference use only, and does not constitute a recommendation to buy or sell any particular security or other investment and does not constitute an offer to buy from or sell to any particular investor. Any company or securities mentioned in this report may not be suitable for any particular investor, depending on that investor's financial position and needs.

[Return to Table of Contents](#)



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 I, 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.

[Return to Table of Contents](#)



TABLE OF CONTENTS

Company Overview..... 5

Company Profile..... 6

Product Portfolio Summary..... 6

Product Portfolio Drug Pipeline Detail..... 10

 Phase 2 Clinical..... 11

 Discovery..... 14

[Return to Table of Contents](#)

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.

[Return to Table of Contents](#)

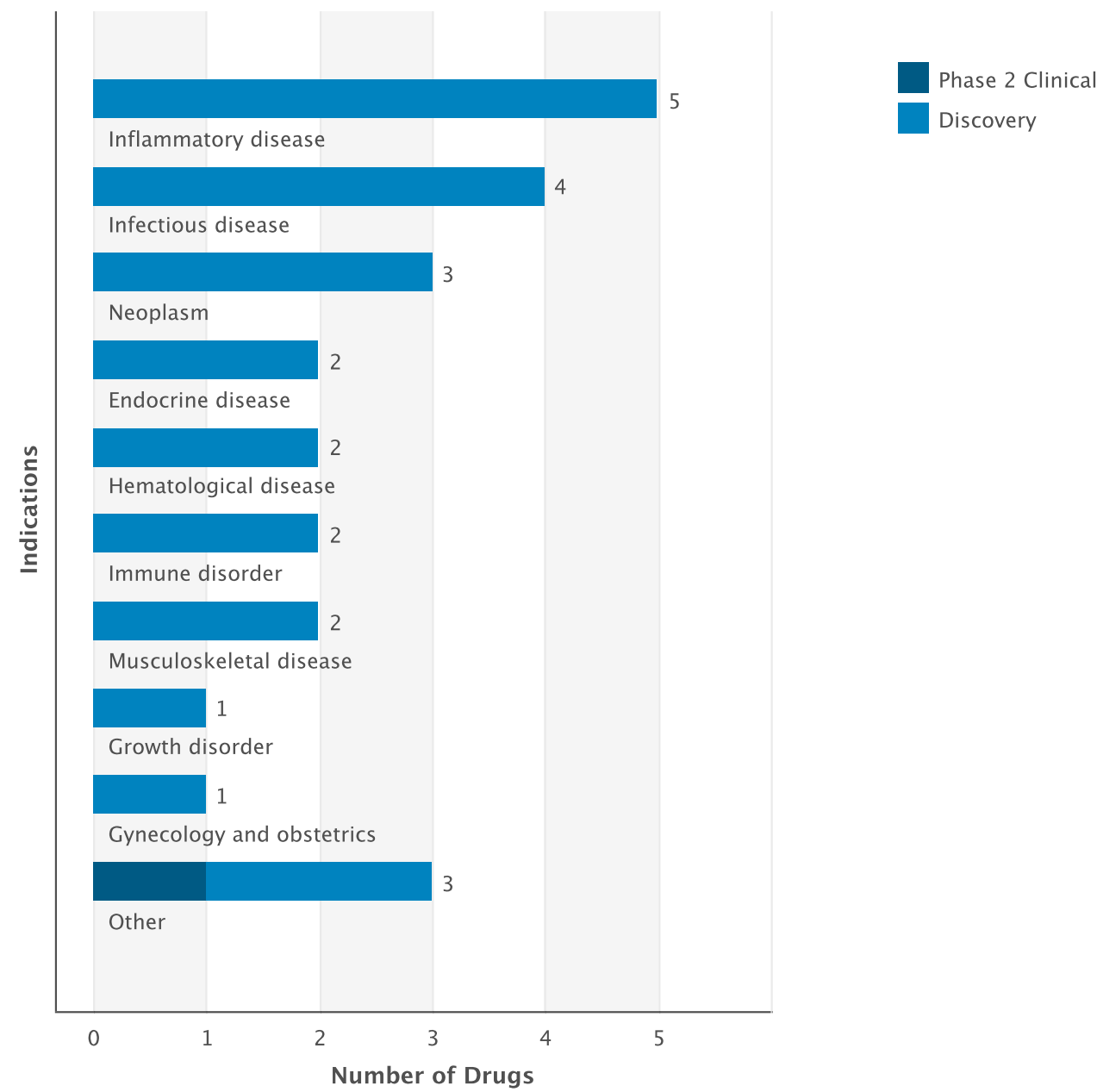


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



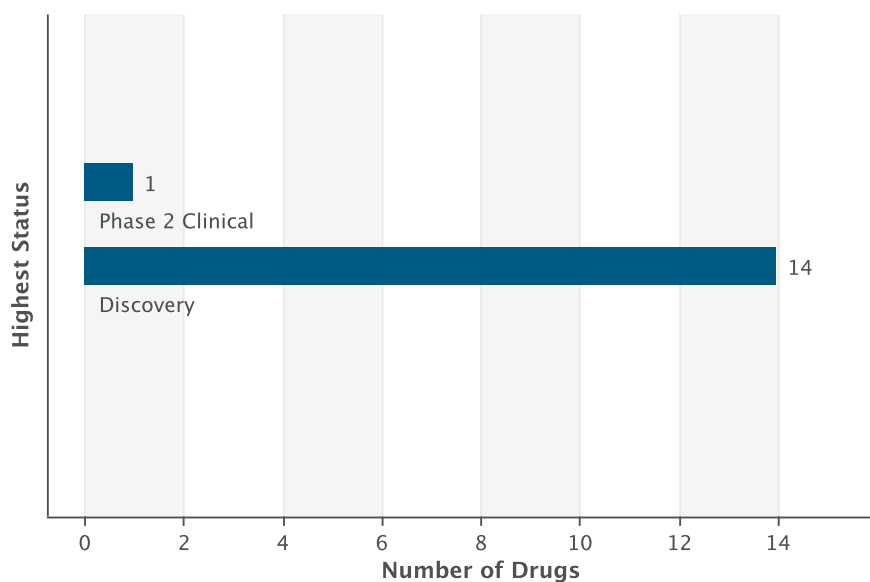
[Return to Table of Contents](#)

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



[Return to Table of Contents](#)

Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 2 Clinical	1
Discovery	14
No Development Reported	4

DEALS

Deal Type	Principal		Partner		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 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

[Return to Table of Contents](#)



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

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

[Return to Table of Contents](#)

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	Development Status	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

[Return to Table of Contents](#)



PF-582 DRUG NAMES

Names	Type
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

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
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

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
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

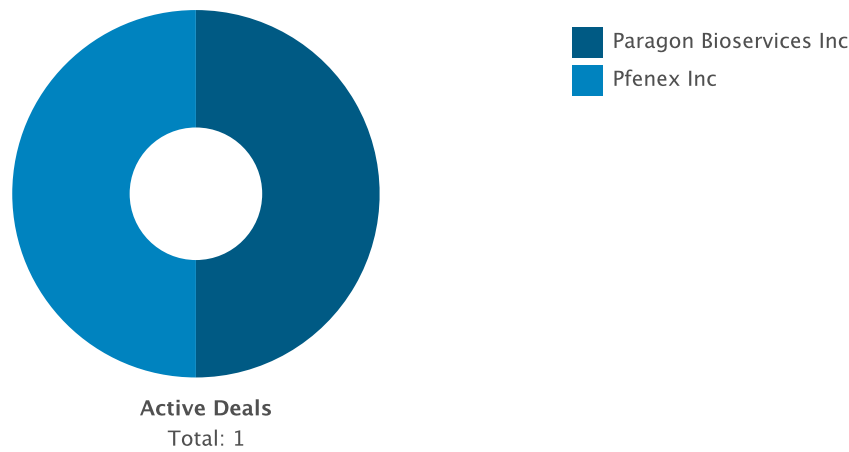
[Return to Table of Contents](#)



PF-582 DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

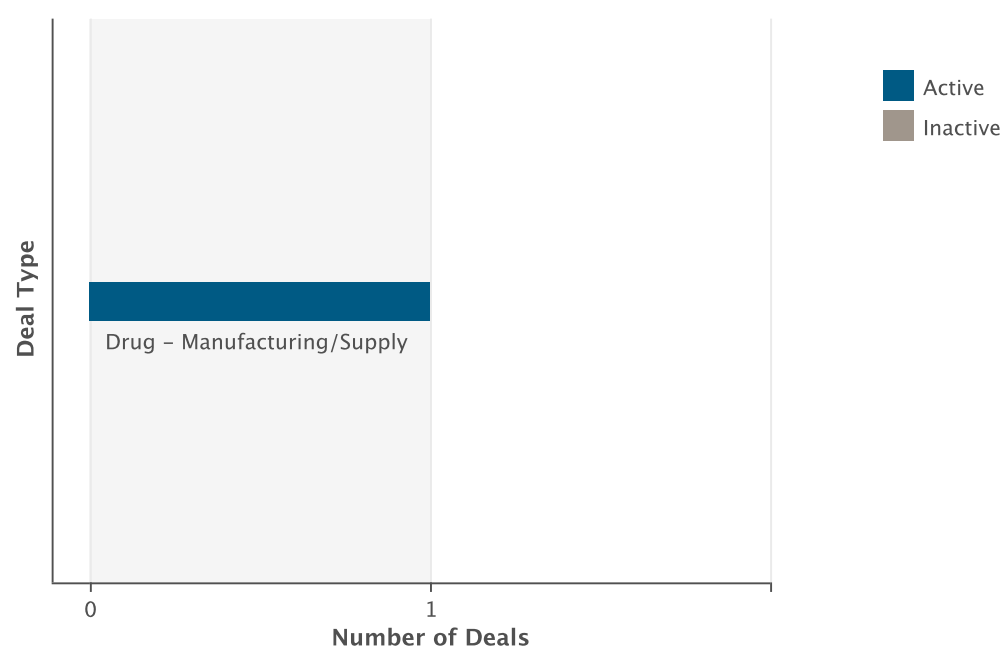


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Pfenex Inc	0	0	1	0	1
Paragon Bioservices Inc	1	0	0	0	1

[Return to Table of Contents](#)

Deals by Type Chart



Deals by Type Table

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

[Return to Table of Contents](#)

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	Development Status	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

[Return to Table of Contents](#)



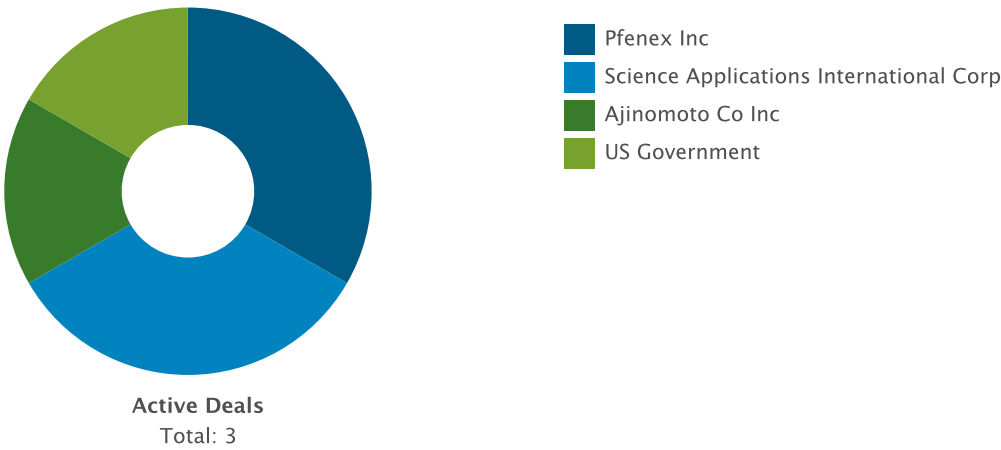
Px-533 DRUG NAMES

Names	Type
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

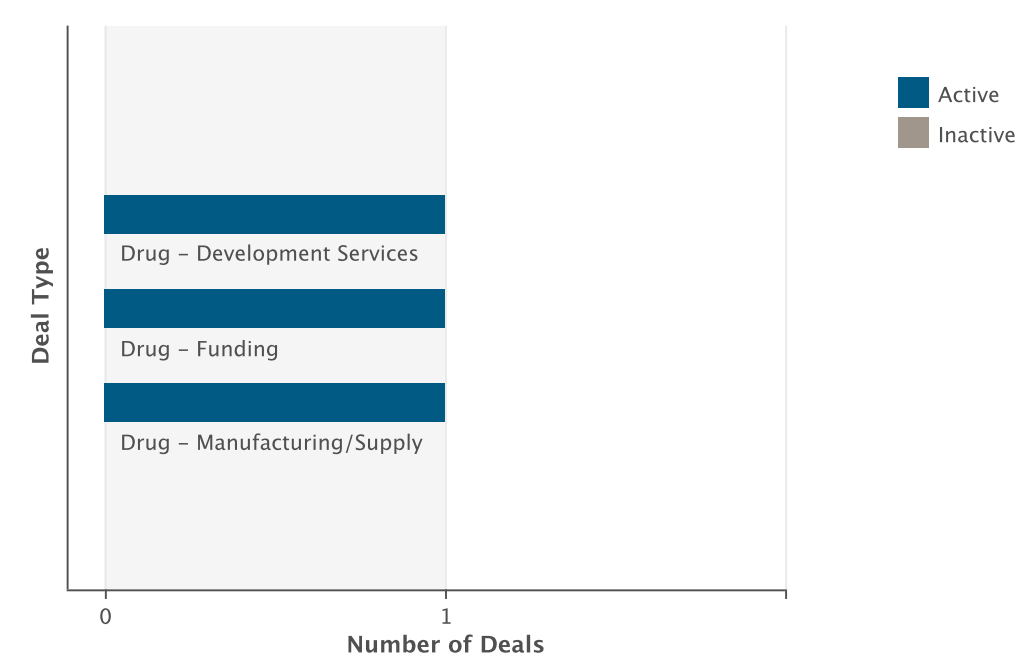


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Pfenex Inc	1	0	1	0	2
Science Applications International Corp	1	0	1	0	2
US Government	0	0	1	0	1
Ajinomoto Co Inc	1	0	0	0	1

[Return to Table of Contents](#)

Deals by Type Chart



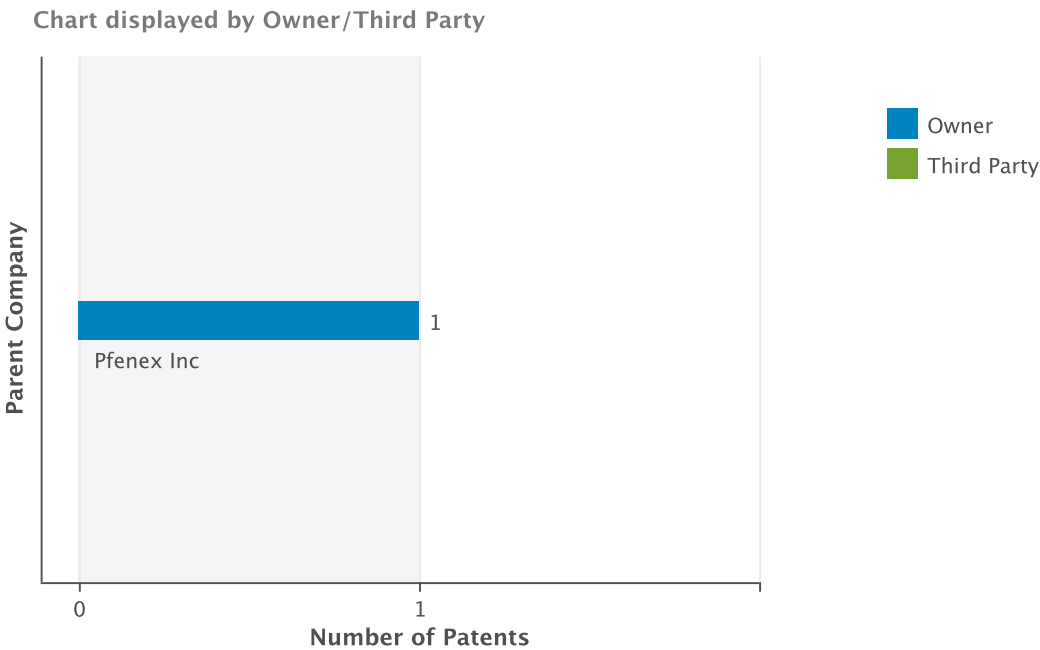
Deals by Type Table

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

[Return to Table of Contents](#)

PATENTS

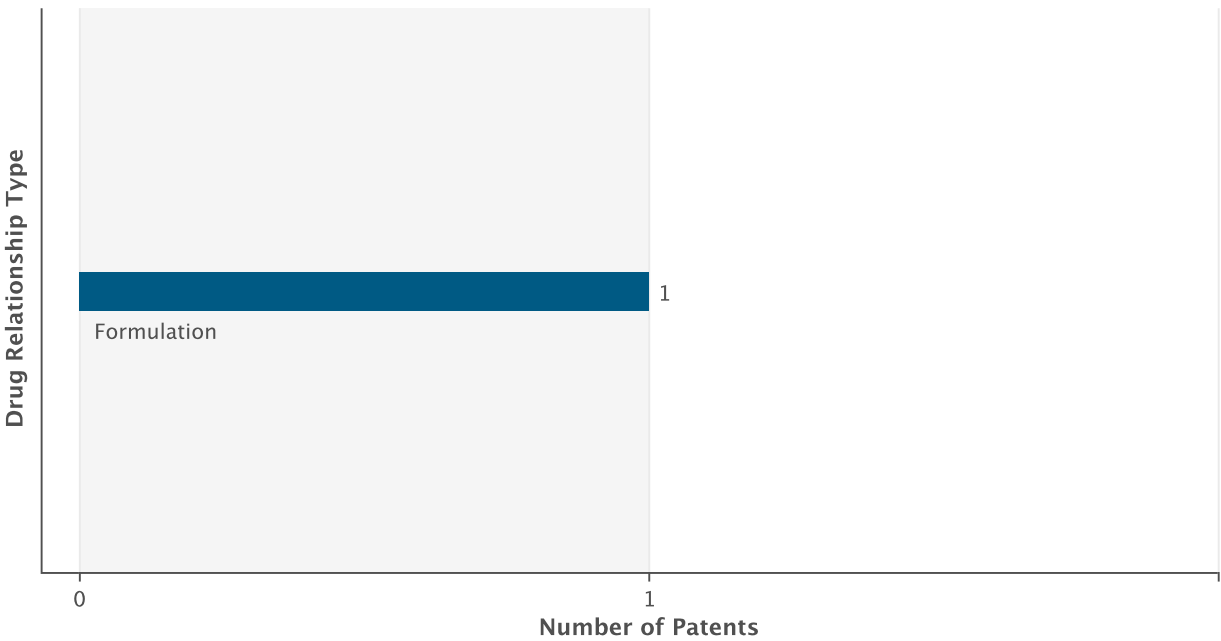
Patents by Parent Company Chart



Patents by Parent Company Table

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

Patents by Drug Relationship Type Chart



[Return to Table of Contents](#)

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	Development Status	Date
Pfenex Inc	Neutropenia	US	Discovery	29-Mar-2010
Ranbaxy Laboratories Ltd	Neutropenia	India	Discovery	29-Mar-2010

GCSF biosimilar, Pfenex/Ranbaxy DRUG NAMES

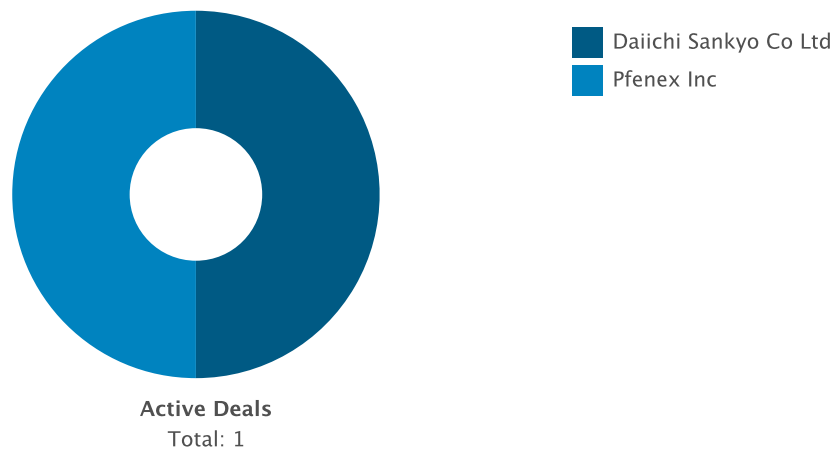
Names	Type
G-CSF	
granulocyte colony-stimulating factor	
GCSF biosimilar, Pfenex/Ranbaxy	

[Return to Table of Contents](#)

GCSF biosimilar, Pfenex/Ranbaxy DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Pfenex Inc	1	0	0	0	1
Daiichi Sankyo Co Ltd	0	0	1	0	1

[Return to Table of Contents](#)

Deals by Type Chart



Deals by Type Table

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

[Return to Table of Contents](#)

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

[Return to Table of Contents](#)



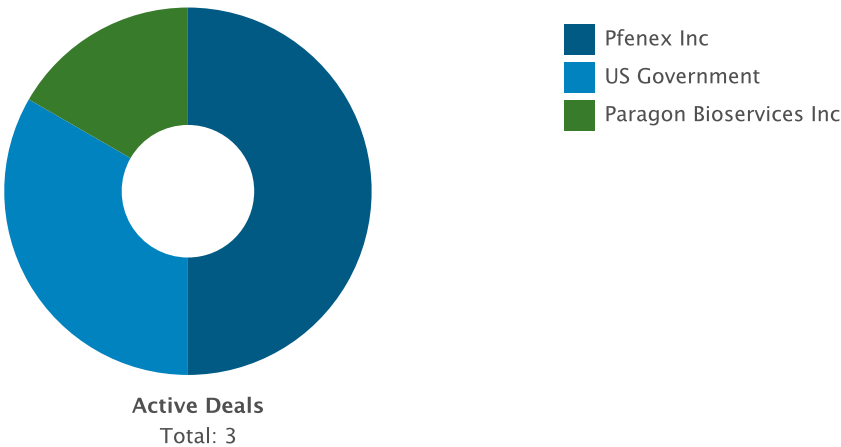
Px-563L DRUG NAMES

Names	Type
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

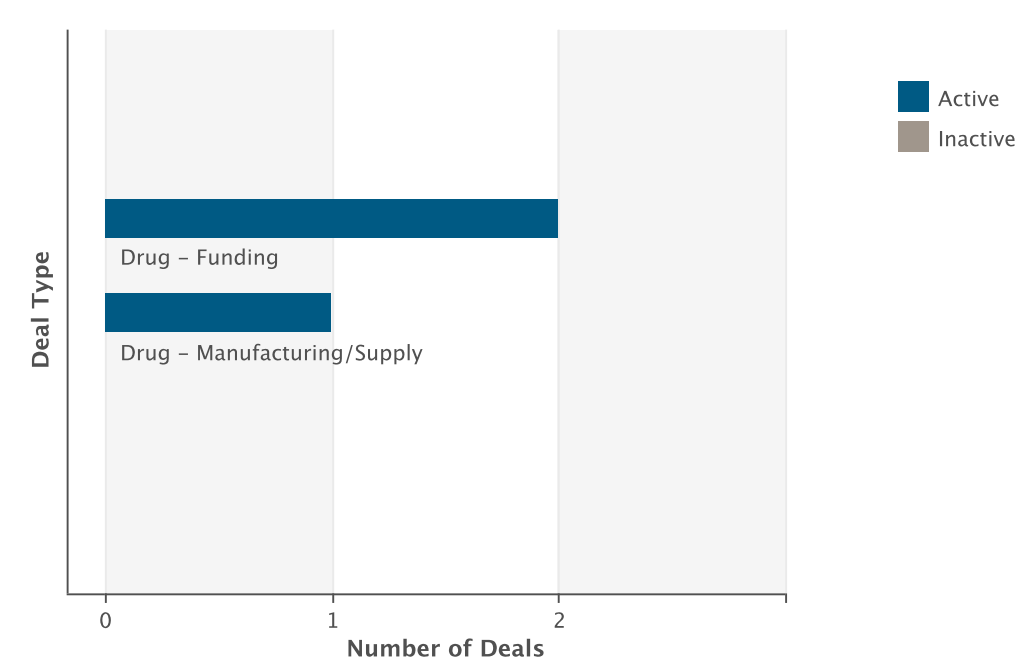


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Pfenex Inc	2	0	1	0	3
US Government	0	0	2	0	2
Paragon Bioservices Inc	1	0	0	0	1

[Return to Table of Contents](#)

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	Development Status	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

[Return to Table of Contents](#)



PF-530 DRUG NAMES

Names	Type
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

[Return to Table of Contents](#)

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	Development Status	Date
Pfenex Inc	Growth hormone deficiency	US	Discovery	29-Mar-2010
Ranbaxy Laboratories Ltd	Growth hormone deficiency	India	Discovery	29-Mar-2010

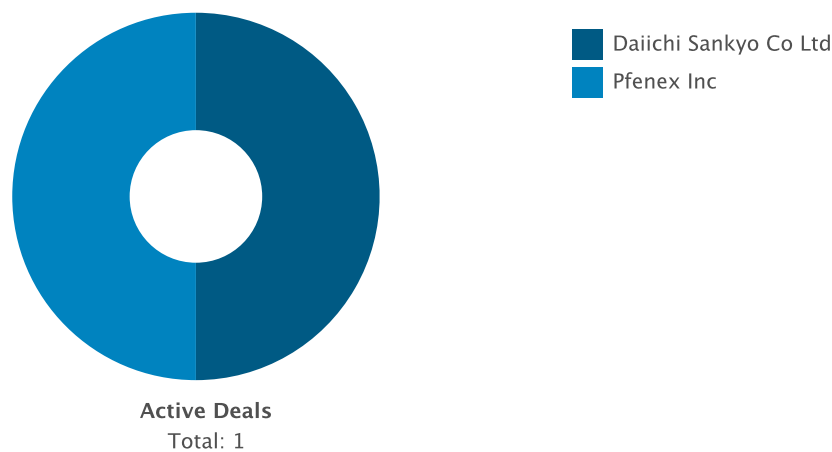
somatropin biosimilar, Pfenex/Ranbaxy DRUG NAMES

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

[Return to Table of Contents](#)

DEALS

Deals by Parent Company Chart

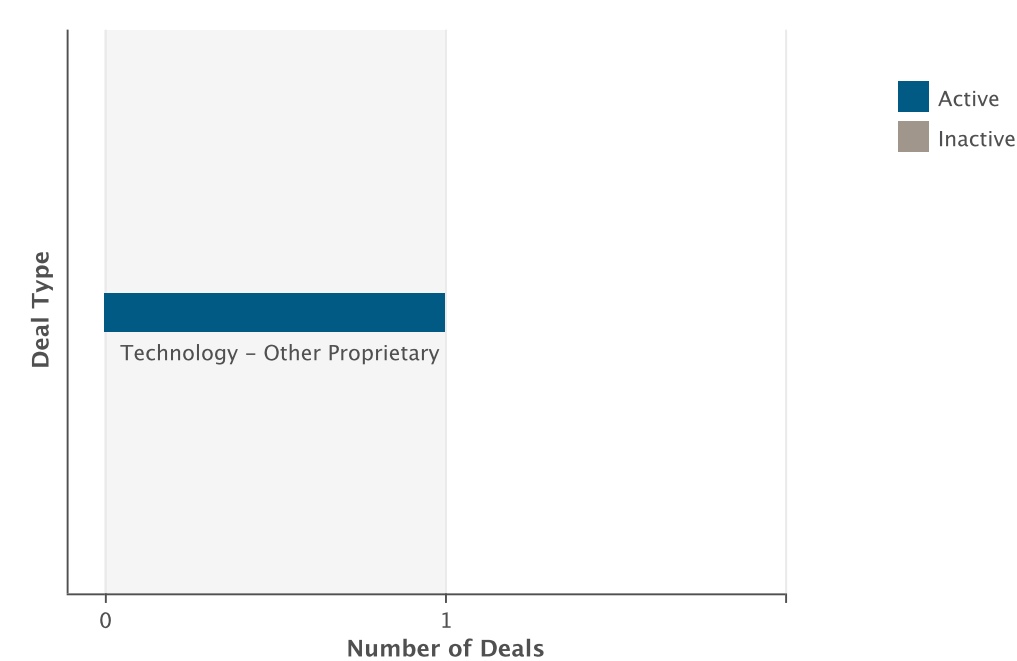


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Daiichi Sankyo Co Ltd	0	0	1	0	1
Pfenex Inc	1	0	0	0	1

[Return to Table of Contents](#)

Deals by Type Chart



Deals by Type Table

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

[Return to Table of Contents](#)

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	Development Status	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

[Return to Table of Contents](#)

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

Names	Type
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	

[Return to Table of Contents](#)

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

[Return to Table of Contents](#)



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

Names	Type
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	Development Status	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

[Return to Table of Contents](#)



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

Names	Type
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	

[Return to Table of Contents](#)

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	Development Status	Date
Pfenex/Stelis Joint Venture	Cancer	India	Discovery	16-Apr-2013
Inbiopro Solutions Pvt Ltd	Cancer	India	Discontinued	09-Dec-2010

[Return to Table of Contents](#)



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

Names	Type
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	

[Return to Table of Contents](#)

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

[Return to Table of Contents](#)



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

Names	Type
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	Development Status	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	

[Return to Table of Contents](#)





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	Development Status	Date
Glide Pharma	Bacillus anthracis infection	UK	Discovery	30-Apr-2013
Pfenex Inc	Bacillus anthracis infection	US	Discovery	30-Apr-2013

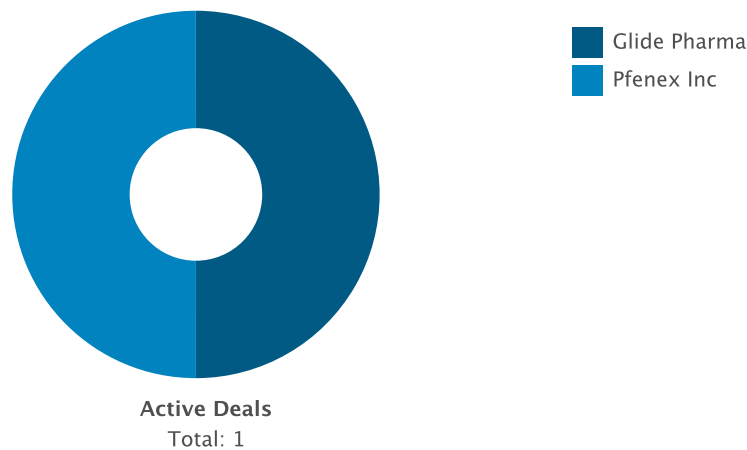
rPA vaccine (solid, anthrax), Pfenex / Glide DRUG NAMES

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

[Return to Table of Contents](#)

DEALS

Deals by Parent Company Chart

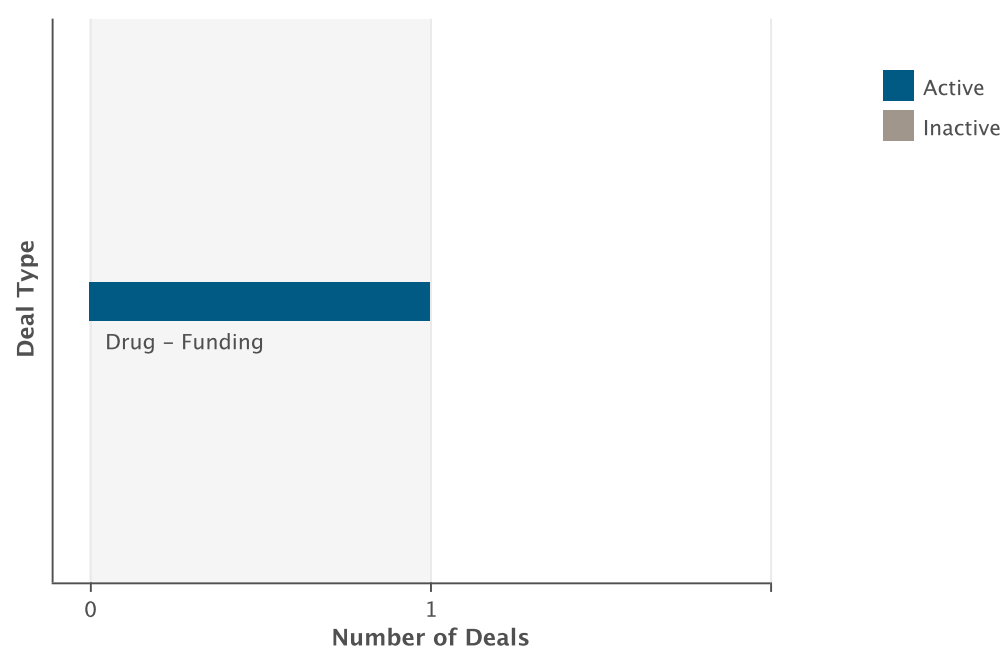


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Glide Pharma	1	0	0	0	1
Pfenex Inc	0	0	1	0	1

[Return to Table of Contents](#)

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Funding	1	0	1

[Return to Table of Contents](#)

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	Development Status	Date
Pfenex Inc	Inflammatory disease	US	Discovery	26-Feb-2013

IFN alpha 2b biosimilar, Pfenex DRUG NAMES

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

[Return to Table of Contents](#)



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	Development Status	Date
Pfenex Inc	Inflammatory disease	US	Discovery	26-Mar-2013

PF-688 DRUG NAMES

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

[Return to Table of Contents](#)

This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis™ for Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information.

For more information about *Cortellis for Competitive Intelligence*, visit:

http://cortellis.thomsonreuters.com/cortellis_for_you/?cid=thomsonone.

For subscription information, e-mail scientific.lifesciences@thomsonreuters.com.

© 2012 Thomson Reuters. All rights reserved.
Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks and trademarks of Thomson Reuters and its affiliated companies.

[Return to Table of Contents](#)

