

# **Alder Biopharmaceuticals Inc**

## **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

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

Publication Date: 02-May-2015

### **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

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

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

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

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

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

### **DISCLAIMER**

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

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



### **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.

THOMSON REUTERS

# **TABLE OF CONTENTS**

| Company Overview                       | 5  |
|--|----|
| Company Profile                        | 6  |
| Product Portfolio Summary              | 7  |
| Product Portfolio Drug Pipeline Detail | 12 |
| Phase 2 Clinical                       | 13 |
| Discovery                              | 27 |



# Alder Biopharmaceuticals Inc

### **COMPANY OVERVIEW**

| Company Name                             | Alder Biopharmaceuticals Inc   |
|--|--|
| Parent Company Name                      | Alder Biopharmaceuticals Inc   |
| Website                                  | http://www.alderbio.com/   |
| Country                                  | US   |
| Number of Drugs in Active<br>Development | 4  |
| Number of Inactive Drugs                 | 6  |
| Number of Patents as Owner               | 20   |
| Number of Patents as Third Party         | 0  |
| Number of Deals                          | 3  |
| Key Indications                          | Cachexia,Rheumatoid arthritis,Anemia,Fatigue,Graft versus host disease,Migraine,Pain,Psoriatic arthritis,Crohns disease,Cushings disease,Oral mucositis  |
| Key Target-based Actions                 | Hepatocyte growth factor antagonist,NGF receptor antagonist,IL-6 antagonist,CGRP receptor antagonist,Proprotein convertase PC9 inhibitor,ACTH receptor antagonist,Interleukin-6 ligand inhibitor,Albumin agonist,C-reactive protein inhibitor,Albumin modulator,C-reactive protein modulator,CD126 antagonist,CGRP receptor agonist,Cytokine receptor agonist,Hepatocyte growth factor agonist,Interferon antagonist,Jak1 tyrosine kinase inhibitor,Jak2 tyrosine kinase inhibitor,Jak3 tyrosine kinase inhibitor,LDL receptor agonist,MAP kinase inhibitor,NGF receptor agonist,Proprotein convertase PC9 stimulator,STAT-3 inhibitor,Syk tyrosine kinase inhibitor,TNF alpha ligand,Triosephosphate dehydrogenase modulator,p38 MAP kinase |
| Key Technologies                         | Biological therapeutic, Parenteral formulation unspecified, Monoclonal antibody humanized, Monoclonal antibody, Protein recombinant, Intravenous formulation, Subcutaneous formulation, Infusion, Antibody fragment, Antibody  |

### **COMPANY PROFILE**

## SUMMARY

Alder Biopharmaceuticals Inc, founded in January 2004, is focused on the identification, development and manufacture of antibody therapeutics for cancer, inflammatory, autoimmune and cardivascular diseases.

#### LICENSING AGREEMENTS

In December 2005, Alder agreed to identify and manufacture Schering-Plough's antibody therapeutics. Using its yeast production system and high throughput antibody selection technology, Alder would work on up to ten Schering-Plough antibodies. Alder would receive milestone payments, research support and royalties. In June 2009, the agreement was expanded to include candidates with potential applications to central nervous system disorders. Alder would receive an upfront payment, milestones, royalties and committed funding for Alder personnel engaged in the project.

In November 2005, Alder agreed to use its yeast production system to produce research materials for one of Seattle Genetics' preclinical therapeutic antibodies.

#### **FINANCIAL**

In January 2015, a public offering of 4 million shares of company's common stock was initiated; underwriters were to be be granted a 30-day option to purchase up to 600,000 additional shares at the public offering price. Later that month, the company priced the underwritten public offering of 6 million shares at \$29.50 each and also granted the underwriters a 30-day option to purchase up to 0.9 million additional shares. At that time, the offering was expected to close on January 13, 2015. Later, in January 2015, the underwriters exercised there option to purchase an additional 0.9 million shares of common stock, and the company raised \$203.6 million through the offering of 6.9 million shares.

In December 2014, the company was added to the NASDAQ Biotechnology Index (NBI) which would become effective



upon market open on December 22, 2014.

In June 2014, the company was added to the Russell 3000 Index.

In May 2014, the company announced the pricing of its initial public offering of 8 million shares of its common stock at a price of \$10 per share. The shares had begun trading on the NASDAQ Global Market under the ticker symbol "ALDR". Alder had granted the underwriters a 30-day option to buy up to 1.2 million additional shares of common stock at the initial public offering price to cover over-allotments, if any. The offering was expected to close on May 13, 2014. Later that month, the offering was closed and the company raised net proceeds of \$80.1 million from the sale of an aggregate of 8,875,396 shares of its common stock, including 875,396 shares pursuant to the partial exercise of the underwriters' over-allotment option.

In April 2012, the company closed a \$38 million series D financing.

In January 2007, Alder raised \$40 million from a series C financing round.

In July 2006, Alder raised \$16 million in a series B financing round.

In August 2005, Alder raised \$11.1 million in a series A financing.

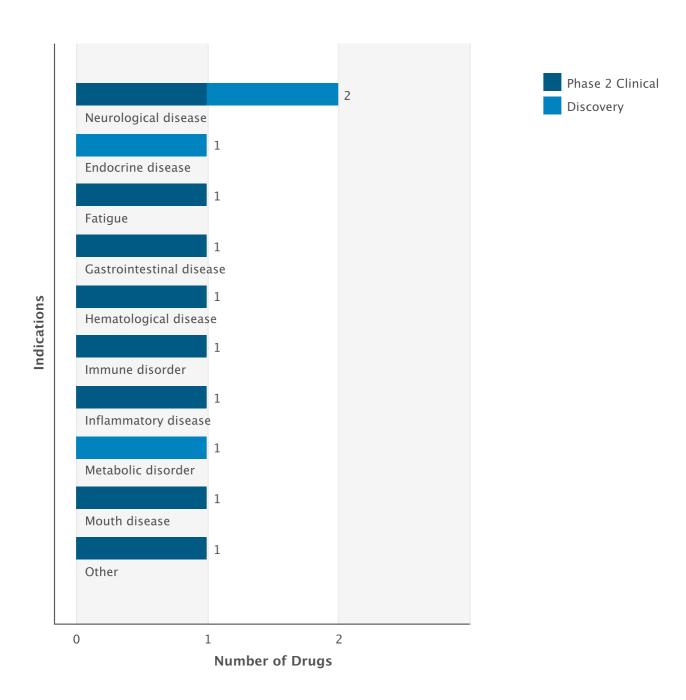


## PRODUCT PORTFOLIO SUMMARY

### **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart



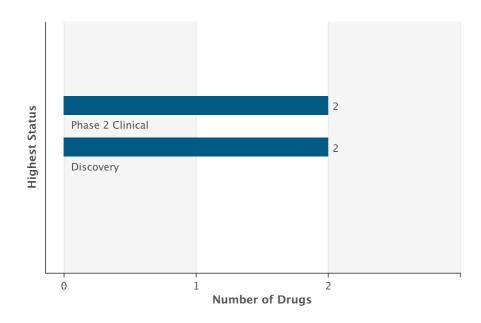


# Drugs by Indication Table

| Indication               | Active | Inactive | Total |
|--------------------------|--------|----------|-------|
| Neurological disease     | 2      | 1        | 3     |
| Inflammatory disease     | 1      | 1        | 2     |
| Metabolic disorder       | 1      | 1        | 2     |
| Hematological disease    | 1      | 1        | 2     |
| Neoplasm                 | 0      | 2        | 2     |
| Fatigue                  | 1      | 0        | 1     |
| Endocrine disease        | 1      | 0        | 1     |
| Nutritional disorder     | 1      | 0        | 1     |
| Musculoskeletal disease  | 1      | 0        | 1     |
| Immune disorder          | 1      | 0        | 1     |
| Gastrointestinal disease | 1      | 0        | 1     |
| Cardiovascular disease   | 0      | 1        | 1     |
| Mouth 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 2 Clinical        | 2               |
| Discovery               | 2               |
| No Development Reported | 6               |

### **DEALS**

| Deal Type                                    | Principal |          | Partner |          | Total |
|--|-----------|----------|---------|----------|-------|
|  | Active    | Inactive | Active  | Inactive |       |
| Technology - Other Proprietary               | 1         | 0        | 0       | 0        | 1     |
| Drug - Screening/Evaluation                  | 1         | 0        | 0       | 0        | 1     |
| Drug - Development/Commercialization License | 1         | 0        | 0       | 0        | 1     |

## **CLINICAL TRIALS**

## Trials by Condition Studied

| Condition Studied       | Ongoing | All |
|-------------------------|---------|-----|
| Neurological disease    | 1       | 4   |
| Nutritional disorder    | 0       | 4   |
| Fatigue                 | 0       | 3   |
| Immune disorder         | 0       | 3   |
| Musculoskeletal disease | 0       | 2   |
| Inflammatory disease    | 0       | 2   |
| Neoplasm                | 0       | 2   |
| Hematological disease   | 0       | 1   |
| Respiratory disease     | 0       | 1   |
| Mouth disease           | 0       | 1   |

# Trials by Phase

| Phase   | Ongoing | All |
|---------|---------|-----|
| Phase 2 | 1       | 5   |
| Phase 1 | 0       | 6   |

### **Phase Definitions**



#### Phase 3 Clinical

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

#### Phase 2 Clinical

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

#### Phase 1 Clinical

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

#### **PATENTS** \*

| Indication               | As Owner | As Third Party | Total |
|--------------------------|----------|----------------|-------|
| Cardiovascular disease   | 5        | 0              | 5     |
| Endocrine disease        | 5        | 0              | 5     |
| Gastrointestinal disease | 8        | 0              | 8     |
| Genitourinary disease    | 3        | 0              | 3     |
| Growth disorder          | 1        | 0              | 1     |
| Hematological disease    | 3        | 0              | 3     |
| Degeneration             | 3        | 0              | 3     |
| Immune disorder          | 7        | 0              | 7     |
| Psychiatric disorder     | 1        | 0              | 1     |
| Musculoskeletal disease  | 7        | 0              | 7     |
| Neoplasm                 | 10       | 0              | 10    |
| Ocular disease           | 2        | 0              | 2     |
| Metabolic disorder       | 4        | 0              | 4     |
| Neurological disease     | 6        | 0              | 6     |
| Nutritional disorder     | 6        | 0              | 6     |
| Respiratory disease      | 3        | 0              | 3     |
| Infectious disease       | 4        | 0              | 4     |
| Injury                   | 2        | 0              | 2     |
| Inflammatory disease     | 8        | 0              | 8     |
| Fatigue                  | 4        | 0              | 4     |
| Temperature disorder     | 2        | 0              | 2     |



1

THOMSON REUTERS

<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

#### **ALD-403**

#### **ALD-403 SNAPSHOT**

| Drug Name       ALD-403         Key Synonyms       Key Synonyms         Originator Company       Alder Biopharmaceuticals Inc         Active Companies       Alder Biopharmaceuticals Inc         Inactive Companies       Phase 2 Clinical         Active Indications       Migraine         Target-based Actions       CGRP receptor antagonist         Other Actions       Companies |                      |                              |
|---|----------------------|------------------------------|
| Originator Company  Alder Biopharmaceuticals Inc  Active Companies  Inactive Companies  Highest Status  Phase 2 Clinical  Active Indications  Migraine  CGRP receptor antagonist  | Drug Name            | ALD-403                      |
| Active Companies Inactive Companies Highest Status Phase 2 Clinical Active Indications Migraine Target-based Actions CGRP receptor antagonist   | Key Synonyms         |                              |
| Inactive Companies  Highest Status  Phase 2 Clinical  Active Indications  Migraine  Target-based Actions  CGRP receptor antagonist  | Originator Company   | Alder Biopharmaceuticals Inc |
| Highest Status Phase 2 Clinical  Active Indications Migraine  CGRP receptor antagonist  | Active Companies     | Alder Biopharmaceuticals Inc |
| Active Indications  Migraine  CGRP receptor antagonist  | Inactive Companies   |                              |
| Target-based Actions CGRP receptor antagonist   | Highest Status       | Phase 2 Clinical             |
|   | Active Indications   | Migraine                     |
| Other Actions   | Target-based Actions | CGRP receptor antagonist     |
|   | Other Actions        |                              |
| Technologies Biological therapeutic;Subcutaneous formulation;Intravenous formulation;Infusion;Protein recombinant;Monoclonal antibody humanized   | Technologies         |                              |
| Last Change Date 17-Apr-2015  | Last Change Date     | 17-Apr-2015                  |

### **ALD-403 DEVELOPMENT PROFILE**

### **SUMMARY**

Alder Biopharmaceuticals is developing ALD-403, a genetically engineered, humanized mAb that inhibits calcitonin gene-related peptide (CGRP), as a once-monthly sc and quarterly iv infusion, for the potential prevention of both episodic and chronic migraine .

In October 2014, a phase IIb trial of the iv formulation in chronic migraine was initiated; primary endpoint data were expected in the second half of 2015. At that time, a phase IIb trial of the sc formulation for frequent episodic migraine was expected to begin in 1H15, and a phase III trial of the iv formulation, which might combine both episodic and chronic migraine, was expected to be initiated in 2H16.

#### **ALD-403 DEVELOPMENT STATUS**

### **CURRENT DEVELOPMENT STATUS**

| Company                            | Indication | Country     | <b>Development Status</b> | Date        |
|------------------------------------|------------|-------------|---------------------------|-------------|
| Alder<br>Biopharmaceuticals<br>Inc | Migraine   | Australia   | Phase 2 Clinical          | 09-Mar-2015 |
| Alder<br>Biopharmaceuticals<br>Inc | Migraine   | New Zealand | Phase 2 Clinical          | 09-Mar-2015 |
| Alder<br>Biopharmaceuticals        | Migraine   | US          | Phase 2 Clinical          | 20-Oct-2014 |



| Company | Indication | Country | <b>Development Status</b> | Date        |
|---------|------------|---------|---------------------------|-------------|
| Inc     | Migraine   | US      | Phase 2 Clinical          | 20-Oct-2014 |
|         |            |         |                           |             |

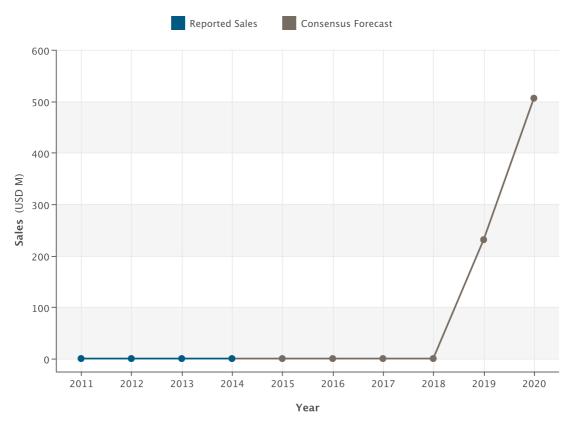
## **ALD-403 DRUG NAMES**

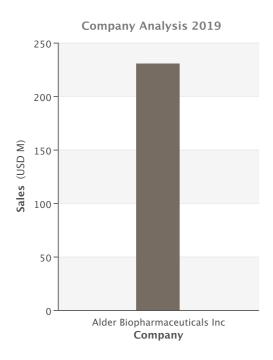
| Names  | Туре          |
|--|---------------|
| mAb (migraine), Alder  |               |
| CGRP inhibitor (humanized mAb, migraine), Alder                            |               |
| ALD-403  | Research Code |
| calcitonin gene-related peptide inhibitor (humanized mAb, migraine), Alder |               |

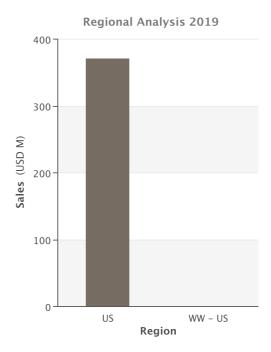
### **ALD-403 SALES AND FORECASTS**

### **CHARTS**

### **Total Sales**









### **COMMENTARY**

### **CONSENSUS SALES INFORMATION**

Consensus forecast data for Alder Biopharmaceuticals are presented.

## REGIONAL DEVELOPMENT AND MARKETING RIGHTS

Alder Biopharmaceuticals holds worldwide development and marketing rights.

### **ALD-403 CLINICAL TRIALS**

### Trials by Phase and Condition Studied

|              | se 4<br>nical | Phase 3<br>Clinical |     | Phase 2<br>Clinical |     | Phase 1<br>Clinical |     | Phase<br>Unspecified |     | Total        |     |
|--------------|---------------|---------------------|-----|---------------------|-----|---------------------|-----|----------------------|-----|--------------|-----|
| On-<br>going | All           | On-<br>going        | All | On-<br>going        | All | On-<br>going        | All | On-<br>going         | All | On-<br>going | All |
| Migraine     |               |                     |     |                     |     |                     |     |                      |     |              |     |
| 0            | 0             | 0                   | 0   | 1                   | 2   | 0                   | 2   | 0                    | 0   | 1            | 4   |

### Total Trials by Phase and Status

|                           | se 4<br>nical |              | se 3<br>nical |              | se 2<br>nical | Pha<br>Clin  | se 1<br>nical | Phase<br>Unspecified |     | То           | tal |
|---------------------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|----------------------|-----|--------------|-----|
| On-<br>going              | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going         | All | On-<br>going | All |
| Total by Phase and Status |               |              |               |              |               |              |               |                      |     |              |     |
| 0                         | 0             | 0            | 0             | 1            | 2             | 0            | 3             | 0                    | 0   | 1            | 5   |

#### **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

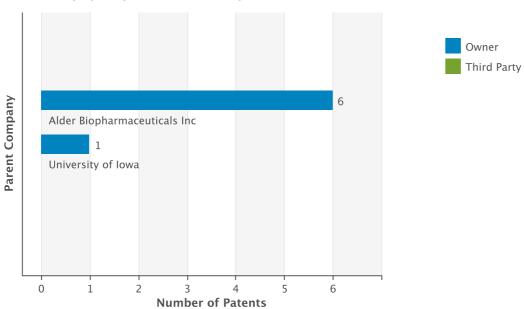
THOMSON REUTERS

## **ALD-403 DEALS AND PATENTS**

### **PATENTS**

## **Patents by Parent Company Chart**

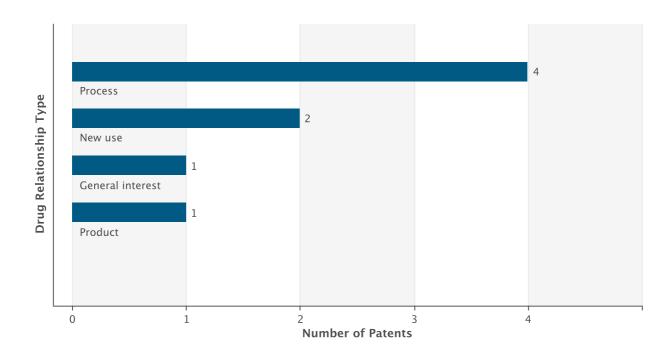
Chart displayed by Owner/Third Party



## **Patents by Parent Company Table**

| Company Name                 | As Owner | As Third Party | Total |
|------------------------------|----------|----------------|-------|
| Alder Biopharmaceuticals Inc | 6        | 0              | 6     |
| University of Iowa           | 1        | 0              | 1     |

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



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

| Drug Relationship | Total |
|-------------------|-------|
| Process           | 4     |
| New use           | 2     |
| General interest  | 1     |
| Product           | 1     |



### clazakizumab

#### clazakizumab SNAPSHOT

| Drug Name            | clazakizumab   |
|----------------------|--|
| Key Synonyms         | clazakizumab   |
| Originator Company   | Alder Biopharmaceuticals Inc   |
| Active Companies     | Alder Biopharmaceuticals Inc   |
| Inactive Companies   | Bristol-Myers Squibb Co  |
| Highest Status       | Phase 2 Clinical   |
| Active Indications   | Anemia;Oral mucositis;Graft versus host disease;Cachexia;Fatigue;Crohns disease;Psoriatic arthritis;Rheumatoid arthritis           |
| Target-based Actions | IL-6 antagonist  |
| Other Actions        | Anti-inflammatory  |
| Technologies         | Biological therapeutic;Subcutaneous formulation;Intravenous formulation;Infusion;Protein recombinant;Monoclonal antibody humanized |
| Last Change Date     | 15-Dec-2014  |

#### clazakizumab DEVELOPMENT PROFILE

#### **SUMMARY**

Alder Biopharmaceuticals is developing clazakizumab (ALD-518; BMS-945429), a neutralizing humanized monoclonal antibody against IL-6 produced in the company's Mab X-press yeast culture system, for the potential iv or sc treatment of cancer-related anemia, fatigue, cachexia, oral mucositis and graft versus host disease (GVHD). In November 2014, the company was seeking to outlicense the drug.

In September 2008, Alder initiated a phase II trial in cancer-related anemia, fatigue and cachexia; in June 2010, positive results from the phase II study were presented,; in July 2011, the drug was still listed as being in phase II development for these indications by Alder. In July 2011, a phase II oral mucositis trial was initiated. In March 2012, Alder initiated a phase I/II trial in GVHD patients. In June 2011, former licensee Bristol-Myers Squibb (BMS) initiated a phase IIb RA trial. In January 2012, BMS initiated a phase II psoriatic arthritis trial. In August 2012, a phase II Crohn's disease trial was initiated; however, by June 2013, the trial had been terminated. In February 2014, the drug was listed as being in phase II development on BMS pipeline. However, in September 2014, BMS terminated its collaboration with Alder. At that time, Alder would continue development of drug for autoimmune/inflammatory diseases.

### clazakizumab DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

| Company                            | Indication | Country   | Development Status | Date        |
|------------------------------------|------------|-----------|--------------------|-------------|
| Alder<br>Biopharmaceuticals<br>Inc | Anemia     | US        | Phase 2 Clinical   | 06-Jun-2010 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia   | Australia | Phase 2 Clinical   | 30-Sep-2008 |



| Company                            | Indication                | Country               | <b>Development Status</b> | Date        |
|------------------------------------|---------------------------|-----------------------|---------------------------|-------------|
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | Canada                | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | Eastern<br>Europe     | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | Georgia               | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | India                 | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | New Zealand           | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Cachexia                  | Russian<br>Federation | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Crohns disease            | US                    | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | Australia             | Phase 2 Clinical          | 22-Jan-2009 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | Canada                | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | Eastern<br>Europe     | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | Georgia               | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | India                 | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | New Zealand           | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Fatigue                   | Russian<br>Federation | Phase 2 Clinical          | 30-Sep-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Graft versus host disease | US                    | Phase 2 Clinical          | 29-Mar-2012 |
| Alder<br>Biopharmaceuticals<br>Inc | Oral mucositis            | US                    | Phase 2 Clinical          | 25-Jul-2011 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | Argentina             | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | Australia             | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | Canada                | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | EU                    | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | South Africa          | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Psoriatic arthritis       | US                    | Phase 2 Clinical          | 02-Sep-2014 |



| Company                            | Indication           | Country               | <b>Development Status</b> | Date        |
|------------------------------------|----------------------|-----------------------|---------------------------|-------------|
| Alder                              | Rheumatoid arthritis | Canada                | Phase 2 Clinical          | 31-Oct-2008 |
| Biopharmaceuticals Inc             | Turodinatora aramite | Janaaa                | That I omnoun             | 01 001 2000 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Europe                | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Far East              | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Georgia               | Phase 2 Clinical          | 31-Oct-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | India                 | Phase 2 Clinical          | 31-Oct-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Italy                 | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Japan                 | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | Russian<br>Federation | Phase 2 Clinical          | 31-Oct-2008 |
| Alder Biopharmaceuticals Inc       | Rheumatoid arthritis | Serbia                | Phase 2 Clinical          | 31-Oct-2008 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | South Africa          | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | South America         | Phase 2 Clinical          | 02-Sep-2014 |
| Alder<br>Biopharmaceuticals<br>Inc | Rheumatoid arthritis | US                    | Phase 2 Clinical          | 31-Oct-2008 |
| Bristol-Myers Squibb<br>Co         | Crohns disease       | US                    | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Psoriatic arthritis  | Argentina             | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         |                      | Australia             | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Psoriatic arthritis  | Canada                | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Psoriatic arthritis  | EU                    | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Psoriatic arthritis  | South Africa          | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Psoriatic arthritis  | US                    | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Rheumatoid arthritis | Canada                | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Rheumatoid arthritis | Europe                | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Rheumatoid arthritis | Far East              | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Rheumatoid arthritis | Italy                 | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co         | Rheumatoid arthritis | Japan                 | Discontinued              | 02-Sep-2014 |



| Company                    | Indication           | Country       | <b>Development Status</b> | Date        |
|----------------------------|----------------------|---------------|---------------------------|-------------|
| Bristol-Myers Squibb<br>Co | Rheumatoid arthritis | South Africa  | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co | Rheumatoid arthritis | South America | Discontinued              | 02-Sep-2014 |
| Bristol-Myers Squibb<br>Co | Rheumatoid arthritis | US            | Discontinued              | 02-Sep-2014 |

#### clazakizumab DRUG NAMES

| Names  | Туре          |
|--|---------------|
| anti-IL6 monoclonal antibody (rheumatoid arthritis/cancer), Alder Biopharmaceuticals/BMS |               |
| clazakizumab   | PINN, USAN    |
| BMS-945429   | Research Code |
| anti-IL6 mAb (rheumatoid arthritis/cancer),<br>Alder/Bristol-Myers Squibb                |               |
| ALD-518  | Research Code |

#### clazakizumab SALES AND FORECASTS

### **COMMENTARY**

#### **CONSENSUS SALES INFORMATION**

No Consensus forecast data for Alder Biopharmaceuticals are currently available.

### **REGIONAL DEVELOPMENT AND MARKETING RIGHTS**

In November 2009, Bristol-Myers Squibb (BMS) entered into a worldwide, exclusive development and commercialization agreement for Alder Biopharmaceuticals' clazakizumab in all indications, including rheumatoid arthritis and other autoimmune diseases, but excluding oncology-associated conditions; at the time, this transaction was still pending approval [1056039]. By June 2011, the agreement had closed [1201269]. In September 2014, Alder BioPharmaceuticals regained worldwide rights to clazakizumab after BMS decided to end further development of the drug and terminated the agreement with Alder [1590051].

#### clazakizumab CLINICAL TRIALS

## Trials by Phase and Condition Studied

| Pha<br>Clin  |              |              | se 3<br>nical |              | se 2<br>iical |              | se 1<br>nical | Pha<br>Unspe |     | То           | tal |
|--------------|--------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|-----|--------------|-----|
| On-<br>going | All          | On-<br>going | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going | All | On-<br>going | All |
| Rheumat      | oid arthriti | S            |               |              |               |              |               |              |     |              |     |
| 0            | 0            | 0            | 0             | 2            | 3             | 0            | 1             | 0            | 0   | 2            | 4   |
| Cachexia     |              |              |               |              |               |              |               |              |     |              |     |
| 0            | 0            | 0            | 0             | 0            | 1             | 0            | 2             | 0            | 0   | 0            | 3   |



| Fatigue    |                     |               |        |   |   |   |   |   |   |   |   |
|------------|---------------------|---------------|--------|---|---|---|---|---|---|---|---|
| 0          | 0                   | 0             | 0      | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 2 |
| Psoriatic  | Psoriatic arthritis |               |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 |
| Oral muc   | ositis              |               |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Metastati  | c non sma           | all cell lung | cancer |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Cancer     |                     |               |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Graft vers | sus host d          | isease        |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Crohns d   | isease              |               |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Anemia     |                     |               |        |   |   |   |   |   |   |   |   |
| 0          | 0                   | 0             | 0      | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |

## Total Trials by Phase and Status

|                           | se 4<br>nical |              | se 3<br>nical |              | se 2<br>nical |              | se 1<br>nical |              | ase<br>ecified | То           | tal |
|---------------------------|---------------|--------------|---------------|--------------|---------------|--------------|---------------|--------------|----------------|--------------|-----|
| On-<br>going              | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going | All           | On-<br>going | All            | On-<br>going | All |
| Total by Phase and Status |               |              |               |              |               |              |               |              |                |              |     |
| 0                         | 0             | 0            | 0             | 3            | 7             | 0            | 3             | 0            | 0              | 3            | 10  |

### **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

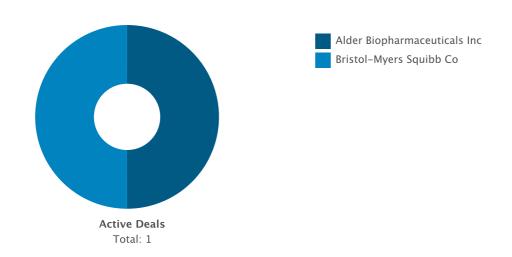
Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0



## clazakizumab DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



## **Deals by Parent Company Table**

| Company Name                 |   | <b>cipal</b><br>Inactive |   | tner<br>Inactive | Total |
|------------------------------|---|--------------------------|---|------------------|-------|
| Alder Biopharmaceuticals Inc | 1 | 0                        | 0 | 0                | 1     |
| Bristol-Myers Squibb Co      | 0 | 0                        | 1 | 0                | 1     |

# **Deals by Type Chart**



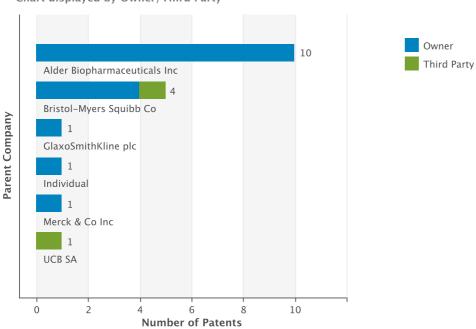
## **Deals by Type Table**

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

### **PATENTS**

## **Patents by Parent Company Chart**

Chart displayed by Owner/Third Party

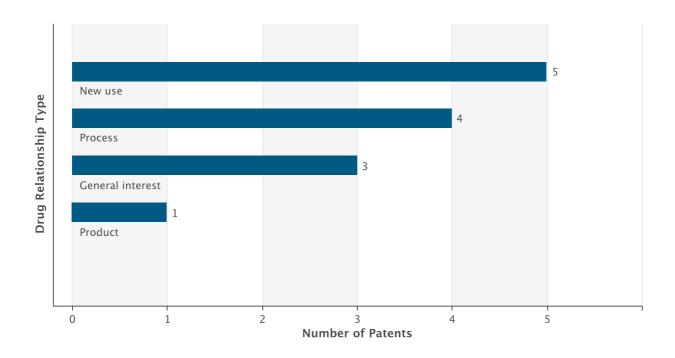


## **Patents by Parent Company Table**

| Company Name                 | As Owner | As Third Party | Total |
|------------------------------|----------|----------------|-------|
| Alder Biopharmaceuticals Inc | 10       | 0              | 10    |
| Bristol-Myers Squibb Co      | 4        | 1              | 4     |
| Individual                   | 1        | 0              | 1     |
| UCB SA                       | 0        | 1              | 1     |
| Merck & Co Inc               | 1        | 0              | 1     |
| GlaxoSmithKline plc          | 1        | 0              | 1     |

THOMSON REUTERS

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



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

| Drug Relationship | Total |
|-------------------|-------|
| New use           | 5     |
| Process           | 4     |
| General interest  | 3     |
| Product           | 1     |



## **ALD-1613**

#### **ALD-1613 SNAPSHOT**

| Drug Name            | ALD-1613  |
|----------------------|---|
| Key Synonyms         |   |
| Originator Company   | Alder Biopharmaceuticals Inc  |
| Active Companies     | Alder Biopharmaceuticals Inc  |
| Inactive Companies   |   |
| Highest Status       | Discovery   |
| Active Indications   | Cushings disease  |
| Target-based Actions | ACTH receptor antagonist  |
| Other Actions        |   |
| Technologies         | Biological therapeutic;Parenteral formulation unspecified;Monoclonal antibody |
| Last Change Date     | 28-Jan-2015   |

### **ALD-1613 DEVELOPMENT PROFILE**

### **SUMMARY**

Alder Biopharmaceuticals is investigating ALD-1613, a monoclonal antibody that inhibits adrenocorticotropic hormone (ACTH), for the potential treatment of Cushing's disease. In January 2015, the mAb was listed as being preclinical development. At that time, the company planned for a phase I trial in first half of 2016. By March 2015, IND-enabling studies had been initiated and a phase I trial was expected to initiate in 2016.

## **ALD-1613 DEVELOPMENT STATUS**

#### **CURRENT DEVELOPMENT STATUS**

| Company                            | Indication       | Country | <b>Development Status</b> | Date        |
|------------------------------------|------------------|---------|---------------------------|-------------|
| Alder<br>Biopharmaceuticals<br>Inc | Cushings disease | US      | Discovery                 | 20-Jan-2015 |

#### **ALD-1613 DRUG NAMES**

| Names    | Туре          |
|----------|---------------|
| ALD-1613 | Research Code |
|          |               |



## **ALD-906**

#### **ALD-906 SNAPSHOT**

| Drug Name            | ALD-906   |
|----------------------|---|
| Key Synonyms         |   |
| Originator Company   | Alder Biopharmaceuticals Inc  |
| Active Companies     | Alder Biopharmaceuticals Inc  |
| Inactive Companies   |   |
| Highest Status       | Discovery   |
| Active Indications   | Pain  |
| Target-based Actions | NGF receptor antagonist   |
| Other Actions        | Analgesic   |
| Technologies         | Biological therapeutic;Parenteral formulation unspecified;Monoclonal antibody |
| Last Change Date     | 22-Nov-2012   |

### **ALD-906 DEVELOPMENT PROFILE**

### **SUMMARY**

Alder Biopharmaceuticals is investigating ALD-906, an anti-nerve growth factor (anti-NGF) mAb, for the potential treatment of pain. In February 2011, the program was listed as being in preclinical development; in November 2012, this was still the case. In February 2011, the company was seeking to outlicense the program to strategic partners; in November 2012, this was still the case.

## **ALD-906 DEVELOPMENT STATUS**

### **CURRENT DEVELOPMENT STATUS**

| Company                            | Indication | Country | <b>Development Status</b> | Date        |
|------------------------------------|------------|---------|---------------------------|-------------|
| Alder<br>Biopharmaceuticals<br>Inc | Pain       | US      | Discovery                 | 23-Feb-2011 |

### **ALD-906 DRUG NAMES**

| Names   | Туре          |
|---|---------------|
| ALD-906   | Research Code |
| anti-NGF mAb (pain), Alder Biopharmaceuticals                                 |               |
| anti-nerve growth factor monoclonal antibody (pain), Alder Biopharmaceuticals |               |

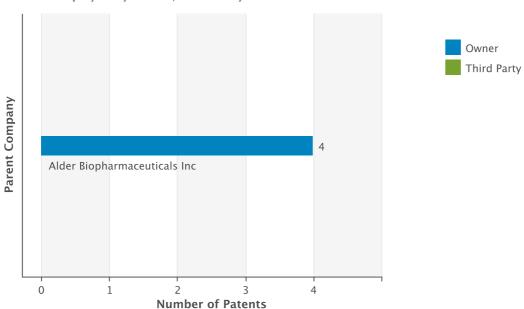


### **ALD-906 DEALS AND PATENTS**

### **PATENTS**

## **Patents by Parent Company Chart**

Chart displayed by Owner/Third Party

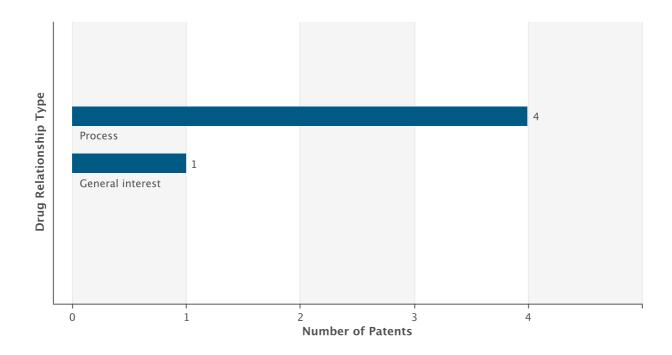


## **Patents by Parent Company Table**

| Company Name                 | As Owner | As Third Party | Total |
|------------------------------|----------|----------------|-------|
| Alder Biopharmaceuticals Inc | 4        | 0              | 4     |

THOMSON REUTERS

# **Patents by Drug Relationship Type Chart**



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

| Drug Relationship | Total |
|-------------------|-------|
| Process           | 4     |
| General interest  | 1     |



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

For more information about *Cortellis for Competitive Intelligence*, visit: http://cortellis.thomsonreuters.com/cortellis\_for\_you/?cid=thomsonone.

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

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

THOMSON REUTERS