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CORTELLIS™

# 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

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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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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** | 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,IL-6 agonist,LDL receptor antagonist,Prolyl |
| **Key Technologies** | Small molecule therapeutic,Biological therapeutic,Oral formulation,Peptide,Protein recombinant,Capsule formulation,Infusion,Intravenous formulation,Monoclonal antibody |

## 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.

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## 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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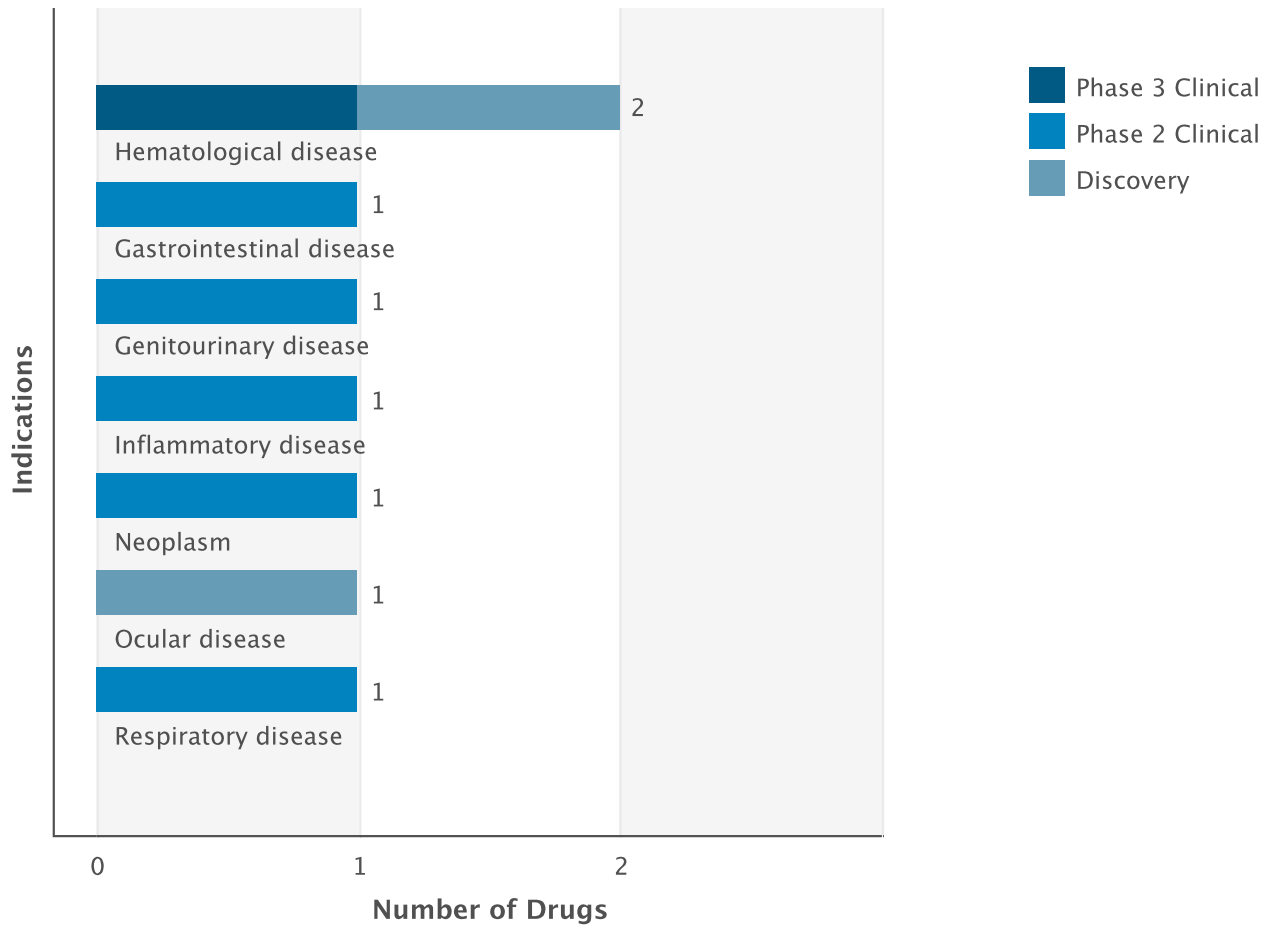
# PRODUCT PORTFOLIO SUMMARY

## DRUGS

### Drugs by Indication

Active Drugs by Indication Chart

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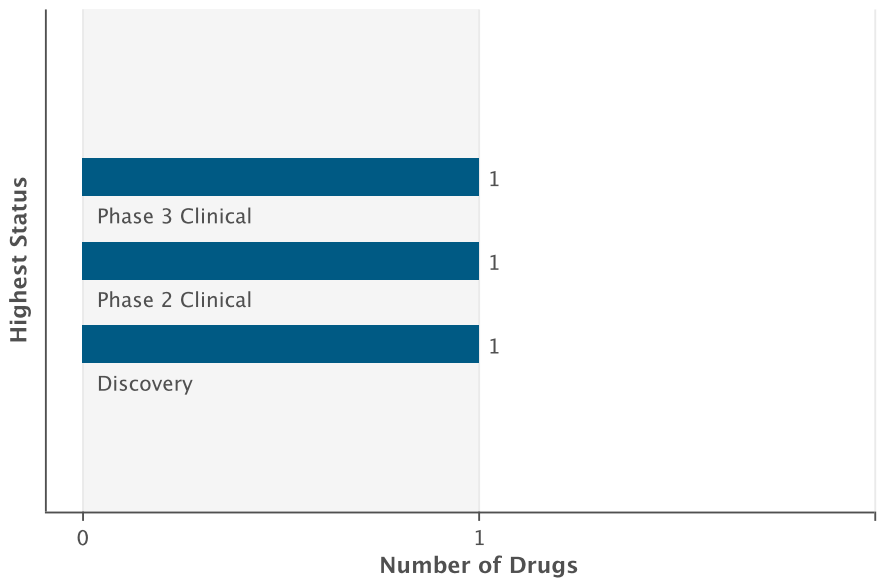
Drugs by Indication Table

| 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

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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 | 8 | 22 |
| 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 |

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Trials by Phase

| Phase | Ongoing | All |
|---|---|---|
| Phase 3 | 7 | 8 |
| 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 | 23 | 0 | 23 |
| 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 |

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| | | | |
|---|---|---|---|
| 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 |

* 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** | 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** | 18-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 .

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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 | 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 |
| AstraZeneca plc | Anemia | China | Phase 2 Clinical | 31-Jul-2013 |

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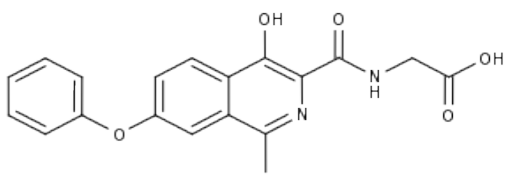
| Company | Indication | Country | Development Status | Date |
|---|---|---|---|---|
| AstraZeneca plc | Anemia | Hong Kong | Phase 2 Clinical | 31-Jul-2013 |
| FibroGen Inc | Anemia | China | Phase 2 Clinical | 15-Nov-2011 |
| FibroGen Inc | Anemia | Hong Kong | Phase 2 Clinical | 31-Oct-2010 |
| AstraZeneca 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 |




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

| CAS Registry Number: | Confidence Level: |
|---|---|
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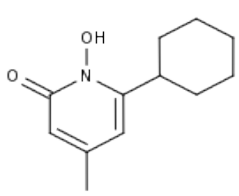


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| Name | Type |
|---|---|
| ciclopirox | BANN; INN; USAN |
| FG-2229 | Research Code |

| CAS Registry Number: | Confidence Level: |
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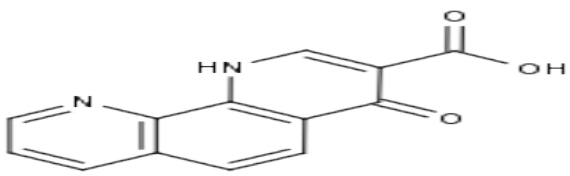
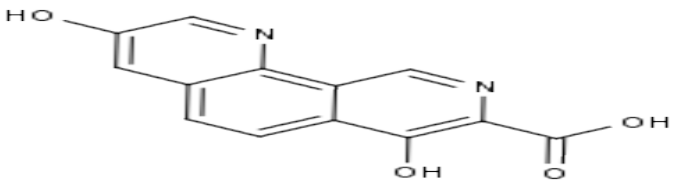
| 312637-46-0 | 3 |




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

| CAS Registry Number: | Confidence Level: |
|---|---|
| | 3 |




| Name | Type |
|---|---|
| FG-1577 | Research Code |

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| CAS Registry Number: | Confidence Level: |
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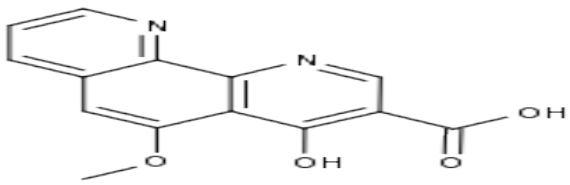

| Name | Type |
|---|---|
| FG-1649 | Research Code |

| CAS Registry Number: | Confidence Level: |
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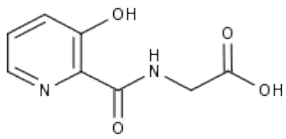
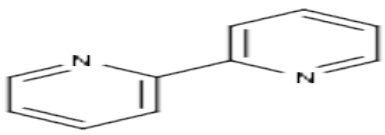


| Name | Type |
|---|---|
| FG-2179 | Research Code |

| CAS Registry Number: | Confidence Level: |
|---|---|
| | 3 |



| Name | Type |
|---|---|
| FG-2909 | Research Code |

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| CAS Registry Number: | Confidence Level: |
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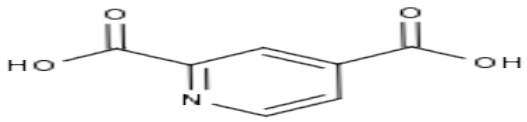
| | 3 |



| Name | Type |
|---|---|
| FG-2910 | Research Code |

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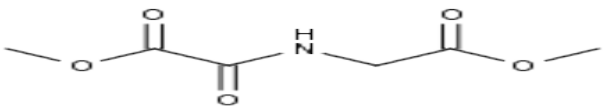

| Name | Type |
|---|---|
| FG-2933 | Research Code |

| CAS Registry Number: | Confidence Level: |
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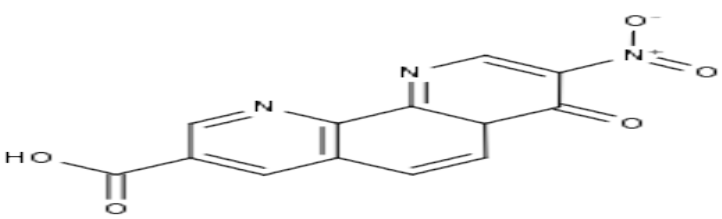

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## roxadustat DRUG NAMES

| Names | Type |
|---|---|
| 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 |

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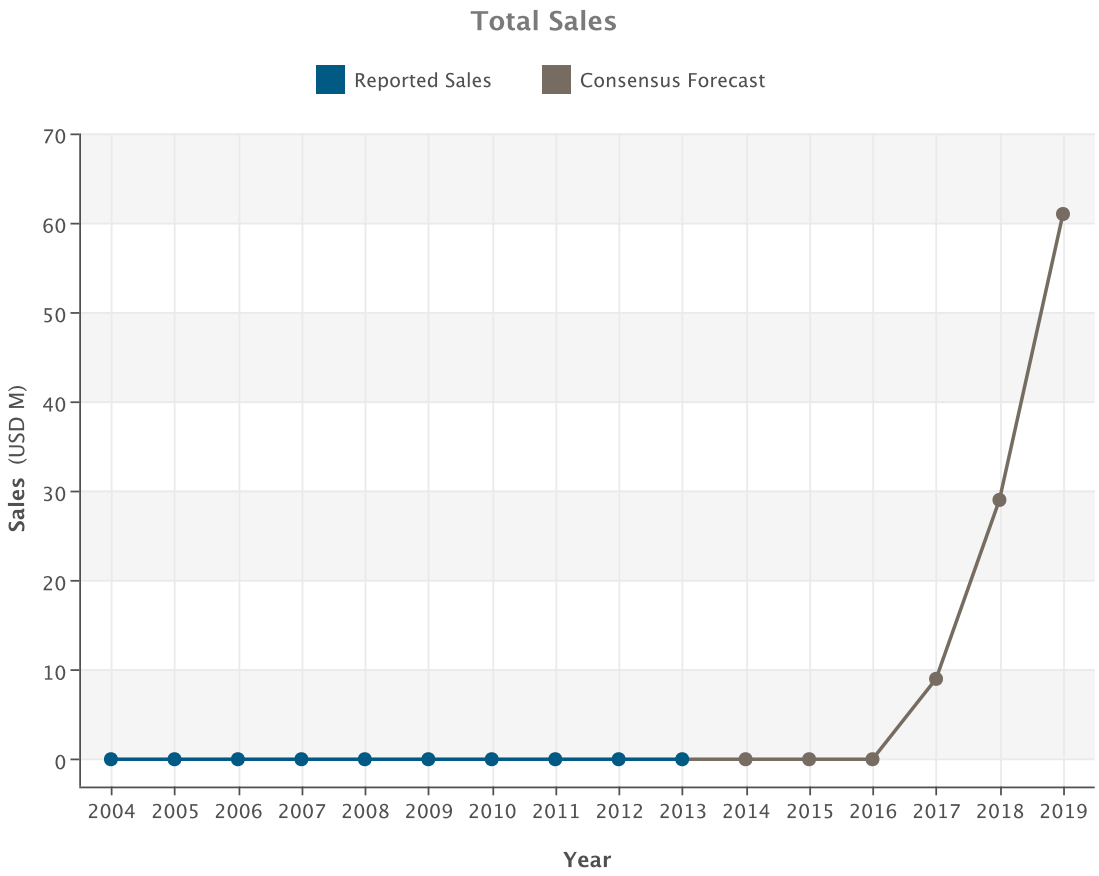
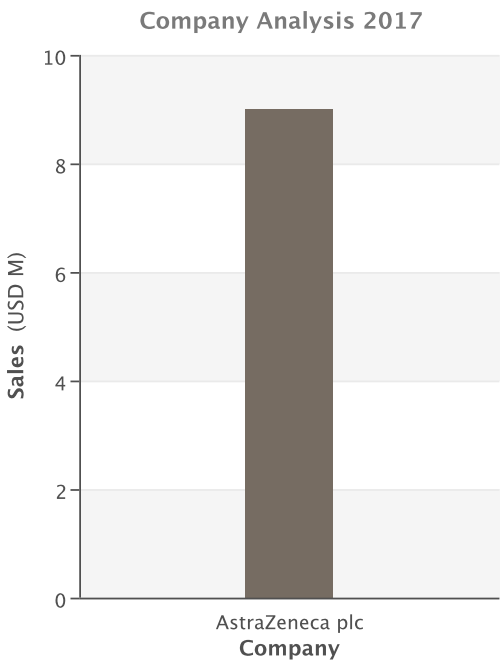
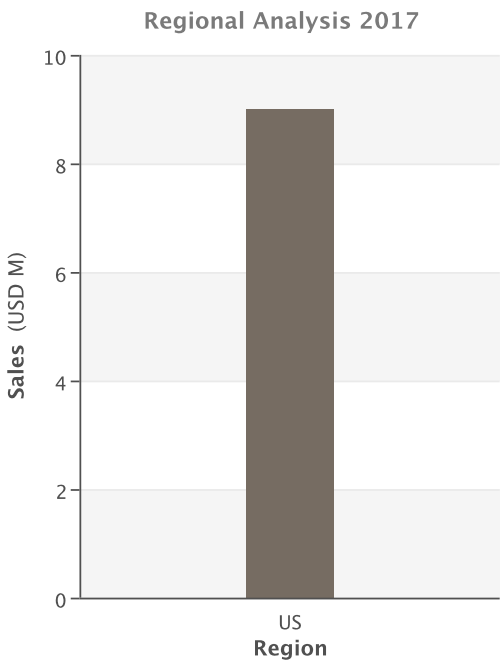
## CHARTS

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## 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

| 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 | 9 | 2 | 10 | 0 | 4 | 0 | 0 | 10 | 23 |
| Stroke | | | | | | | | | | | |
| 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 |
| Scar tissue | | | | | | | | | | | |
| 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 disease | | | | | | | | | | | |
| 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 2 |

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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 | 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 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: 5

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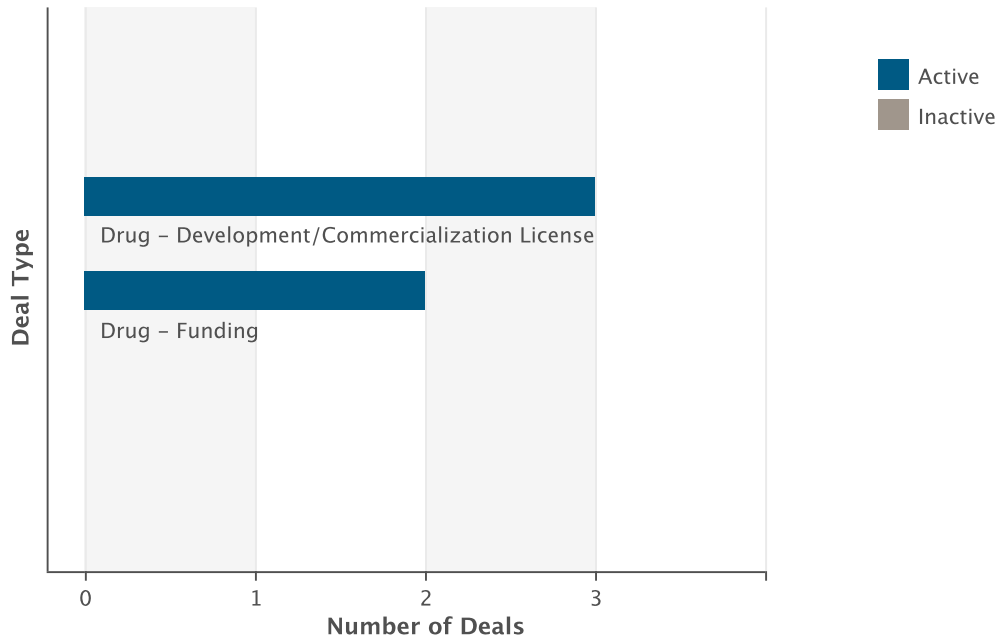
## Deals by Parent Company Table

| Company Name | Principal | | Partner | | Total |
|---|---|---|---|---|---|
| | Active | Inactive | Active | Inactive | |
| 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 |

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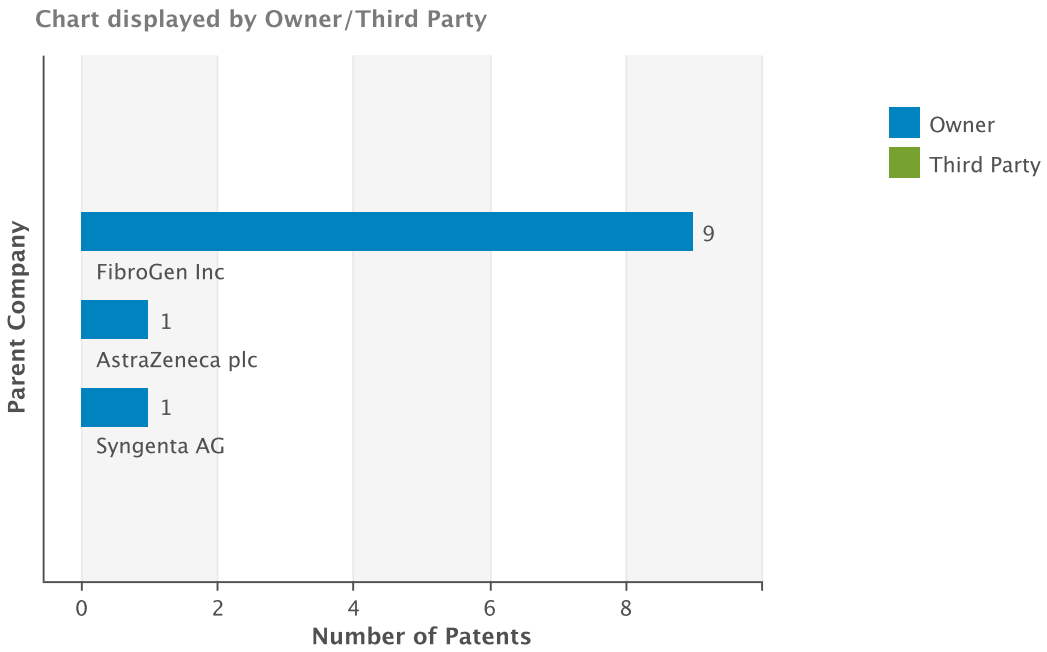
## PATENTS

### Patents by Parent Company Chart




### Patents by Parent Company Table

| Company Name | As Owner | As Third Party | Total |
|---|---|---|---|
| FibroGen Inc | 9 | 0 | 9 |
| Syngenta AG | 1 | 0 | 1 |
| AstraZeneca plc | 1 | 0 | 1 |

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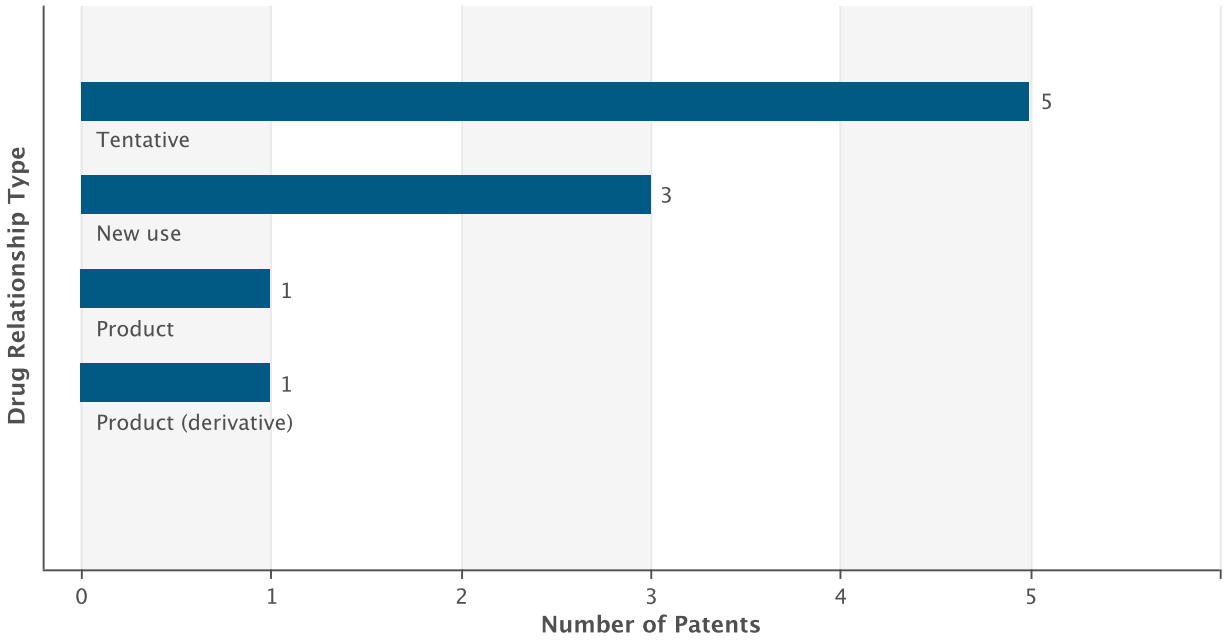
## Patents by Drug Relationship Type Chart




## Patents by Drug Relationship Type Table

| Drug Relationship | Total |
|---|---|
| Tentative | 5 |
| New use | 3 |
| Product (derivative) | 1 |
| Product | 1 |

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# 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.

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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 | 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 |
|---|---|
| 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 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 |

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| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 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 |
| Non-insulin dependent diabetes | | | | | | | | | | | |
| 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 |
| Pulmonary 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 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 | 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**

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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)

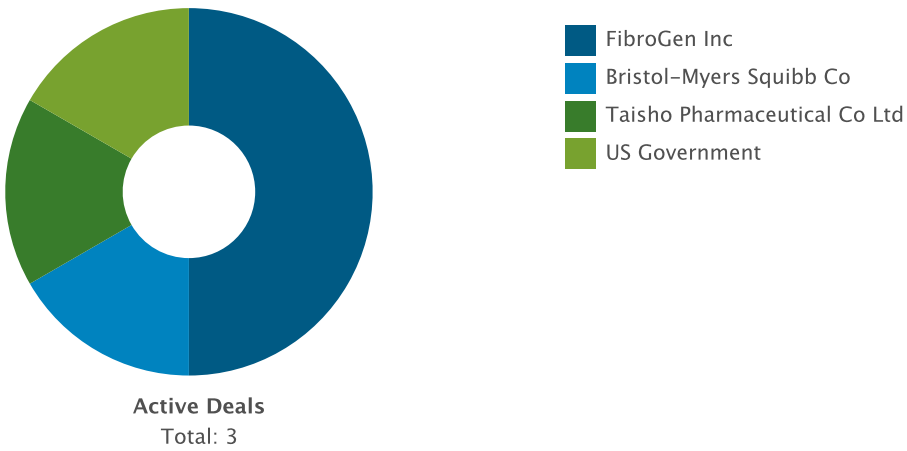
**Phase 1 Clinical**

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




### 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 |
| Taisho Pharmaceutical Co Ltd | 0 | 0 | 1 | 0 | 1 |
| Bristol-Myers Squibb Co | 1 | 0 | 0 | 0 | 1 |

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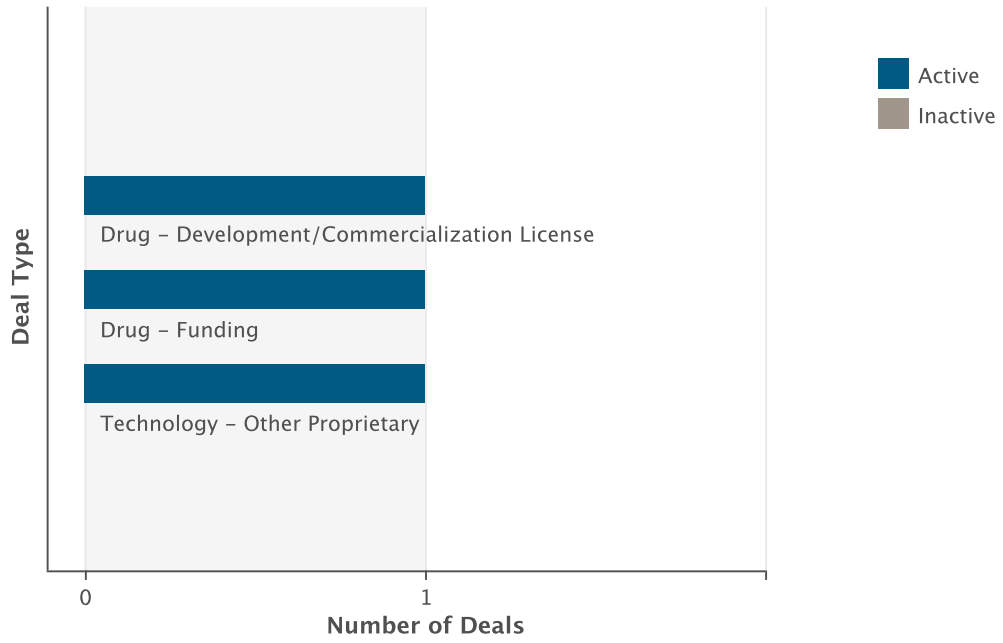
## Deals by Type Chart




## 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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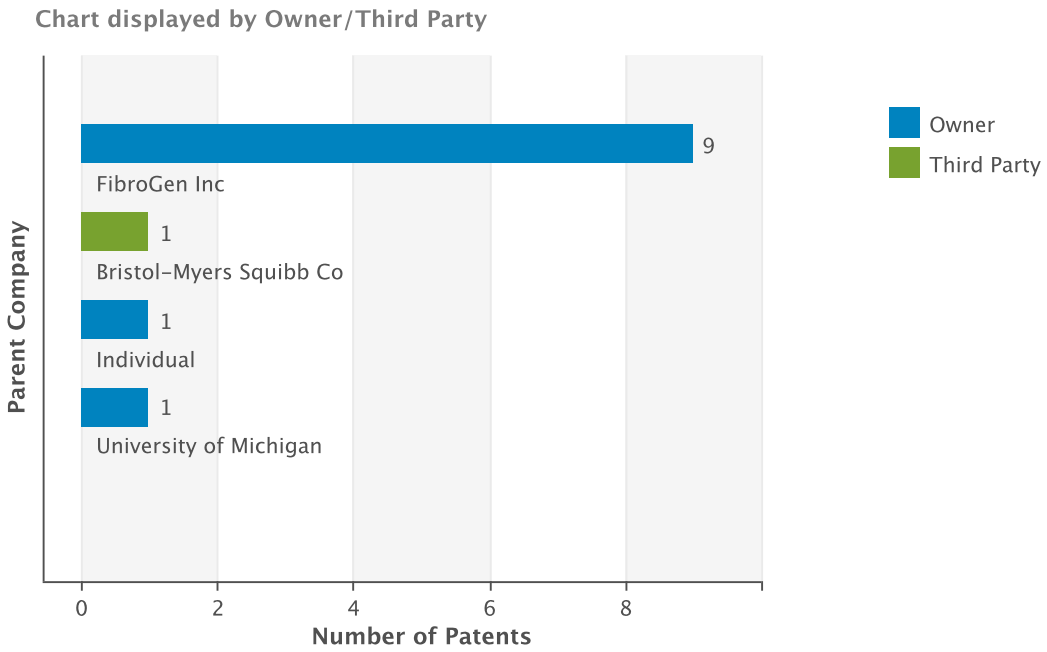
## PATENTS

### Patents by Parent Company Chart




### Patents by Parent Company Table

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

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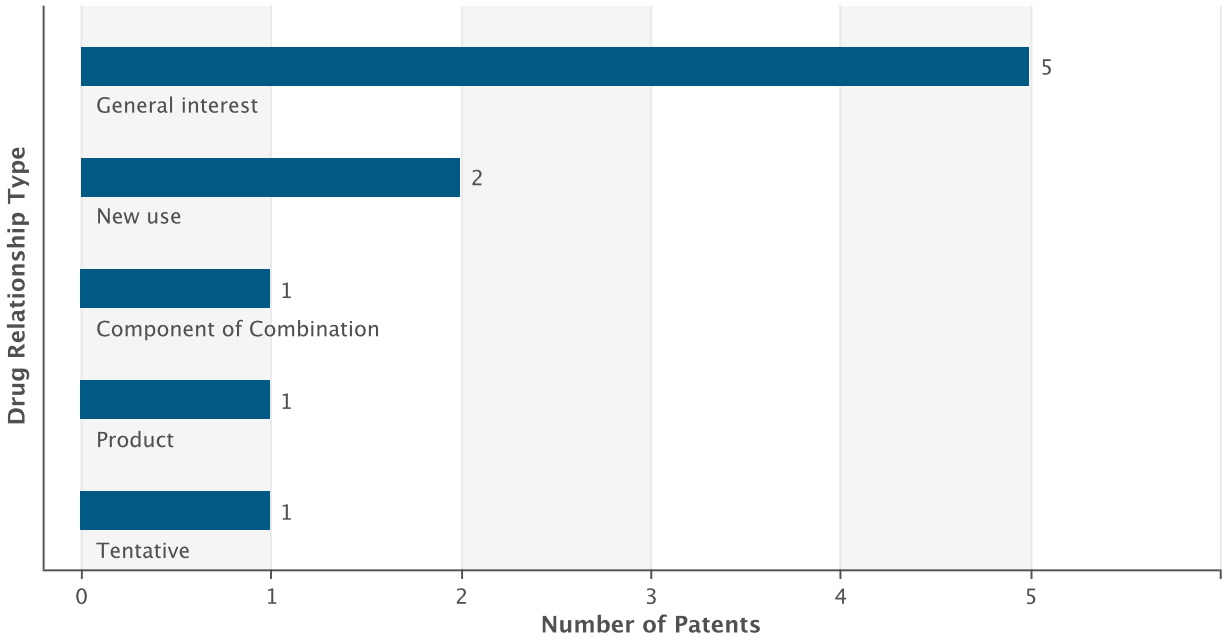
## Patents by Drug Relationship Type Chart




## Patents by Drug Relationship Type Table

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