

# 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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### **THOMSON REUTERS**

3 Times Square New York, New York 10036 United States

Tel: +1 646 223 4000

thomsonreuters.com



# ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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#### **GLOSSARY**

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

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

### **Number of Inactive Drugs**

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

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

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

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

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

#### Patents summary table

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

#### **Number of Deals**

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

#### **Key Indications**

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

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

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

#### **Key Technologies**

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



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# FibroGen Inc

### **COMPANY OVERVIEW**

Company Name	FibroGen Inc
<b>Parent Company Name</b>	FibroGen Inc
Website	http://www.fibrogen.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	9
Number of Patents as Owner	71
Number of Patents as Third Party	2
Number of Deals	12
Key Indications	Anemia,Focal segmental glomerulosclerosis,Diabetic nephropathy,Glioma,Idiopathic pulmonary fibrosis,Pancreas tumor,Glaucoma,Liver fibrosis,Ischemia,Hypoxia
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,Albumin modulator,Angiotensin receptor antagonist,CD66e antagonist,CTGF gene inhibitor,Calcineurin inhibitor,Collagen III agonist,Desmin inhibitor,Dopamine receptor agonist,Erythropoietin receptor agonist,HIF prolyl hydroxylase-1 inhibitor,Hydroxylase inhibitor,Hydroxylase modulator,IL-6 agonist,LDL receptor antagonist,Prolyl hydroxylase inhibitor,TGF beta agonist
Key Technologies	Small molecule therapeutic,Biological therapeutic,Oral formulation,Peptide,Protein recombinant,Capsule formulation,Tablet formulation,Infusion,Intravenous formulation,Monoclonal antibody human

### **COMPANY PROFILE**

#### SUMMARY

FibroGen Inc, 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 subsidary of Fibrogen based in Helsinki, Finland, is a biotechnology focused enterprise that specialises in the development of recombinant collagens and gelatins.

### 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 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.

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.

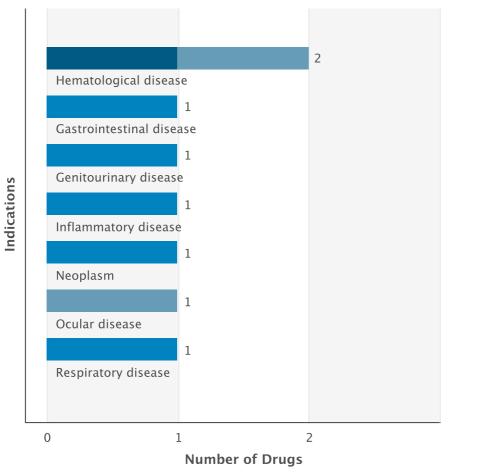
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# PRODUCT PORTFOLIO SUMMARY

### **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart



Phase 2 Clinical
Discovery

Phase 3 Clinical

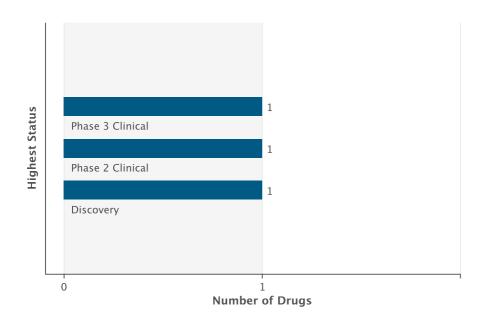


# Drugs by Indication Table

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

# **Drugs by Highest Status**

Active Drugs by Highest Status Chart





# Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Phase 2 Clinical	1
Discovery	1
No Development Reported	9

### **DEALS**

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

### **CLINICAL TRIALS**

# Trials by Condition Studied

Condition Studied	Ongoing	All
Hematological disease	9	23
Genitourinary disease	0	7
Gastrointestinal disease	2	5
Inflammatory disease	2	5
Metabolic disorder	0	3
Endocrine disease	0	3
Respiratory disease	2	3
Neoplasm	1	2
Dermatological disease	0	1
Genetic disorder	0	1
Neurological disease	0	1
Cardiovascular disease	0	1



### Trials by Phase

Phase	Ongoing	All
Phase 3	8	9
Phase 2	5	17
Phase 1	0	12
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
Cardiovascular disease	34	1	35
Endocrine disease	13	0	13
Gastrointestinal disease	23	0	23
Genitourinary disease	25	1	26
Growth disorder	3	0	3
Hematological disease	24	0	24
Degeneration	1	0	1
Immune disorder	10	0	10
Psychiatric disorder	1	0	1
Musculoskeletal disease	17	2	19
Neoplasm	14	1	15
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	23	0	23
Infectious disease	7	0	7
Injury	6	0	6
Inflammatory disease	30	3	33
Gynecology and obstetrics	3	0	3
Dermatological disease	5	0	5
Ulcer	2	0	2
Surgical procedure	0	1	1

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



### PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

#### roxadustat

#### roxadustat SNAPSHOT

Drug Name	roxadustat
Key Synonyms	roxadustat;ciclopirox
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	Oral formulation;Capsule formulation;Tablet formulation;Small molecule therapeutic
Last Change Date	24-Nov-2014

#### roxadustat DEVELOPMENT PROFILE

### **SUMMARY**

FibroGen, Astellas Pharma and AstraZeneca are developing roxadustat (FG-4592, AZD-9941, ASP-1517), 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 June 2014, filings for anemia in CKD/ESRD were expected in 2018 in the US. In February 2013, phase II trials were underway in Japan in CKD patients on dialysisand in July 2013, a phase II trial in Japan in non-dialysis patients was planned for late 2013; by July 2014, the trial had been initiated .



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**

CORRENT DEVELOP				
Company	Indication	Country	<b>Development Status</b>	Date
Astellas Pharma Inc	Anemia	Europe	Phase 3 Clinical	31-May-2013
Astellas Pharma Inc	Anemia	Hungary	Phase 3 Clinical	20-Nov-2014
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	Hungary	Phase 3 Clinical	20-Nov-2014
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



Company	Indication	Country	Development Status	Date
Astellas Pharma Inc	Anemia	Japan	Phase 2 Clinical	01-Feb-2013
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:
808118-40-3	2
	OH OH OH
Name	Туре
roxadustat	INN; USAN
ASP-1517	Research Code
FG-4592	Research Code



CAS Registry Number:	Confidence Level:
29342-05-0	1
O N OH	
T .	
Name	Туре
ciclopirox	BANN; INN; USAN
FG-2229	Research Code

CAS Registry Number:	Confidence Level:
312637-46-0	3
N HN	ОН
Name	Туре
FG-0041	Research Code
FG-041	Research Code

CAS Registry Number:	Confidence Level:
	3
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	2 -
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Name	Туре
FG-1577	Research Code

CAS Registry Number:	Confidence Level:
	N OH
Name	Туре
FG-1649	Research Code

CAS Registry Number:	Confidence Level:
	3
	Н
Name	Туре
FG-2179	Research Code

CAS Registry Number:	Confidence Level:
	3
	✓ N



Name	Туре
FG-2909	Research Code

CAS Registry Number:	Confidence Level:
HO HO	ОН
Name	Type
FG-2910	Research Code

CAS Registry Number:	Confidence Level:
	3
	- H _ O _ O
Name	Туре
FG-2933	Research Code

CAS Registry Number:	Confidence Level:
331830-28-5	3
HO	



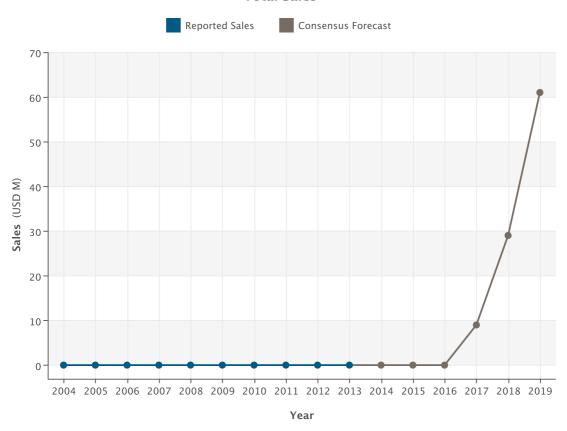
### roxadustat DRUG NAMES

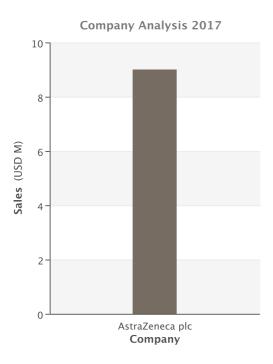
Names	Туре
FG-1649	Research Code
FG-2179	Research Code
FG-2934	Research Code
P4H inhibitors, Fibrogen	
FG-1577	Research Code
prolyl hydroxylase inhibitors, FibroGen/AstraZeneca	
FG-0041	Research Code
roxadustat	USAN, INN
HIF-PH inhibitors (1), FibroGen	
ciclopirox	USAN, BANN, INN
FG-2229	Research Code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

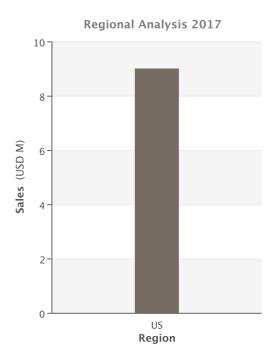


### **CHARTS**











#### **COMMENTARY**

#### **CONSENSUS SALES INFORMATION**

Consensus forecast data for AstraZeneca are presented. No Consensus forecast data for FibroGen and 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 major markets excluding Europe, Japan, the Commonwealth of Independent States, South Africa and the Middle East [1458823].

#### roxadustat CLINICAL TRIALS

#### Trials by Phase and Condition Studied

	pase 4 Phase 3 Phase 2 inical Clinical 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	9	2	10	0	4	0	0	10	23
Stroke											
0	0	0	0	0	0	0	2	0	0	0	2
Sickle ce	II anemia										
0	0	0	0	0	0	0	2	0	0	0	2
Scar tissu	ıe										
0	0	0	0	0	0	0	2	0	0	0	2
Fibrosis											
0	0	0	0	0	0	0	2	0	0	0	2
Renal dis	ease										
0	0	0	0	0	2	0	0	0	0	0	2



### Total Trials by Phase and Status

	se 4 lical		se 3 nical				Phase 1 Clinical		Phase Unspecified		tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Total by	Phase an	d Status									
0	0	8	9	2	11	0	8	0	2	10	30

#### **Phase Definitions**

#### Phase 3 Clinical

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

#### Phase 2 Clinical

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

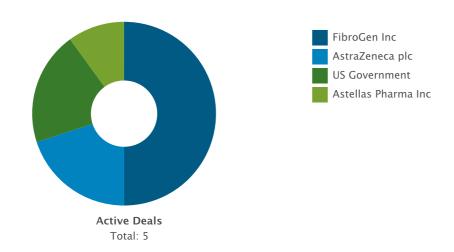
#### Phase 1 Clinical

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

#### roxadustat DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

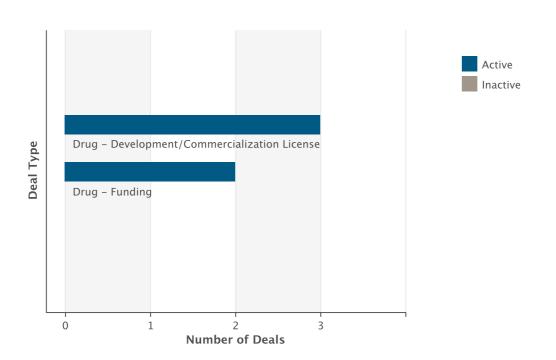




# **Deals by Parent Company Table**

Company Name	Principal Active Inactive		· · · · · · · · · · · · · · · · · · ·		Total
FibroGen Inc	4	0	1	0	5
US Government	0	0	2	0	2
AstraZeneca plc	1	0	1	0	2
Astellas Pharma Inc	0	0	1	0	1

# **Deals by Type Chart**



### **Deals by Type Table**

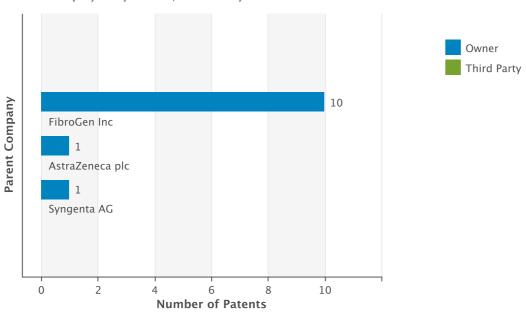
Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	3	0	3
Drug - Funding	2	0	2



### **PATENTS**

# **Patents by Parent Company Chart**

Chart displayed by Owner/Third Party

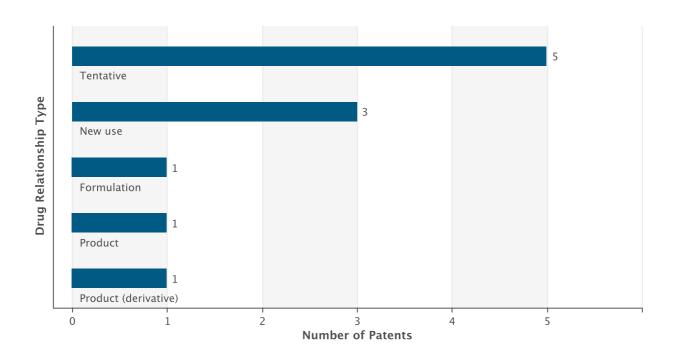


# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
FibroGen Inc	10	0	10
Syngenta AG	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	5
New use	3
Product (derivative)	1
Product	1
Formulation	1



### FG-3019

#### **FG-3019 SNAPSHOT**

Drug Name	FG-3019
Key Synonyms	
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc
Inactive Companies	Taisho Pharmaceutical Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	Diabetic nephropathy;Liver fibrosis;Pancreas tumor;Glaucoma;Glioma;Focal segmental glomerulosclerosis;Idiopathic pulmonary fibrosis
Target-based Actions	Connective tissue growth factor ligand inhibitor
Other Actions	Anticancer monoclonal antibody; Fibrosuppressant; Angiogenesis inhibitor
Technologies	Monoclonal antibody human;Intravenous formulation;Infusion;Biological therapeutic;Protein recombinant
Last Change Date	10-Oct-2014

#### **FG-3019 DEVELOPMENT PROFILE**

#### **SUMMARY**

FibroGen is developing FG-3019, 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 liver fibrosis, idiopathic pulmonary fibrosis (IPF), pancreatic cancer, focal segmental glomerulosclerosis (FSGS) and diabetic nephropathy (DN),.. The drug is also being investigated for orthotopic glioma and glaucoma. 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 May 2012, preliminary data were reported; in November 2013, interim analysis data were reported. In September 2014, one year data from a phase II trial in patients with IPF were presented. At that time, the company planned to expand another phase II trial outside the US. 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. In January 2011, positive data from the phase I/II study for pancreatic cancer were presented. 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 November 2011, the company was seeking to outlicense the drug.

Fibrogen had been collaborating with Taisho 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 by August 2005 this strategic alliance was not listed on FibroGen's website.

FibroGen also investigated CTGF as an inductive agent for tissue repair (CTGF, FibroGen); however, by August 2005, no further development had been reported.



### **FG-3019 DEVELOPMENT STATUS**

### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	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	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	Туре
anti-CTGF, FibroGen/Taisho	
FG-3019	Research Code
anti-CCN2, FibroGen/Taisho	
anti-connective tissue growth factor, FibroGen/Taisho	

### **FG-3019 CLINICAL TRIALS**

# Trials by Phase and Condition Studied

Phase 4 Clinical			Phase 3 Pha Clinical Clin						ase ecified	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	1	1	0	0	0	0	1	1	
Focal seg	gmental gl	omerulosc	elerosis									
0	0	0	0	0	0	0	1	0	0	0	1	
Microalbu	uminuria											
0	0	0	0	0	0	0	1	0	0	0	1	
Non-insu	lin depend	lent diabet	es									
0	0	0	0	0	0	0	1	0	0	0	1	
Metastati	c pancrea	s cancer										
0	0	0	0	0	0	0	1	0	0	0	1	
Pulmona	ry fibrosis											
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	

# Total Trials by Phase and Status

Phase 4 Phase 3 Clinical 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	4	5	0	6	0	0	4	11

### **Phase Definitions**

Phase 3 Clinical

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

Phase 2 Clinical



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

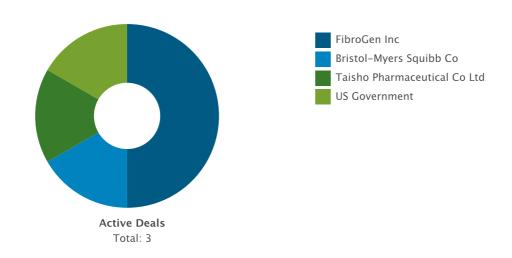
### Phase 1 Clinical

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

#### **FG-3019 DEALS AND PATENTS**

**DEALS** 

### **Deals by Parent Company Chart**

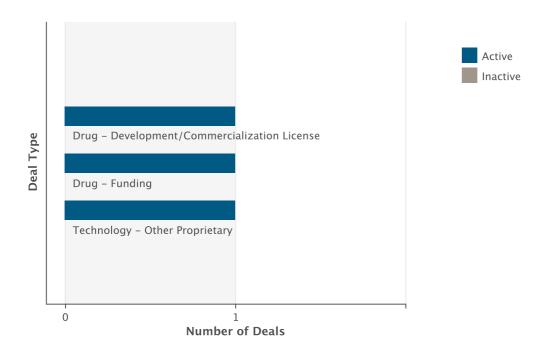


# **Deals by Parent Company Table**

Company Name	Prin Active	cipal Inactive	Par Active	tner Inactive	Total
FibroGen Inc	2	0	1	0	3
US Government	0	0	1	0	1
Taisho Pharmaceutical Co Ltd	0	0	1	0	1
Bristol-Myers Squibb Co	1	0	0	0	1



# **Deals by Type Chart**



### **Deals by Type Table**

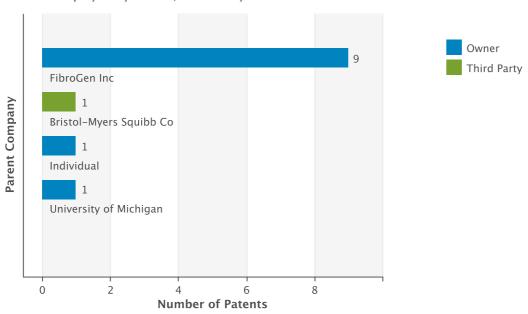
Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	1	0	1
Technology - Other Proprietary	1	0	1
Drug - Funding	1	0	1



### **PATENTS**

## **Patents by Parent Company Chart**

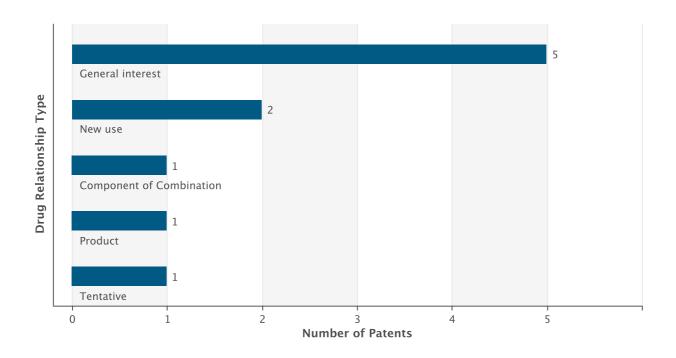
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
FibroGen Inc	9	0	9
University of Michigan	1	0	1
Individual	1	0	1
Bristol-Myers Squibb Co	0	1	1

# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

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



# 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	<b>Development Status</b>	Date
FibroGen Inc	Anemia	US	Discovery	23-Dec-2011

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

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



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