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FibroGen 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

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.

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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 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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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.

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FibroGen Inc

COMPANY OVERVIEW

Company Name	FibroGen Inc
Parent Company Name	FibroGen Inc
Website	http://www.fibrogen.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	8
Number of Patents as Owner	73
Number of Patents as Third Party	2
Number of Deals	13
Key Indications	Anemia,Pancreas tumor,Glioma,Idiopathic pulmonary fibrosis,Diabetic nephropathy,Duchenne dystrophy,Focal segmental glomerulosclerosis,Glaucoma,Liver fibrosis,Ischemia
Key Target-based Actions	HIF prolyl hydroxylase inhibitor,TGF beta antagonist,Connective tissue growth factor ligand inhibitor,Bone morphogenetic protein-1 ligand inhibitor,HIF prolyl hydroxylase-1 modulator,Hydroxylase inhibitor,Angiotensin receptor antagonist,CD66e antagonist,CTGF gene inhibitor,Calcineurin inhibitor,Erythropoietin receptor agonist,HIF prolyl hydroxylase-1 inhibitor,Hydroxylase modulator,IL-6 agonist,LDL receptor antagonist,Prolyl hydroxylase inhibitor,TGF beta agonist
Key Technologies	Small molecule therapeutic,Biological therapeutic,Oral formulation,Protein recombinant,Capsule formulation,Monoclonal antibody human,Tablet formulation,Infusion,Intravenous formulation,Peptide

COMPANY PROFILE

SUMMARY

FibroGen Inc, a spin-out of Duke University, founded in 1994, is a privately held biotechnology company which has developed the only commercially viable method known to produce human collagen and human gelatin in recombinant systems. The company's therapeutic target areas include fibrotic disorders affecting the major organs, diabetes, surgical procedures, and fibroproliferative tumor progression and metastasis.

COMPANY LOCATION

Fibrogen's headquarters are in San Francisco, CA. Fibrogen Europe, a subsidiary of Fibrogen based in Helsinki, Finland, is a biotechnology focused enterprise that specialises in the development of recombinant collagens and gelatins.

In March 2015, the Beijing Chinese FDA had completed the inspections and issued the Pharmaceutical Production Permit (PPP) to FibroGen China facility as per GMP standards.

LICENSING AGREEMENTS

In January 2001, FibroGen and Aventis Pasteur formed a collaboration agreement to develop, using FibroGen's proprietary technology, novel synthetic gelatins with the potential to confer optimum stabilization and activity attenuation specific for certain Aventis Pasteur vaccines.

As of October 1999, FibroGen had a research and development agreement with Medarex Inc to develop monoclonal antibodies to block the fibrogenic cascade. In July 1998, FibroGen signed an agreement with Medarex for the use of the HuMab mouse antibody technology to develop potential antifibrotic therapies using FibroGen's proprietary targets.

In September 1999, FibroGen announced a collaboration with Taisho Pharmaceutical Co Ltd to develop and commercialize human monoclonal antibodies for the treatment of fibrotic kidney diseases; however, no development has been reported by Taisho since May 2002 and in August 2005 this strategic alliance was not listed on FibroGen's

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website.

In 1997, FibroGen licensed ArQule's Mapping Array program to discover and develop drug candidates for fibrosis and excessive scarring; however, since 2002, no development had been reported on this deal.

EARLY R&D/TECHNOLOGY UPDATES/IP NEWS

In December 1998, FibroGen received US-05837258, covering the use of connective tissue growth factor to induce the repair of connective tissue, including bone, cartilage and skin.

As of June 1998, programs were underway at FibroGen for the development of small-molecules which modulate collagen scar formation and human antibodies to neutralize cytokine and enzyme targets.

FINANCIAL

In October 2014, FibroGen filed a registration statement on Form S1 with the US SEC relating to a proposed initial public offering of shares of its common stock. In November 2014, the company announced the pricing of 8,100,000 shares of its common stock at a public offering price of $18.00 per share before underwriting discounts and commissions on the NASDAQ Global Market under the ticker symbol 'FGEN'. At that time, the underwriters were granted a 30-day option to purchase upto 1,215,000 additionally at the initial offering price and the offering was expected to be closed on November 19, 2014; later that month, the company announced that the underwriters of its initial public offering were exercised in full option to purchase an additional 1,215,000 shares of common stock from FibroGen less than the underwriting discount. The initial public offering was a total of 9,315,000 shares of common stock of FibroGen, with gross proceeds of approximately $167.7 million, prior to deducting the underwriting discount and estimated offering expenses. The Company's common stock started trading on the NASDAQ Global Select Market. At that time, the company raised a net proceeds of $171.8 million from the IPO.

In February 2005, FibroGen raised net proceeds of $100 million from a completed a private placement of convertible preferred stock, 15% of which was sold to existing investors. The funds would be used to expand the company's clinical trial activities including anemia, idiopathic pulmonary fibrosis and diabetic nephropathy. New clinical programs in acute renal failure and in rare diseases in anemia and in fibrosis would also be launched, and the metastatic cancers program extended. The funds would also be used for efficacy studies and commercial-scale manufacturing of injectable recombinant human collagen.

In September 2000, FibroGen completed a $56.7 million private placement of convertible preferred stock.

R&D GRANTS

In April 1999, the Finnish government reported that it would fund 50% of the company's recombinant collagen and gelatin costs.

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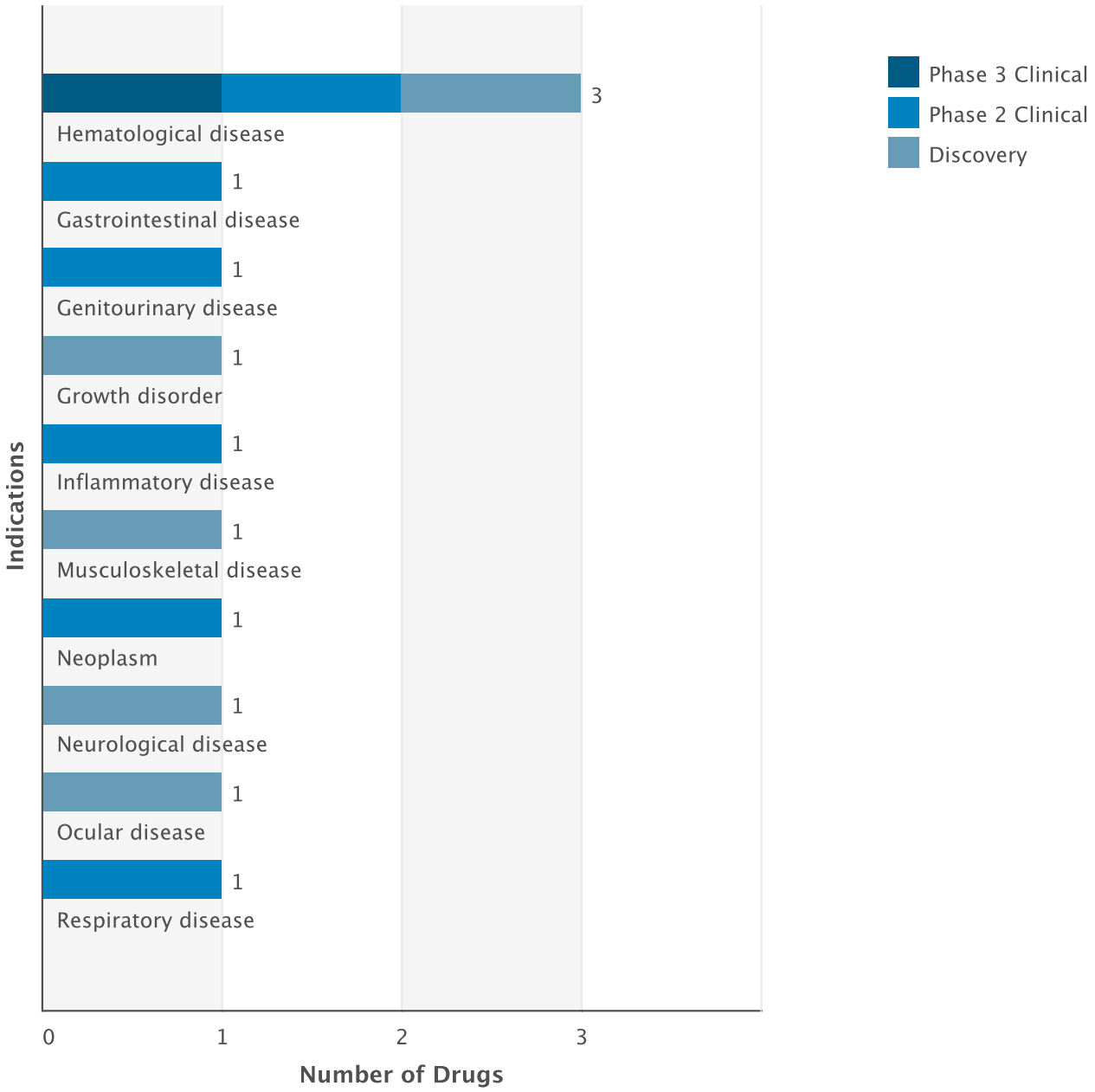
PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



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Drugs by Indication Table

Indication	Active	Inactive	Total
Inflammatory disease	1	4	5
Hematological disease	3	1	4
Musculoskeletal disease	1	2	3
Neurological disease	1	2	3
Gastrointestinal disease	1	1	2
Cardiovascular disease	0	2	2
Neoplasm	1	1	2
Injury	0	2	2
Genitourinary disease	1	1	2
Ocular disease	1	0	1
Dermatological disease	0	1	1
Growth disorder	1	0	1
Genetic disorder	0	1	1
Immune disorder	0	1	1
Respiratory disease	1	0	1

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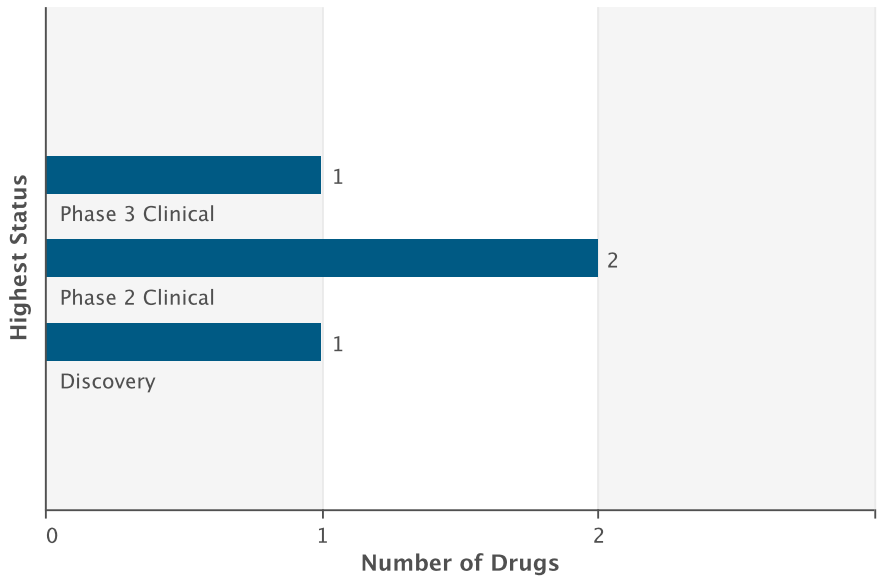
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
No Development Reported	8
Discovery	1
Phase 2 Clinical	2

DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Development/Commercialization License	4	0	1	0	5
Patent - Exclusive Rights	0	0	1	0	1
Drug - Funding	3	0	0	0	3
Technology - Other Proprietary	1	0	2	0	3
Technology - Target Validation	0	0	1	0	1

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CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Hematological disease	9	23
Genitourinary disease	0	8
Inflammatory disease	2	5
Gastrointestinal disease	2	5
Respiratory disease	2	3
Metabolic disorder	0	3
Endocrine disease	0	3
Neoplasm	1	2
Dermatological disease	0	1
Cardiovascular disease	0	1
Genetic disorder	0	1
Neurological disease	0	1

Trials by Phase

Phase	Ongoing	All
Phase 3	8	9
Phase 2	4	16
Phase 1	1	13
Phase not specified	0	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
Immune disorder	10	0	10

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Psychiatric disorder	1	0	1
Musculoskeletal disease	17	2	19
Neoplasm	15	1	16
Ocular disease	6	0	6
Genetic disorder	1	0	1
Metabolic disorder	18	2	20
Neurological disease	15	1	16
Nutritional disorder	2	0	2
Prophylaxis	1	0	1
Respiratory disease	24	0	24
Infectious disease	7	0	7
Injury	6	0	6
Cardiovascular disease	35	1	36
Endocrine disease	13	0	13
Gastrointestinal disease	24	0	24
Genitourinary disease	25	1	26
Growth disorder	3	0	3
Hematological disease	25	0	25
Degeneration	1	0	1
Surgical procedure	0	1	1
Dermatological disease	5	0	5
Ulcer	2	0	2
Gynecology and obstetrics	3	0	3
Inflammatory disease	30	3	33

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

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PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

roxadustat

roxadustat SNAPSHOT

Drug Name	roxadustat
Key Synonyms	ciclopirox;roxadustat
Originator Company	FibroGen Inc
Active Companies	Astellas Pharma Inc;AstraZeneca plc;FibroGen Inc
Inactive Companies	Zeneca Group plc
Highest Status	Phase 3 Clinical
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Erythropoietin modulator
Technologies	Capsule formulation;Oral formulation;Small molecule therapeutic;Tablet formulation
Last Change Date	28-Sep-2015

roxadustat DEVELOPMENT PROFILE

SUMMARY

FibroGen, Astellas Pharma and AstraZeneca are developing roxadustat (FG-4592, AZD-9941, ASP-1517, kebomei), a hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, for the potential oral treatment of anemia in patients with end-stage renal disease (ESRD) and chronic kidney disease (CKD) ,,.

In November 2012, a phase III trial sponsored by FibroGen with collaboration from Astellas and AstraZeneca was initiated in the US in CKD patients not on dialysis ; in May 2013, a phase III trial sponsored by Astellas with collaboration from FibroGen began in Europe in CKD patients not on dialysis. In December 2013, a phase III trial sponsored by FibroGen with collaboration from Astellas and AstraZeneca was initiated in Europe for anemia in patients newly initiated on dialysis with ESRD. In June 2014, a pivotal US phase III study sponsored by AstraZeneca was initiated for anemia in CKD patients on dialysis,. In March 2015, the phase III program was expected to enroll approximately 7,300 dialysis and pre-dialysis patients. In March 2015, filings for anemia in CKD/ESRD were expected in 2018 in the US ; at that time, an MAA submission was expected to precede the planned NDA filing in 2018 . In February 2013, phase II trials were underway in Japan in CKD patients on dialysis ; in February 2015, this was still the case. By July 2014, a phase II trial in Japan in non-dialysis patients had been initiated .

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FibroGen, in collaboration with AstraZeneca (formerly Zeneca), was previously investigating HIF-PH inhibitors as potential antifibrotics or protectants for use in scarring, fibroproliferative disorders and sickle cell disease,, ; however, these indications were not included on FibroGen's August 2005 pipeline and no development has been reported by AstraZeneca since January 2001. FibroGen was also investigating roxadustat for cerebrovascular ischemia ; however, no further development has been reported for this indication. In May 2007, it was reported that all development of roxadustat was suspended by Astellas following a death in a clinical trial of FG-2216 ; in March 2008, the FDA informed the companies that clinical trials could be resumed and, in May 2008, Astellas stated that phase II European trials had been resumed.

FibroGen and Astellas are also developing the HIF-PH inhibitor FG-2216 for the potential treatment of anemia, and FibroGen is investigating the HIF-PH inhibitor FG-4539 for potential use in myocardial infarction and renal failure.

roxadustat DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Astellas Pharma Inc	Anemia	Europe	Phase 3 Clinical	31-May-2013
Astellas Pharma Inc	Anemia	Russian Federation	Phase 3 Clinical	31-May-2013
Astellas Pharma Inc	Anemia	South Africa	Phase 3 Clinical	31-May-2013
AstraZeneca plc	Anemia	Australia	Phase 3 Clinical	30-Nov-2012
AstraZeneca plc	Anemia	Mexico	Phase 3 Clinical	30-Nov-2012
AstraZeneca plc	Anemia	New Zealand	Phase 3 Clinical	30-Nov-2012
AstraZeneca plc	Anemia	Puerto Rico	Phase 3 Clinical	31-Jul-2013
AstraZeneca plc	Anemia	South America	Phase 3 Clinical	30-Nov-2012
AstraZeneca plc	Anemia	US	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	Asia	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	Australia	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	Europe	Phase 3 Clinical	31-May-2013
FibroGen Inc	Anemia	Mexico	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	New Zealand	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	Puerto Rico	Phase 3 Clinical	31-May-2012
FibroGen Inc	Anemia	South America	Phase 3 Clinical	30-Nov-2012
FibroGen Inc	Anemia	US	Phase 3 Clinical	31-May-2012
Astellas Pharma Inc	Anemia	Japan	Phase 2 Clinical	01-Feb-2013

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Company	Indication	Country	Development Status	Date
AstraZeneca plc	Anemia	China	Phase 2 Clinical	31-Jul-2013
AstraZeneca plc	Anemia	Hong Kong	Phase 2 Clinical	31-Jul-2013
FibroGen Inc	Anemia	China	Phase 2 Clinical	15-Nov-2011
FibroGen Inc	Anemia	Hong Kong	Phase 2 Clinical	31-Oct-2010
AstraZeneca plc	Fibrosis	UK	No Development Reported	23-Jun-2003
FibroGen Inc	Fibrosis	US	No Development Reported	09-Aug-2005
FibroGen Inc	Scar tissue	US	No Development Reported	09-Aug-2005
FibroGen Inc	Sickle cell anemia	US	No Development Reported	09-Aug-2005
FibroGen Inc	Stroke	US	No Development Reported	13-Apr-2007

roxadustat CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
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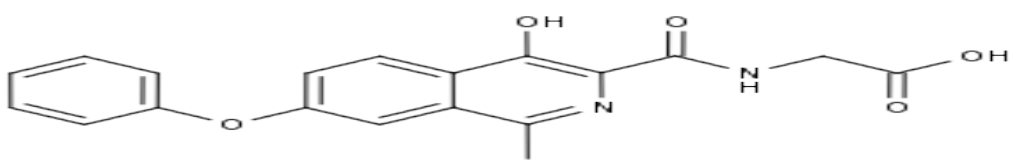

Name	Type
roxadustat	INN; USAN
ASP-1517	Research Code
FG-4592	Research Code

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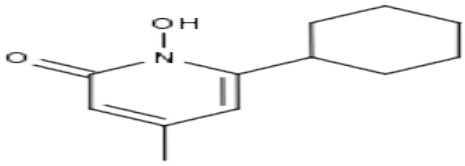
CAS Registry Number:	Confidence Level:
29342-05-0	1



Name	Type
ciclopirox	BANN; INN; USAN
Ciclopoli	Trade Name
FG-2229	Research Code
P-3051	Research Code

CAS Registry Number:	Confidence Level:
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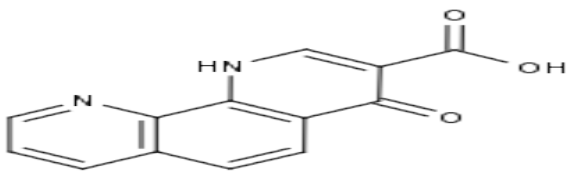

Name	Type
FG-0041	Research Code
FG-041	Research Code

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CAS Registry Number:	Confidence Level:
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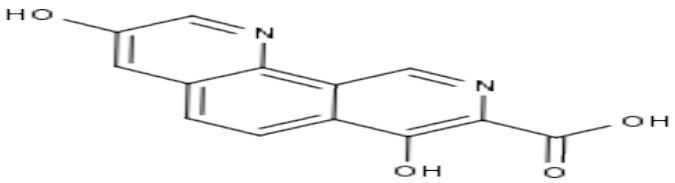

Name	Type
FG-1577	Research Code

CAS Registry Number:	Confidence Level:
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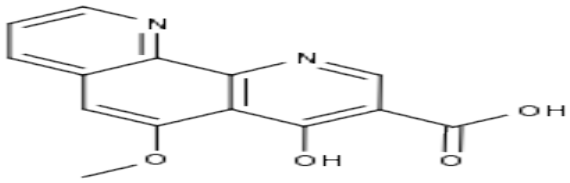

Name	Type
FG-1649	Research Code

CAS Registry Number:	Confidence Level:
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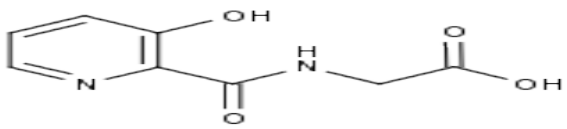

Name	Type
FG-2179	Research Code

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CAS Registry Number:	Confidence Level:
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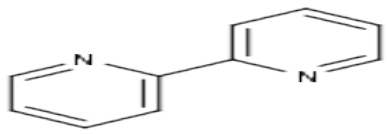

Name	Type
FG-2909	Research Code

CAS Registry Number:	Confidence Level:
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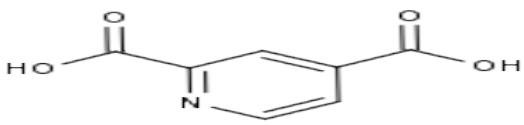

Name	Type
FG-2910	Research Code

CAS Registry Number:	Confidence Level:
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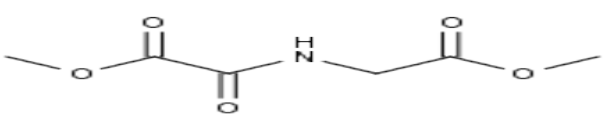

Name	Type
FG-2933	Research Code

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CAS Registry Number:	Confidence Level:
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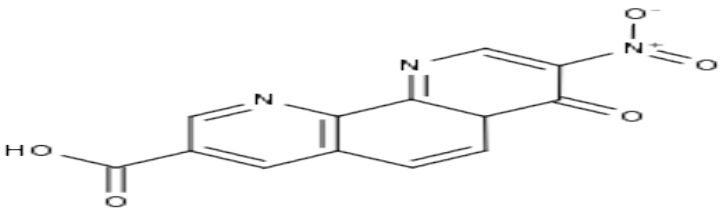

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roxadustat DRUG NAMES

Names	Type
ASP-1517	Research Code
AZD-9941	Research Code
FG-0041	Research Code
FG-041	Research Code
FG-085	Research Code
FG-1577	Research Code
FG-1649	Research Code
FG-2179	Research Code
FG-2229	Research Code
FG-2909	Research Code
FG-2910	Research Code
FG-2933	Research Code
FG-2934	Research Code
FG-4592	Research Code
HIF-PH inhibitors (1), FibroGen	
P4H inhibitors, Fibrogen	
ciclopirox	INN, BANN, USAN
kebomei	
prolyl 4-hydroxylase inhibitors (1), Fibrogen	
prolyl hydroxylase inhibitors (1), FibroGen	
prolyl hydroxylase inhibitors, FibroGen/AstraZeneca	
roxadustat	INN, USAN

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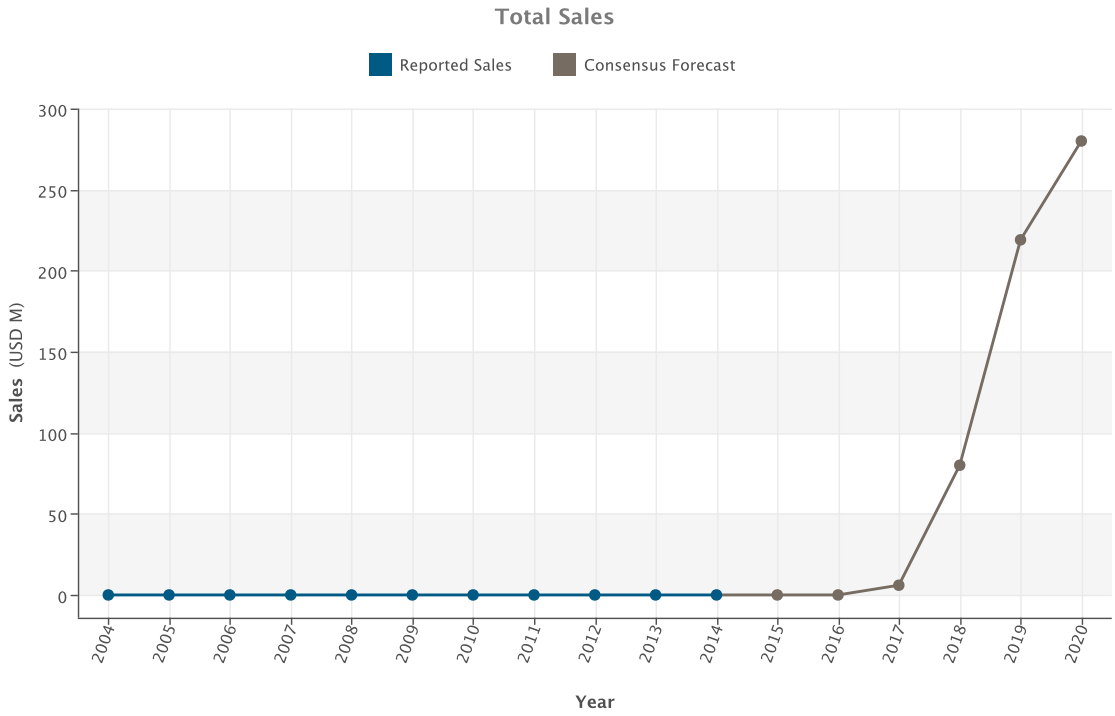
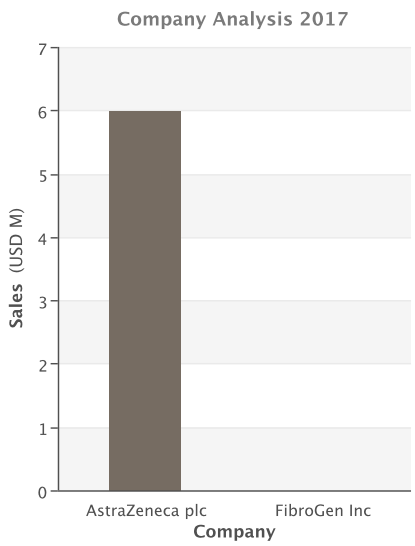
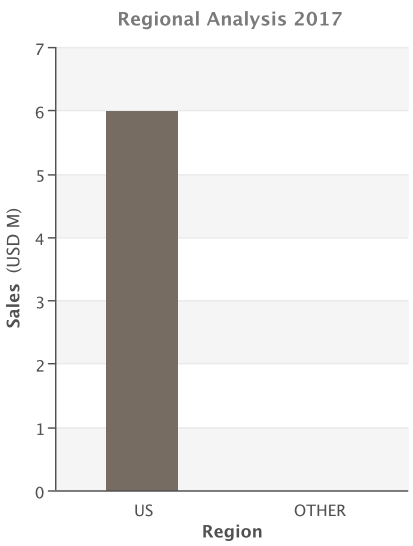
roxadustat SALES AND FORECASTS

CHARTS







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COMMENTARY

CONSENSUS SALES INFORMATION

Consensus forecast data for AstraZeneca and FibroGen are presented; however, no Consensus forecast data beyond 2019 are currently available for Fibrogen. No Consensus forecast data for Astellas are currently available.

REGIONAL DEVELOPMENT AND MARKETING RIGHTS

From September 2004, Yamanouchi Pharmaceutical (now Astellas Pharma) held Japanese rights to develop and market FibroGen's roxadustat; in April 2006 Astellas gained rights to Europe, the Commonwealth of Independent States, the Middle East and South Africa [560832], [664640].

In July 2013, AstraZeneca and FibroGen entered into a strategic collaboration to develop and commercialize roxadustat for the treatment of anemia associated with chronic kidney disease and end-stage renal disease in the US, China and all other not previously licensed to Astellas (ie, excluding Europe, Japan, the Commonwealth of Independent States, South Africa and the Middle East. Under the agreement, AstraZeneca would be responsible for the US commercialization, with FibroGen undertaking specified promotional activities in the end-stage renal disease segment in this market. The companies would also co-commercialize rodaxustat in China where FibroGen would be responsible for clinical trials, regulatory matters, manufacturing and medical affairs, and AstraZeneca would oversee promotional activities and commercial distribution [1458823]. In March 2015, FibroGen noted that under the China agreement, the commercial collaboration was structured as a 50/50 profit share. AstraZeneca would conduct commercialization activities in China as well as serve as the master distributor for roxadustat and would fund roxadustat launch costs in China until FibroGen China had achieved profitability. At that time, AstraZeneca would recoup 50% of their historical launch costs out of initial roxadustat profits in China [1646097].

roxadustat 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
Anemia											
0	0	8	10	2	10	0	4	0	0	10	24
Renal disease											
0	0	0	0	0	3	0	0	0	0	0	3
Scar tissue											
0	0	0	0	0	0	0	2	0	0	0	2
Sickle cell anemia											
0	0	0	0	0	0	0	2	0	0	0	2
Stroke											
0	0	0	0	0	0	0	2	0	0	0	2

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Fibrosis											
0	0	0	0	0	0	0	2	0	0	0	2

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	8	10	2	11	0	8	0	2	10	31

Phase Definitions

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

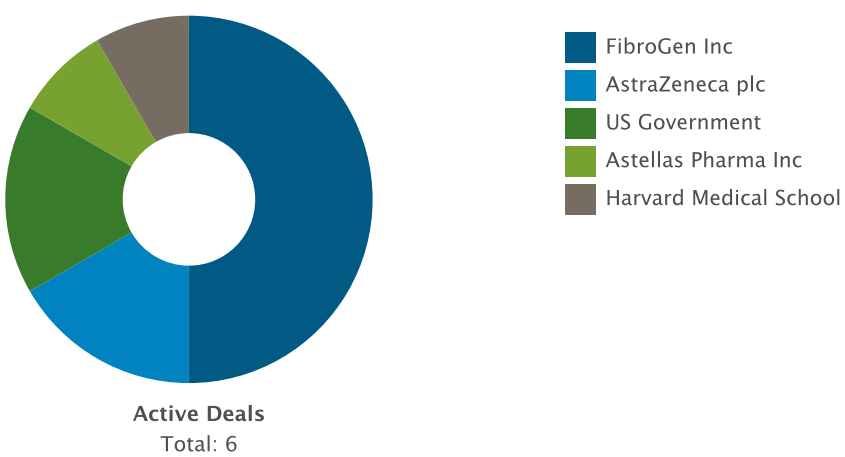
Phase 2 Clinical
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

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

roxadustat DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Active Deals
Total: 6

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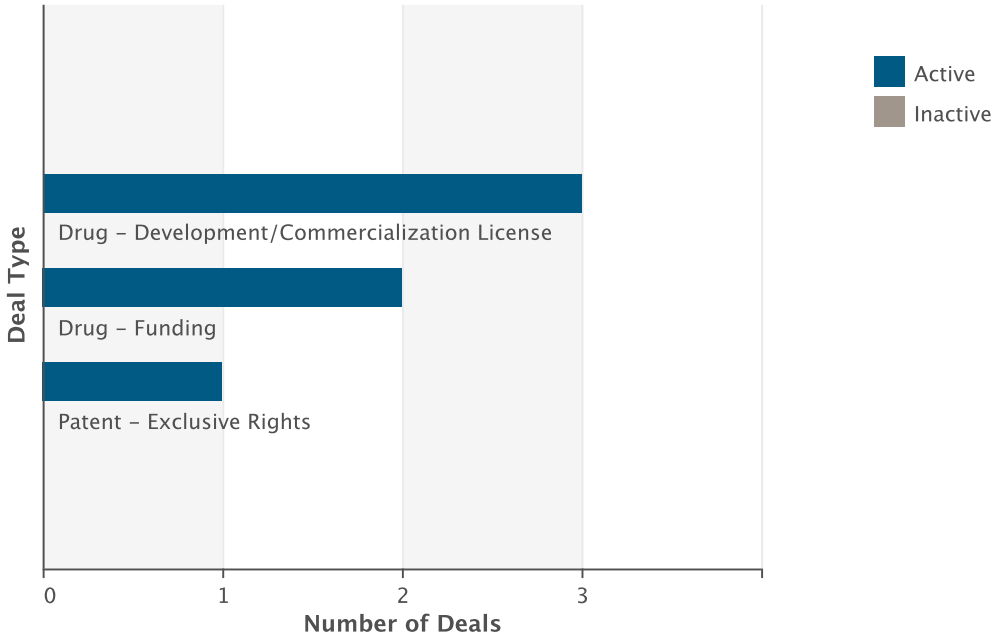
Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
FibroGen Inc	4	0	2	0	6
US Government	0	0	2	0	2
AstraZeneca plc	1	0	1	0	2
Astellas Pharma Inc	0	0	1	0	1
Harvard Medical School	1	0	0	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	3	0	3
Drug - Funding	2	0	2
Patent - Exclusive Rights	1	0	1

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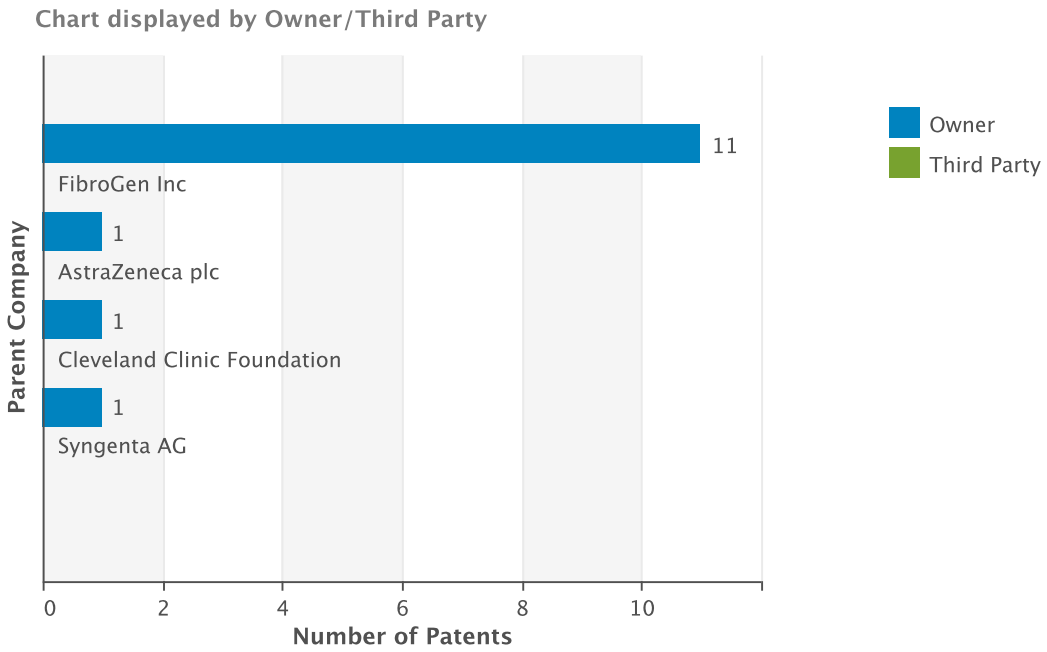
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
FibroGen Inc	11	0	11
Syngenta AG	1	0	1
Cleveland Clinic Foundation	1	0	1
AstraZeneca plc	1	0	1

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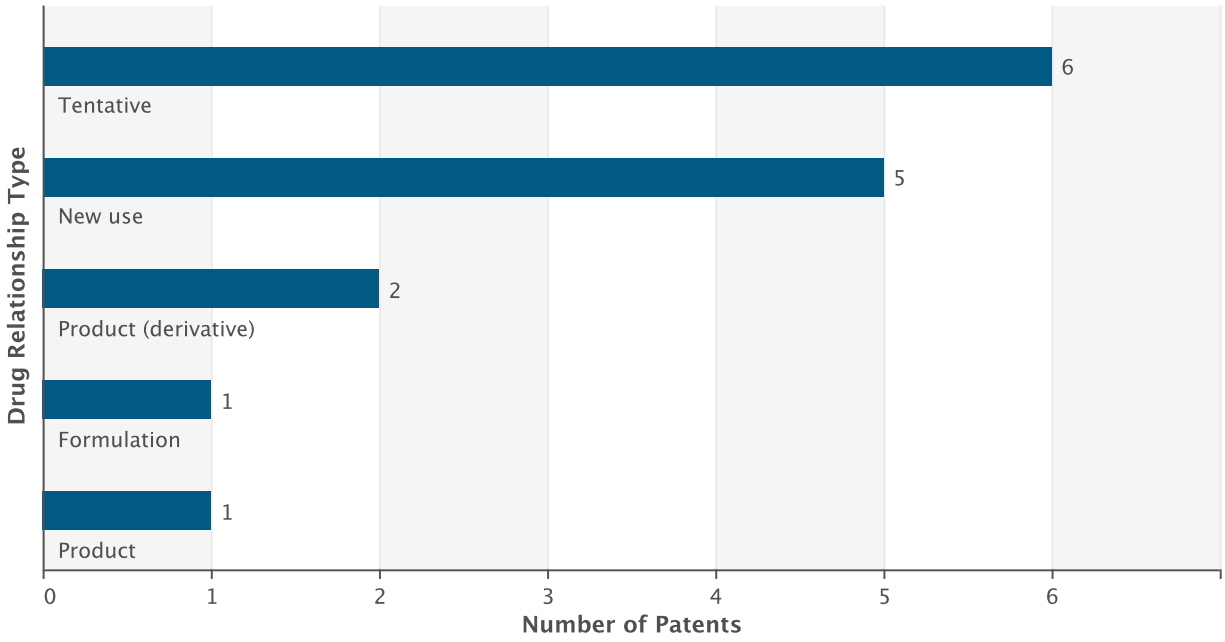
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Tentative	6
New use	5
Product (derivative)	2
Formulation	1
Product	1

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FG-3019

FG-3019 SNAPSHOT

Drug Name	FG-3019
Key Synonyms	pamrevlumab
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc
Inactive Companies	Taisho Pharmaceutical Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	Diabetic nephropathy;Duchenne dystrophy;Focal segmental glomerulosclerosis;Glaucoma;Glioma;Idiopathic pulmonary fibrosis;Liver fibrosis;Pancreas tumor
Target-based Actions	Connective tissue growth factor ligand inhibitor
Other Actions	Angiogenesis inhibitor;Anticancer monoclonal antibody;Fibrosuppressant
Technologies	Biological therapeutic;Infusion;Intravenous formulation;Monoclonal antibody human;Protein recombinant
Last Change Date	14-Aug-2015

FG-3019 DEVELOPMENT PROFILE

SUMMARY

FibroGen is developing FG-3019, presumed to be pamrevlumab, a recombinant human IgG1/kappa monoclonal antibody against connective tissue growth factor (CTGF; CCN2), created using Medarex's UltiMab system, for the potential iv treatment of idiopathic pulmonary fibrosis (IPF), liver fibrosis and pancreatic cancer,,. The company is also investigating the drug for the potential treatment of Duchenne Muscular Dystrophy (DMD). In November 2011, the company was seeking to outlicense the drug.

By September 2010, a phase II trial in advanced liver fibrosis caused by HBV infection had commenced. In January 2011, a phase II IPF trial began. In December 2008, a phase I study began in pancreatic cancer ; in January 2011, positive data were presented. In March 2015, the patient enrollment was expected to be initiated in a clinical trial in the second half of 2015.

The drug is also in development for other indications, including focal segmental glomerulosclerosis (FSGS), diabetic nephropathy (DN), orthotopic glioma and glaucoma,, . A phase I trial in FSGS began in April 2008 and by July 2009, the study had been terminated ; in December 2011, development was ongoing for FSGS. By February 2009, phase Ib trials were underway for albuminuria and steroid-resistant FSGS, and a phase II study had begun for DN; in December 2011, development was ongoing. In May 2015, an IND was expected to be filed for DMD to initiate a phase II study in non-ambulatory patients in the second half of 2015 ; in July 2015, the US FDA reviewed and cleared the IND. At that time, the phase II trial was expected to begin later in 2015 in the US. In August 2015, FibroGen expected to discuss with the FDA plans for a clinical study of FG-3019 in ambulatory DMD patients.

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FG-3019 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
FibroGen Inc	Diabetic nephropathy	US	Phase 2 Clinical	28-Feb-2009
FibroGen Inc	Idiopathic pulmonary fibrosis	US	Phase 2 Clinical	12-Jan-2011
FibroGen Inc	Liver fibrosis	Hong Kong	Phase 2 Clinical	30-Sep-2010
FibroGen Inc	Liver fibrosis	Thailand	Phase 2 Clinical	30-Sep-2010
FibroGen Inc	Pancreas tumor	US	Phase 2 Clinical	21-Jan-2011
FibroGen Inc	Focal segmental glomerulosclerosis	US	Phase 1 Clinical	30-Apr-2008
FibroGen Inc	Duchenne dystrophy	US	Discovery	31-Dec-2014
FibroGen Inc	Glaucoma	US	Discovery	10-May-2012
FibroGen Inc	Glioma	US	Discovery	14-Nov-2011
FibroGen Inc	Connective tissue disease	US	No Development Reported	09-Aug-2005
Taisho Pharmaceutical Co Ltd	Connective tissue disease	US	No Development Reported	19-Feb-2001
Taisho Pharmaceutical Co Ltd	Diabetic nephropathy	US	No Development Reported	01-May-2002
Taisho Pharmaceutical Co Ltd	Fibrosis	US	No Development Reported	19-Feb-2001

FG-3019 DRUG NAMES

Names	Type
FG-3019	Research Code
anti-CCN2, FibroGen/Taisho	
anti-CTGF, FibroGen/Taisho	
anti-connective tissue growth factor, FibroGen/Taisho	
pamrevlumab	PINN

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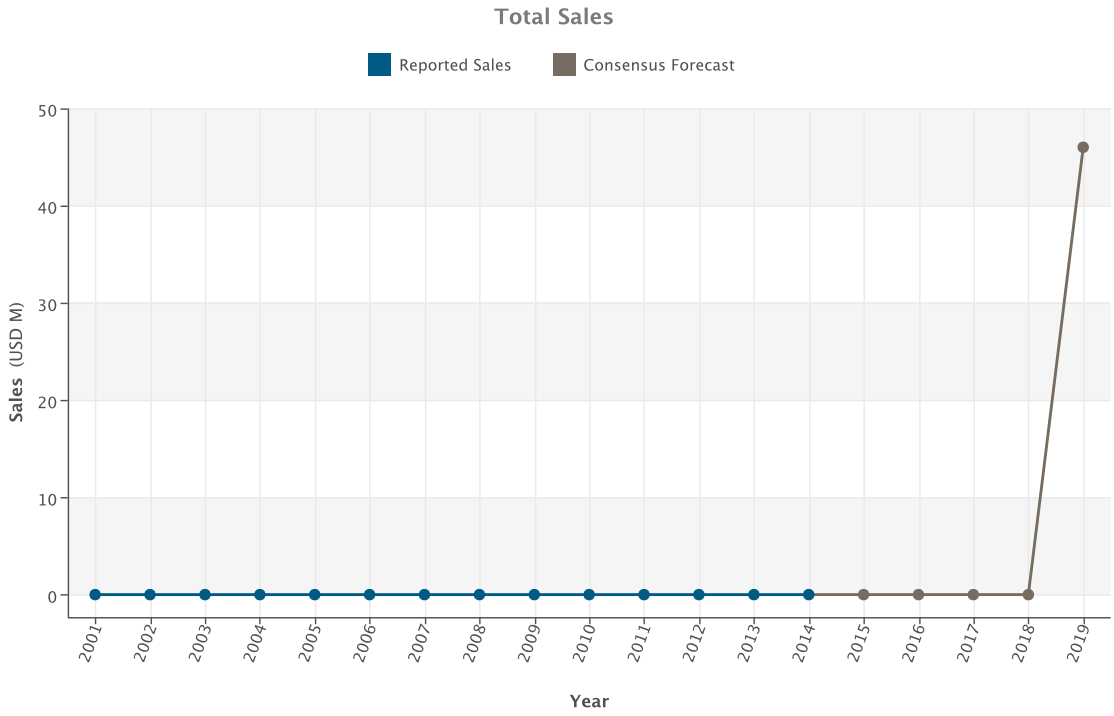
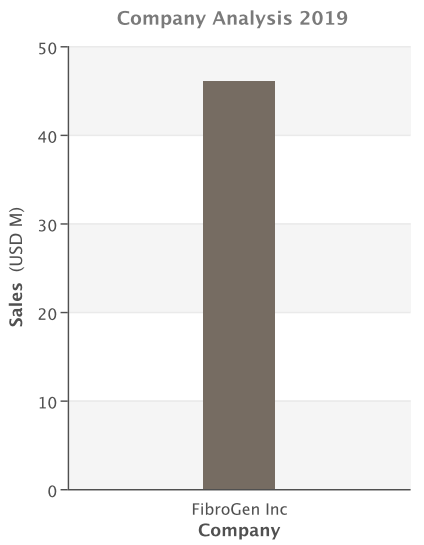
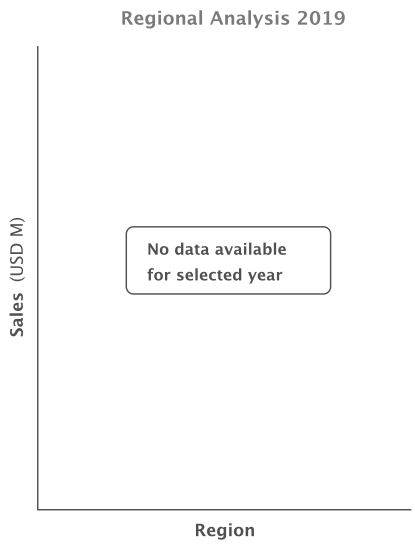
FG-3019 SALES AND FORECASTS

CHARTS







COMMENTARY

CONSENSUS SALES INFORMATION

Consensus forecast data for FibroGen are presented; however, no Consensus forecast data beyond 2019 are currently available.

REGIONAL DEVELOPMENT AND MARKETING RIGHTS

FibroGen hold rights worldwide.

FG-3019 CLINICAL TRIALS

Trials by Phase and Condition Studied

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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
Diabetic nephropathy											
0	0	0	0	0	1	0	2	0	0	0	3
Idiopathic pulmonary fibrosis											
0	0	0	0	2	2	0	0	0	0	2	2
Liver fibrosis											
0	0	0	0	1	1	0	0	0	0	1	1
Pancreas tumor											
0	0	0	0	0	0	1	1	0	0	1	1
Pulmonary fibrosis											
0	0	0	0	0	0	0	1	0	0	0	1
Focal segmental glomerulosclerosis											
0	0	0	0	0	0	0	1	0	0	0	1
Microalbuminuria											
0	0	0	0	0	0	0	1	0	0	0	1
Diabetes mellitus											
0	0	0	0	0	0	0	1	0	0	0	1
Metastatic pancreas cancer											
0	0	0	0	0	0	0	1	0	0	0	1
Non-insulin dependent diabetes											
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	3	4	1	7	0	0	4	11

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Phase Definitions

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

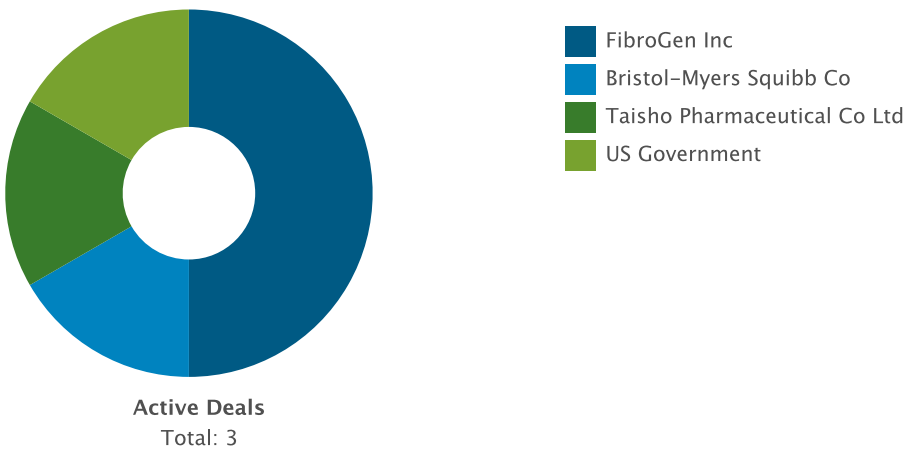
Phase 2 Clinical
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

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

FG-3019 DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Active Deals
Total: 3

Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
FibroGen Inc	2	0	1	0	3
US Government	0	0	1	0	1
Bristol-Myers Squibb Co	1	0	0	0	1
Taisho Pharmaceutical Co Ltd	0	0	1	0	1

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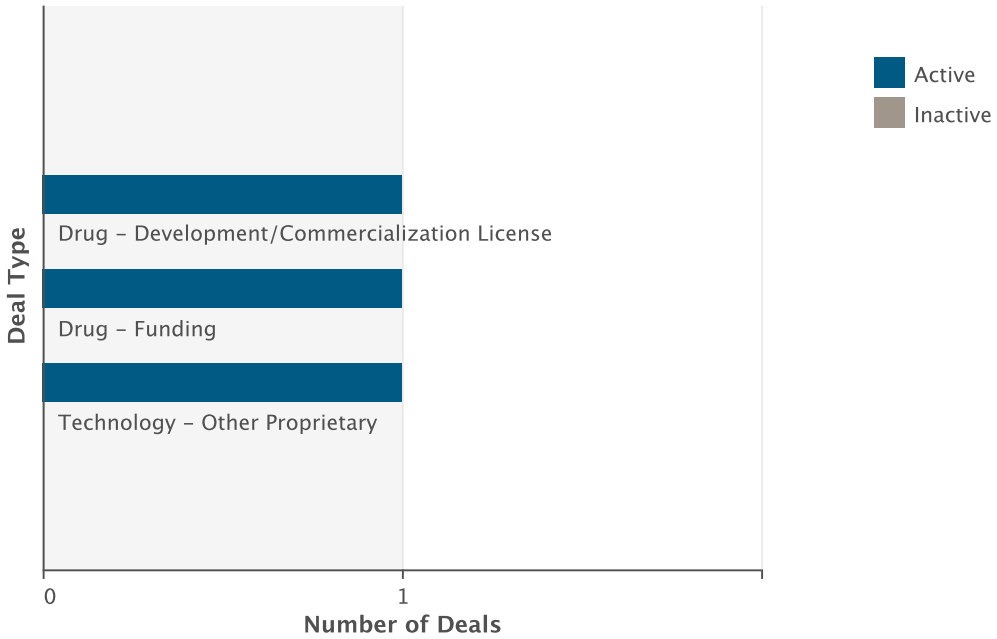
Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	1	0	1
Technology - Other Proprietary	1	0	1
Drug - Funding	1	0	1

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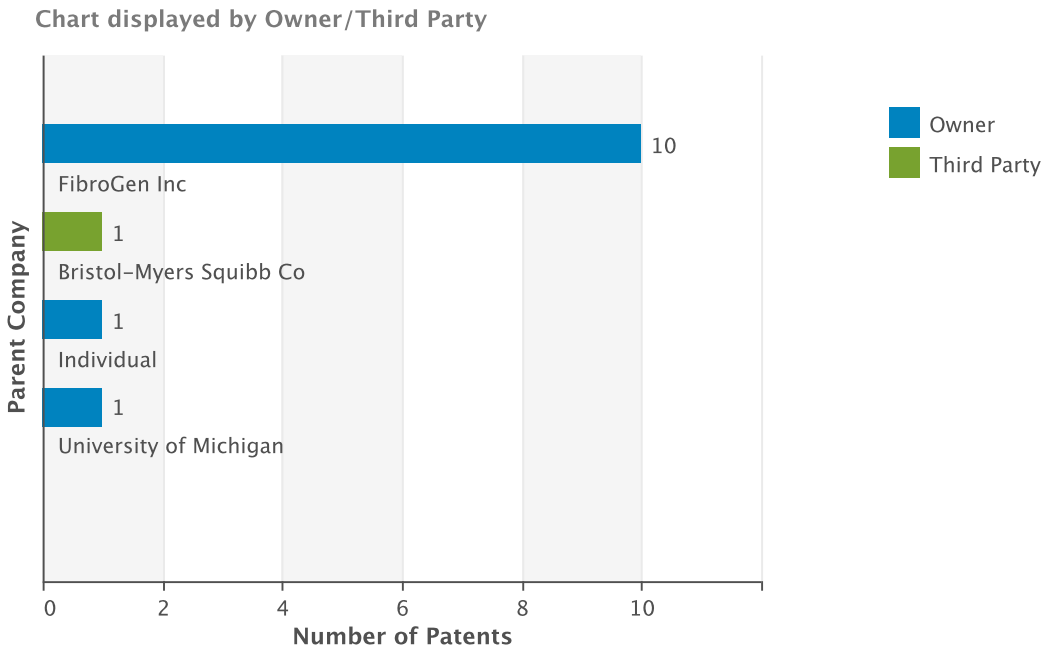
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
FibroGen Inc	10	0	10
University of Michigan	1	0	1
Individual	1	0	1
Bristol-Myers Squibb Co	0	1	1

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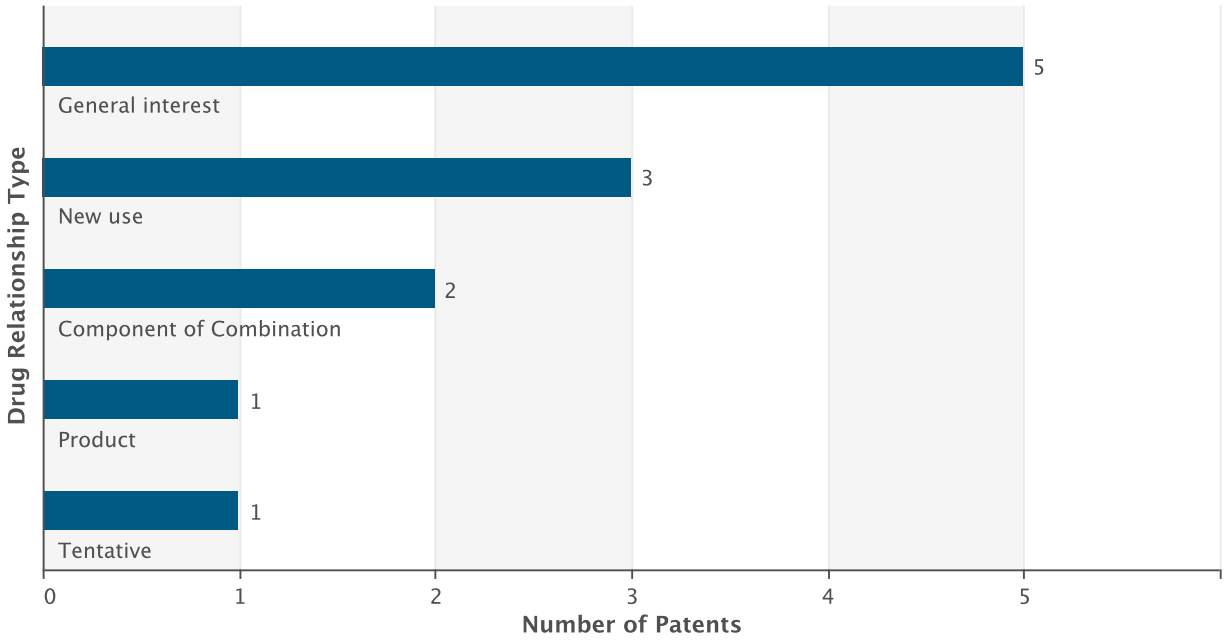
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
General interest	5
New use	3
Component of Combination	2
Product	1
Tentative	1

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FG-2216

FG-2216 SNAPSHOT

Drug Name	FG-2216
Key Synonyms	
Originator Company	FibroGen Inc
Active Companies	Astellas Pharma Inc;FibroGen Inc
Inactive Companies	Yamanouchi Pharmaceutical Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Erythropoietin release stimulator;Hematopoietic stimulant
Technologies	Oral formulation;Small molecule therapeutic
Last Change Date	03-Feb-2015

FG-2216 DEVELOPMENT PROFILE

SUMMARY

FibroGen, in collaboration with Astellas Pharma is developing FG-2216 (YM-311), an oral erythropoiesis release stimulator and inhibitor of hypoxia-inducible factor-prolyl hydroxylase (HIF-PH), for the potential treatment of anemia, including sickle cell anemia, renal anemia and chemotherapy-induced anemia,,. By July 2006, the drug was reported to be in phase II studies. In May 2007, it was reported that all development of the drug was suspended by Astellas following a death in a clinical trial ; in March 2008, the FDA informed the companies that clinical trials could be resumed. Astellas was to implement a hepatic monitoring plan in future trials, and carry out supplemental DDI studies. Astellas also planned to implement trials to study the drug in ESA responders. In May 2009, Astellas listed the drug as being in phase II trials in Europe and phase I trials in Japan ; in February 2015, this was still the case. In May 2010, Astellas expected US approval after fiscal 2014.

FibroGen and Astellas are also investigating FG-4592, a HIF-PH inhibitor, for anemia. FibroGen is also investigating other HIF-PH inhibitors for myocardial infarction, stroke, acute kidney injury and multiple sclerosis.

FG-2216 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Astellas Pharma Inc	Anemia	Europe	Phase 2 Clinical	03-Jul-2006
FibroGen Inc	Anemia	Europe	Phase 2 Clinical	06-Dec-2004

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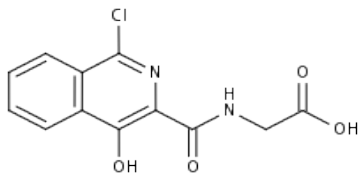
Company	Indication	Country	Development Status	Date
FibroGen Inc	Anemia	US	Phase 2 Clinical	31-Dec-2005
Astellas Pharma Inc	Anemia	Japan	Phase 1 Clinical	28-Apr-2006
FibroGen Inc	Anemia	Western Europe	Phase 1 Clinical	24-Sep-2004

FG-2216 CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
	4



Name	Type
FG-2216	Research Code
YM-311	Research Code

FG-2216 DRUG NAMES

Names	Type
EPO release stimulator (anemia), Fibrogen/Astellas	
FG-2216	Research Code
YM-311	Research Code

FG-2216 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
Anemia											
0	0	0	0	0	3	0	1	0	0	0	4

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Renal disease											
0	0	0	0	0	1	0	0	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	3	0	1	0	0	0	4

Phase Definitions

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

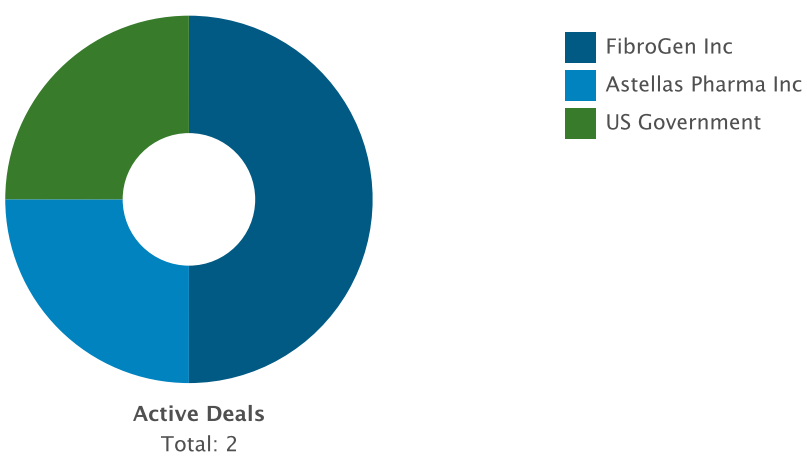
Phase 2 Clinical
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

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

FG-2216 DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



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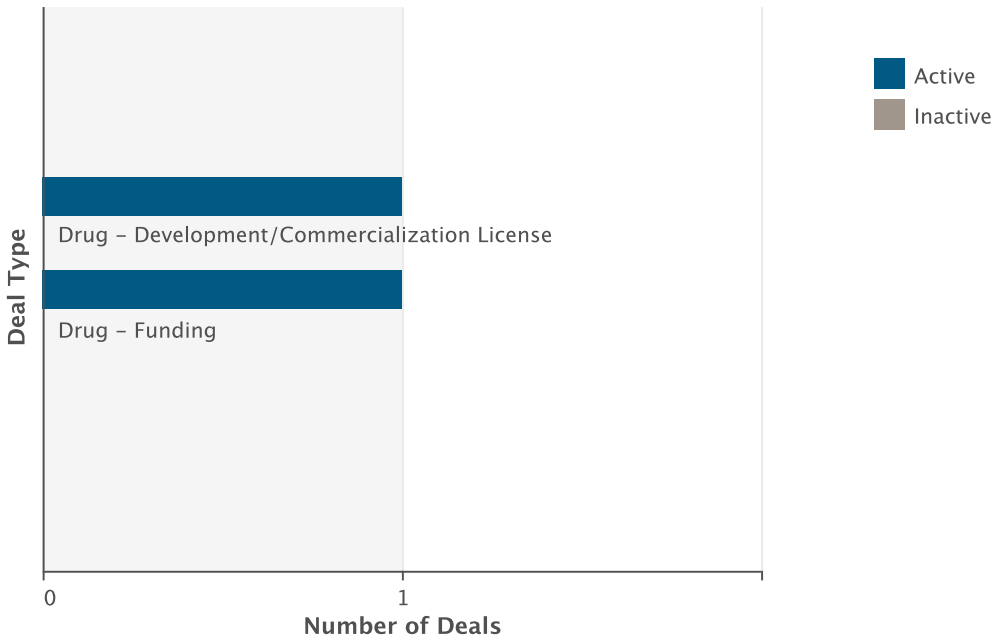
Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
FibroGen Inc	2	0	0	0	2
US Government	0	0	1	0	1
Astellas Pharma Inc	0	0	1	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	1	0	1
Drug - Funding	1	0	1

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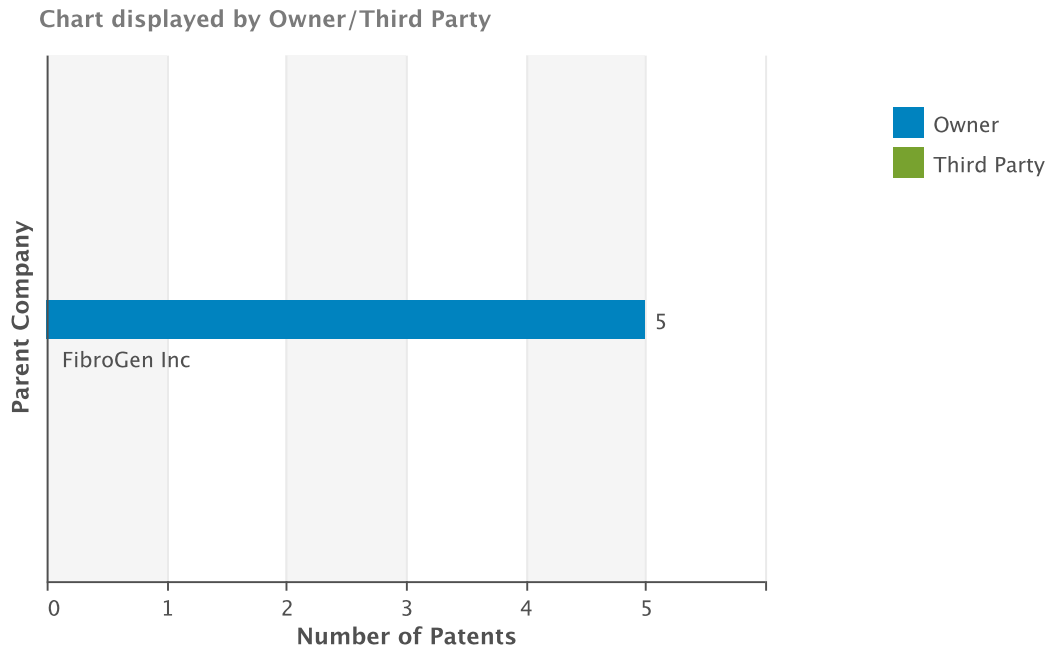
PATENTS

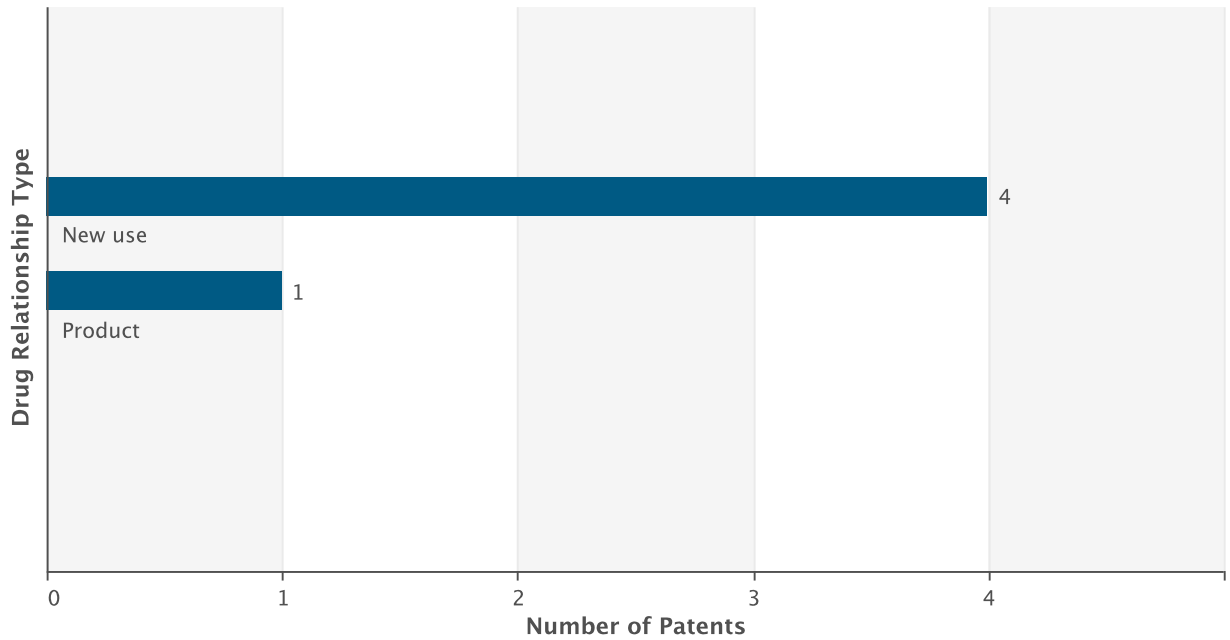
Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
FibroGen Inc	5	0	5

Patents by Drug Relationship Type Chart



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Patents by Drug Relationship Type Table

Drug Relationship	Total
New use	4
Product	1

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next generation HIF-PH inhibitors (anemia), FibroGen

next generation HIF-PH inhibitors (anemia), FibroGen SNAPSHOT

Drug Name	next generation HIF-PH inhibitors (anemia), FibroGen
Key Synonyms	
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Blood system agent
Technologies	Small molecule therapeutic
Last Change Date	25-Sep-2014

next generation HIF-PH inhibitors (anemia), FibroGen DEVELOPMENT PROFILE

SUMMARY

FibroGen is investigating next generation hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitors that stimulate HIF-dependent erythropoietin secretion for the potential treatment of anemia. In December 2011, the program was in research. At that time, the company planned to initiate clinical development in the "near future". In September 2014, development was presumed to be ongoing.

next generation HIF-PH inhibitors (anemia), FibroGen DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
FibroGen Inc	Anemia	US	Discovery	23-Dec-2011

next generation HIF-PH inhibitors (anemia), FibroGen DRUG NAMES

Names	Type
next generation HIF-PH inhibitors (anemia), FibroGen	

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