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Intercept Pharmaceuticals Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

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ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

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GLOSSARY

Number of Drugs in Active Development

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

Number of Inactive Drugs

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

Number of Patents as Owner

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

Number of Patents as Third Party

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

Patents summary table

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

Number of Deals

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

Key Indications

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

Key Target-based Actions

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

Key Technologies

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

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Intercept Pharmaceuticals Inc

COMPANY OVERVIEW

Company Name	Intercept Pharmaceuticals Inc
Parent Company Name	Genextra SpA
Website	http://www.interceptpharma.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	0
Number of Patents as Owner	10
Number of Patents as Third Party	0
Number of Deals	4
Key Indications	Metabolic disorder,Diabetic nephropathy,Diarrhea,Fibrosis,Non-alcoholic steatohepatitis,Non-insulin dependent diabetes,Portal hypertension,Primary biliary cirrhosis,Inflammatory disease,Autoimmune disease,Cancer,Gastrointestinal disease,Liver disease,Renal disease
Key Target-based Actions	G-protein coupled bile acid receptor 1 agonist,Farnesoid X receptor agonist,G-protein coupled bile acid receptor 1 modulator
Key Technologies	Small molecule therapeutic,Oral formulation,Systemic formulation unspecified

COMPANY PROFILE

SUMMARY

Intercept Pharmaceuticals Inc, headquartered in New York City, NY, is focused on the development of small-molecule drugs for the treatment of chronic liver and metabolic diseases. In May 2006, Genextra acquired Intercept Pharmaceuticals.

FINANCIAL

In October 2012, the company announced the pricing of its initial public offering of 5,000,000 shares of common stock, at a price of $15 per share, before underwriting discounts. The underwriters were issued a 30-day option to purchase up to an additional 750,000 shares of common stock from Intercept. At that time, the company's shares were expected to begin trading on NASDAQ , on October 11, 2012 under the trading symbol ICPT; later that month, the underwriters purchased the additional shares. The sale of the shares was closed on October 16, 2012.

In September 2012, the company filed a form S-1 registration statement with the US SEC for a proposed IPO of its common stock shares. All the shares would be offered by Intercept, and might not be sold until the registration statement had been effective. At that time, the number of shares and price range for the offering was not determined.

In August 2012, Intercept completed a $30 million series C preferred stock financing.

In January 2010, Intercept raised $25 million from a preferred series B financing by its majority shareholder, Genextra.

In July 2008, the company raised $25 million in equity financing.

In May 2006, Intercept raised $41 million in equity financing.

In May 2005, Intercept completed a $1.3 million convertible debt financing round.

In August 2004, Intercept completed a $3 million first round financing. It was to use the proceeds to complete its acquisition of INT-747 and related intellectual property and to complete preclinical trials of the drug.

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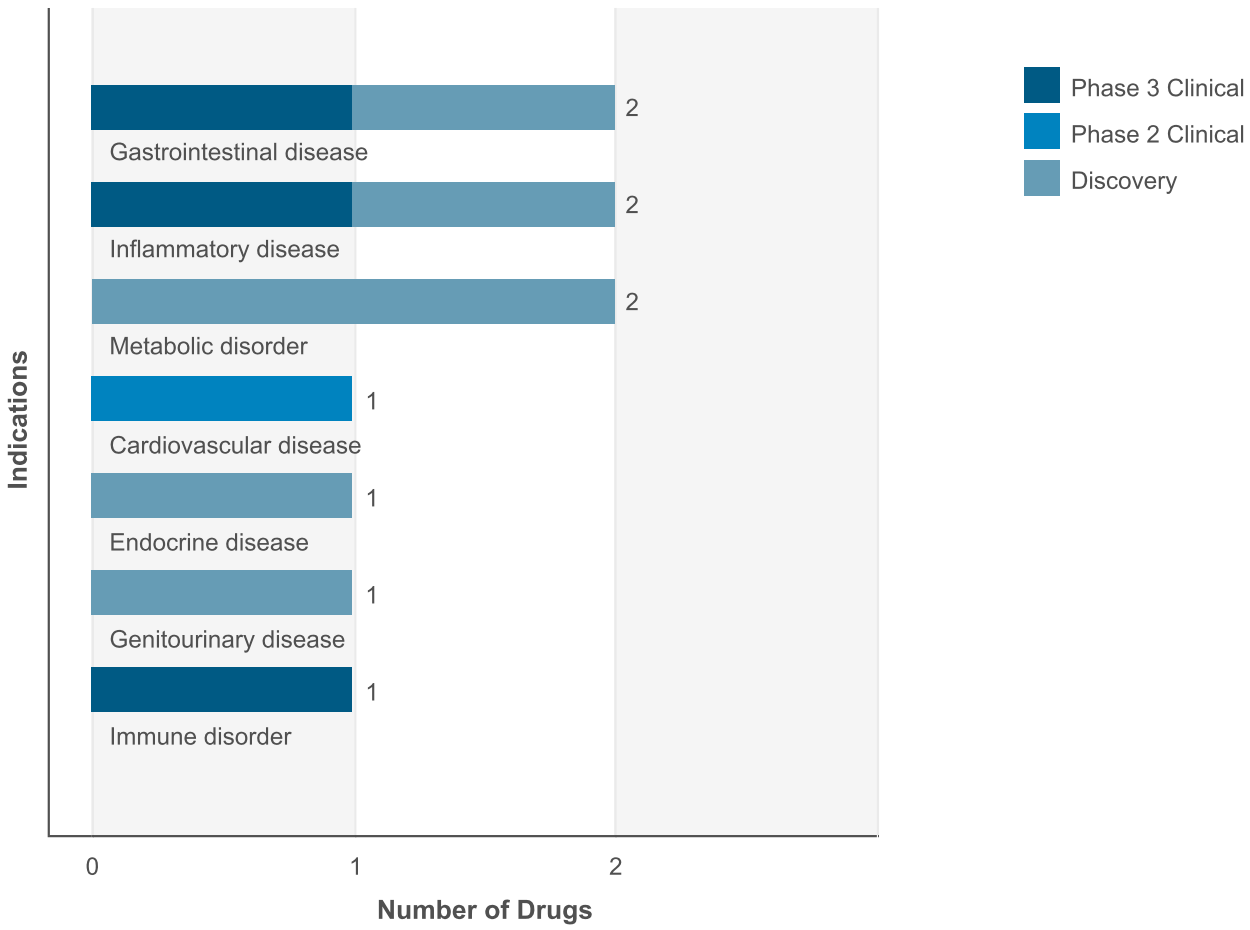
PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



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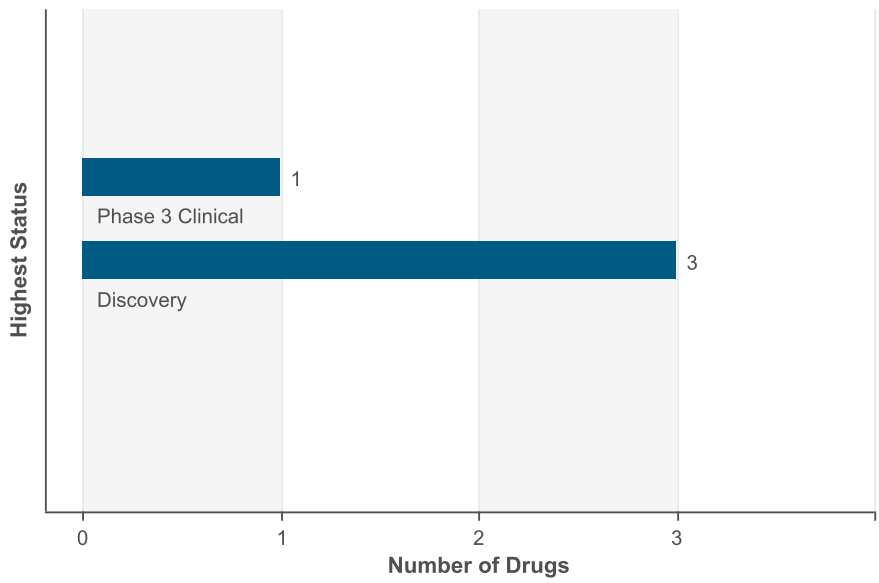
Drugs by Indication Table

Indication	Active	Inactive	Total
Metabolic disorder	2	1	3
Gastrointestinal disease	2	0	2
Inflammatory disease	2	0	2
Endocrine disease	1	0	1
Genitourinary disease	1	0	1
Cardiovascular disease	1	0	1
Immune disorder	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
Discovery	3

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DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - CRADA	1	0	0	0	1
Drug - Development/Commercialization License	2	0	1	0	3

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Gastrointestinal disease	1	5
Immune disorder	1	3
Inflammatory disease	0	2
Metabolic disorder	0	2
Endocrine disease	0	2
Cardiovascular disease	0	1

Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	0	4
Phase 1	0	1

Phase Definitions

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

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

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

PATENTS *

Indication	As Owner	As Third Party	Total
Cardiovascular disease	8	0	8
Endocrine disease	3	0	3
Gastrointestinal disease	10	0	10

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Genitourinary disease	7	0	7
Immune disorder	3	0	3
Neoplasm	3	0	3
Ocular disease	1	0	1
Metabolic disorder	9	0	9
Neurological disease	1	0	1
Nutritional disorder	5	0	5
Inflammatory disease	5	0	5

* 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

obeticholic acid

obeticholic acid SNAPSHOT

Drug Name	obeticholic acid
Key Synonyms	obeticholic acid
Originator Company	Universita di Perugia
Active Companies	Intercept Pharmaceuticals Inc;Dainippon Sumitomo Pharma Co Ltd
Inactive Companies	Universita di Perugia
Highest Status	Phase 3 Clinical
Active Indications	Liver disease;Primary biliary cirrhosis;Portal hypertension;Diarrhea;Non-alcoholic steatohepatitis
Target-based Actions	Farnesoid X receptor agonist
Other Actions	Antidiarrhoeal;Antihypertensive;Bile acid modulator
Technologies	Oral formulation;Small molecule therapeutic
Last Change Date	20-Dec-2012

obeticholic acid DEVELOPMENT PROFILE

SUMMARY

Intercept Pharmaceuticals (a wholly-owned subsidiary of Genextra), under license from the University of Perugia, is developing the farnesoid X receptor (FXR) agonist obeticholic acid (INT-747; UPF-747; 6ECDCA, OCA) for the potential once-daily oral treatment of portal hypertension and liver diseases, such as primary biliary cirrhosis (PBC), bile acid diarrhea and non-alcoholic fatty liver disease (NAFLD), including non-alcoholic steatohepatitis (NASH) ,. Intercept's Asian licensee Dainippon Sumitomo Pharma is developing the drug (as DSP-1747) for PBC, NASH and other chronic liver diseases. In March 2011, Intercept initiated a phase II/III NASH trial. By October 2012, a phase II trial for NASH was underway in Japan. In March 2011, a phase III PBC trial was expected to initiate in Europe ; in January 2012, a phase III PBC trial began in the US. In December 2012, results from the trial were expected in the second quarter of 2014. In August 2012, the drug was in phase IIa for portal hypertension ; in November 2012, data were reported. In July 2012, a phase IIa trial for bile acid diarrhea was initiated.

Previously, the University of Perugia was investigating the compound for the potential treatment of cholestasis. By June 2010, Intercept was also investigating a series of preclinical backup and follow-on FXR compounds, including other bile acid derived and synthetic small molecule compounds, which were being optimized.

obeticholic acid DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

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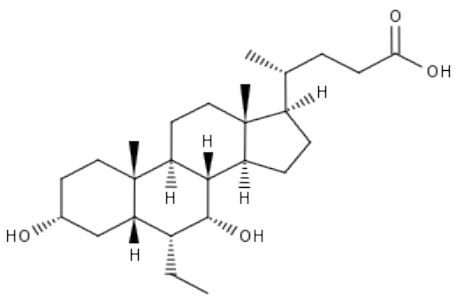
Company	Indication	Country	Development Status	Date
Intercept Pharmaceuticals Inc	Non-alcoholic steatohepatitis	US	Phase 3 Clinical	03-Mar-2011
Intercept Pharmaceuticals Inc	Primary biliary cirrhosis	US	Phase 3 Clinical	06-Jan-2011
Dainippon Sumitomo Pharma Co Ltd	Non-alcoholic steatohepatitis	Japan	Phase 2 Clinical	31-Oct-2012
Intercept Pharmaceuticals Inc	Diarrhea	UK	Phase 2 Clinical	31-Jul-2012
Intercept Pharmaceuticals Inc	Portal hypertension	Western Europe	Phase 2 Clinical	13-Aug-2012
Dainippon Sumitomo Pharma Co Ltd	Liver disease	China	Discovery	30-Mar-2011
Universita di Perugia	Jaundice	Italy	Discontinued	12-Aug-2004
Universita di Perugia	Liver disease	Italy	Discontinued	12-Aug-2004

obeticholic acid CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
459789-99-2	2



Name	Type
obeticholic acid	INN; USAN
INT-747	Research Code
6ECDCA	

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obeticholic acid DRUG NAMES

Names	Type
OCA, Intercept	
DSP-1747	Research Code
FXR agonists, Intercept	
INT-747	Research Code
6ECDCA	
farnesoid X receptor agonists, Intercept	
obeticholic acid	INN, USAN
UPF-747	Research Code

obeticholic acid 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
Non-alcoholic steatohepatitis											
0	0	0	0	2	3	0	1	0	0	2	4
Primary biliary cirrhosis											
0	0	1	1	0	1	0	1	0	0	1	3
Non-insulin dependent diabetes											
0	0	0	0	0	1	0	1	0	0	0	2
Diarrhea											
0	0	0	0	1	1	0	0	0	0	1	1
Portal hypertension											
0	0	0	0	0	1	0	0	0	0	0	1
Biliary cirrhosis											
0	0	0	0	0	1	0	0	0	0	0	1
Liver disease											
0	0	0	0	0	0	0	1	0	0	0	1

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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	1	1	3	7	0	1	0	0	4	9

Phase Definitions

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

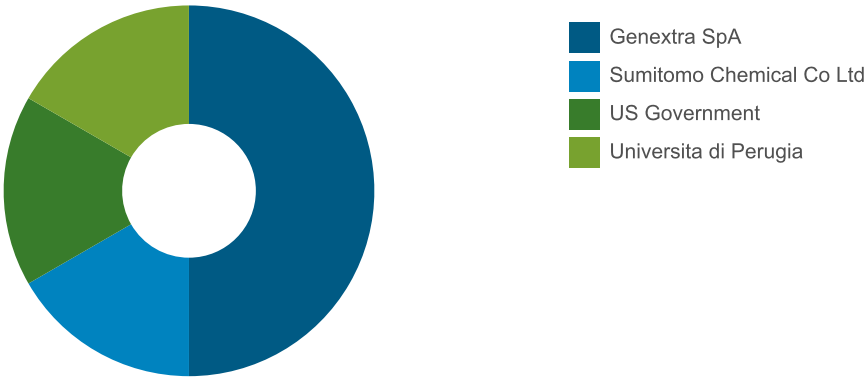
Phase 2 Clinical
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

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

obeticholic acid DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Active Deals
Total: 3

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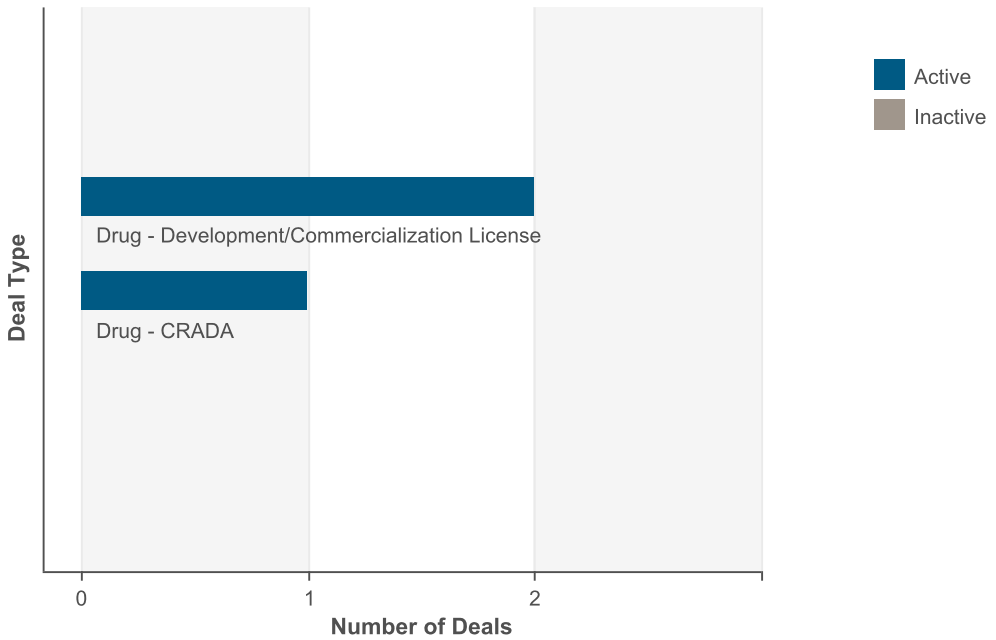
Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Genextra SpA	2	0	1	0	3
Universita di Perugia	1	0	0	0	1
Sumitomo Chemical Co Ltd	0	0	1	0	1
US Government	0	0	1	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	2	0	2
Drug - CRADA	1	0	1

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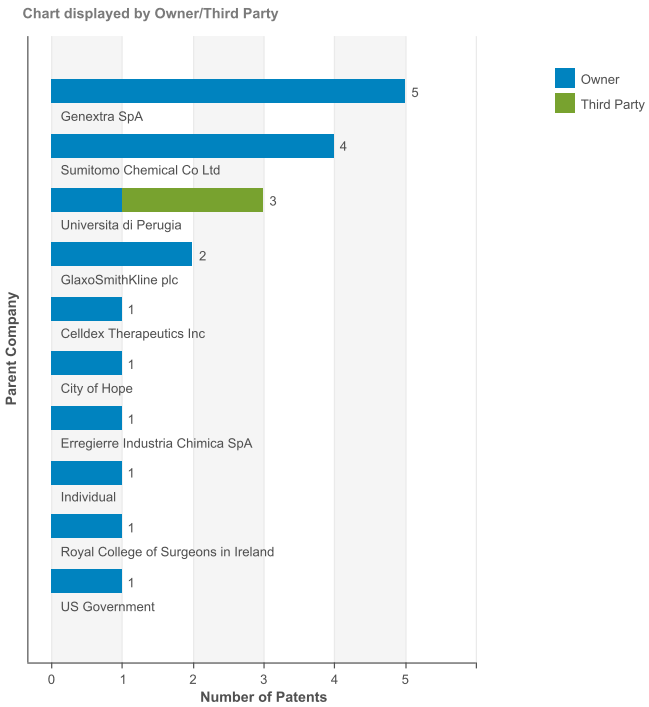
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Genextra SpA	5	0	5
Sumitomo Chemical Co Ltd	4	0	4
Universita di Perugia	1	2	3
GlaxoSmithKline plc	2	0	2
City of Hope	1	0	1
Individual	1	0	1
Celldex Therapeutics Inc	1	0	1
Royal College of Surgeons in Ireland	1	0	1
Erregierre Industria Chimica SpA	1	0	1
US Government	1	0	1

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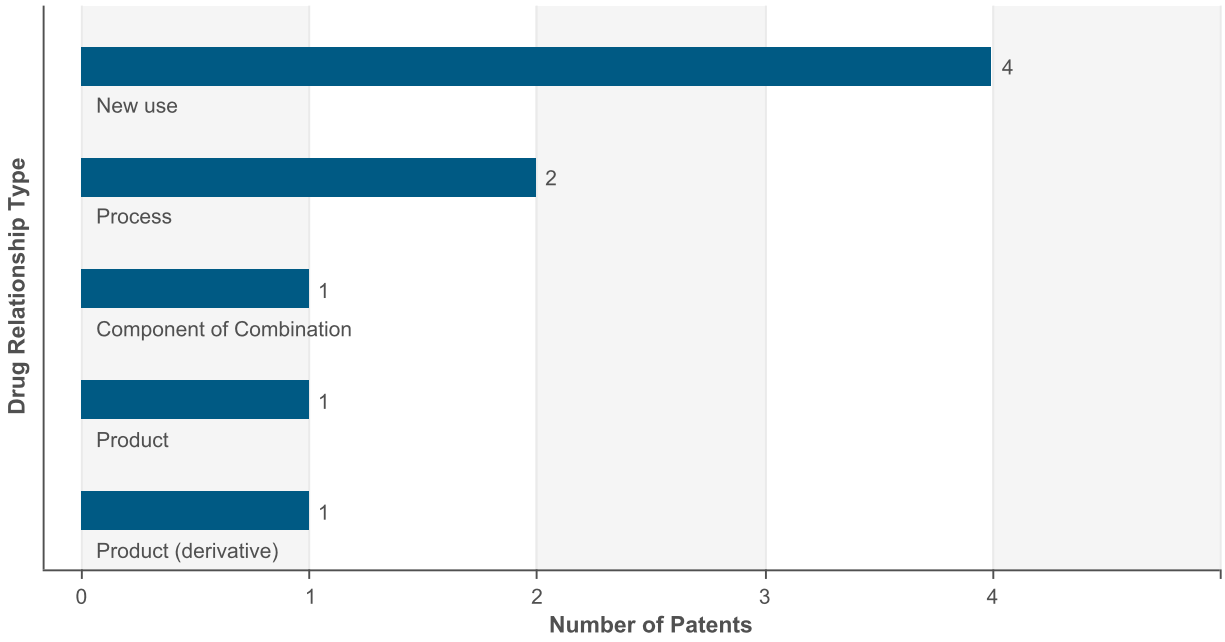
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
New use	4
Process	2
Component of Combination	1
Product	1
Product (derivative)	1

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INT-767

INT-767 SNAPSHOT

Drug Name	INT-767
Key Synonyms	
Originator Company	Intercept Pharmaceuticals Inc
Active Companies	Intercept Pharmaceuticals Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Diabetic nephropathy;Fibrosis
Target-based Actions	Farnesoid X receptor agonist;G-protein coupled bile acid receptor 1 agonist
Other Actions	
Technologies	Small molecule therapeutic;Systemic formulation unspecified
Last Change Date	13-Aug-2012

INT-767 DEVELOPMENT PROFILE

SUMMARY

Intercept is investigating INT-767, a dual farnesoid X receptor (FRX) and TGR5 agonist for the potential treatment of fibrosis and chronic kidney diseases including diabetic nephropathy ,. In June 2010, the drug was in preclinical development ; in August 2012, this was still the case.

Intercept was previously investigating INT-767, for the potential treatment of metabolic diseases. However, no further development was reported for this indication since August 2012 .

Intercept was also previously investigating FRX and TGR5 bile acid derived back ups. In June 2010, the compounds were under preclinical development. However, no further development was reported since August 2012 .

INT-767 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Intercept Pharmaceuticals Inc	Diabetic nephropathy	US	Discovery	17-Dec-2007
Intercept Pharmaceuticals Inc	Fibrosis	US	Discovery	01-Jan-2010
Intercept Pharmaceuticals Inc	Metabolic disorder	US	No Development Reported	13-Aug-2012

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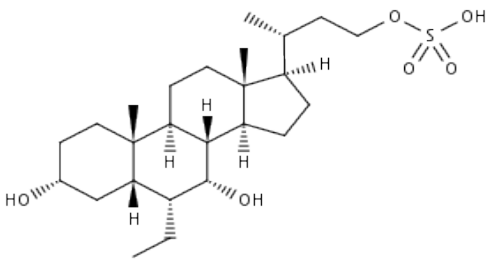
INT-767 CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
	4



Name	Type
INT-767	Research Code

INT-767 DRUG NAMES

Names	Type
farnesoid X receptor (FXR)/TGR5 agonist (metabolic disorder/fibrosis), Intercept	
farnesoid X receptor (FXR)/TGR5 agonist (diabetic nephropathy), Intercept	
INT-767	Research Code

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TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals

TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals SNAPSHOT

Drug Name	TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals
Key Synonyms	
Originator Company	Intercept Pharmaceuticals Inc
Active Companies	Intercept Pharmaceuticals Inc;Servier
Inactive Companies	
Highest Status	Discovery
Active Indications	Non-insulin dependent diabetes
Target-based Actions	G-protein coupled bile acid receptor 1 agonist
Other Actions	Hypoglycemic agent
Technologies	Small molecule therapeutic
Last Change Date	18-Aug-2011

TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

Servier, in collaboration with Intercept Pharmaceuticals, is investigating bile acid analog-based TGR5 agonists for the potential treatment of type 2 diabetes and other metabolic disorders.

TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Intercept Pharmaceuticals Inc	Non-insulin dependent diabetes	US	Discovery	09-Aug-2011
Servier	Non-insulin dependent diabetes	France	Discovery	09-Aug-2011

TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals DRUG NAMES

Names	Type
TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals	

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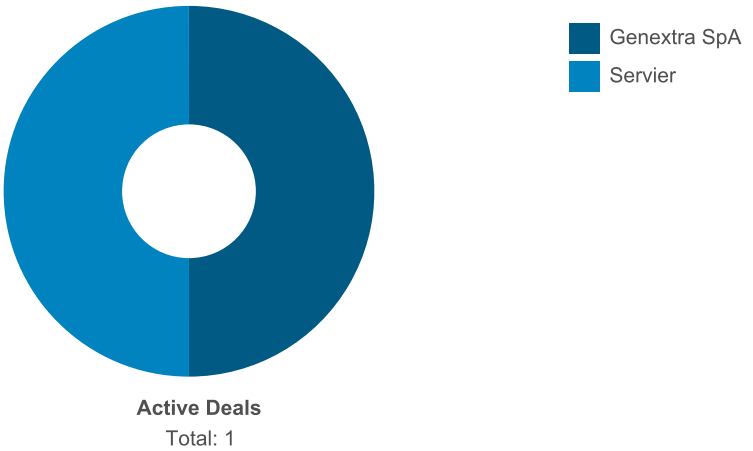
DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Servier	0	0	1	0	1
Genextra SpA	1	0	0	0	1

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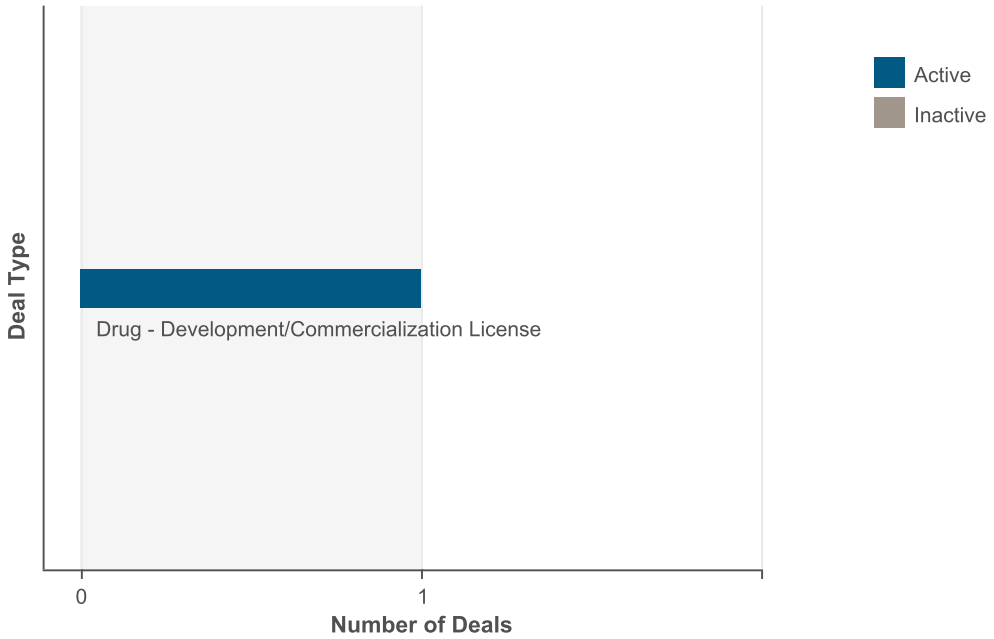
Deals by Type Chart



Deals by Type Table

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

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INT-777

INT-777 SNAPSHOT

Drug Name	INT-777
Key Synonyms	
Originator Company	Intercept Pharmaceuticals Inc
Active Companies	Intercept Pharmaceuticals Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Metabolic disorder
Target-based Actions	G-protein coupled bile acid receptor 1 agonist
Other Actions	
Technologies	Oral formulation;Small molecule therapeutic
Last Change Date	30-Nov-2012

INT-777 DEVELOPMENT PROFILE

SUMMARY

Intercept Pharmaceuticals is investigating INT-777, a modified bile acid and TGR5 agonist, for the potential oral treatment of metabolic disorders including diabetes and obesity,. By December 2007, the drug was in preclinical development; in August 2012, this was still the case.

By June 2010, Intercept was also characterizing additional series of backup TGR5 agonists, including other bile acid derived and synthetic small molecule compounds.

INT-777 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Intercept Pharmaceuticals Inc	Metabolic disorder	US	Discovery	17-Dec-2007

INT-777 CHEMICAL STRUCTURES

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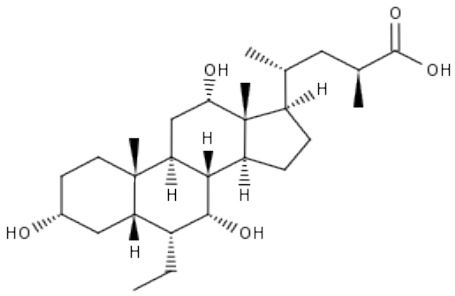
CAS Registry Number:	Confidence Level:
	3



Name	Type
INT-777	Research Code

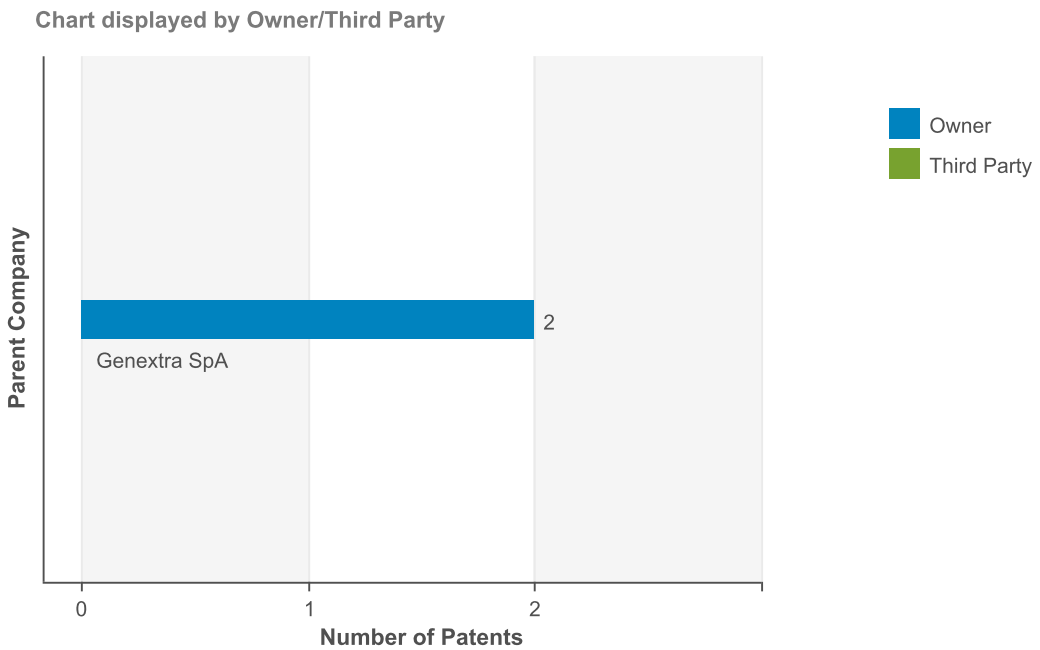
INT-777 DRUG NAMES

Names	Type
INT-777	Research Code
TGR5 agonist (oral, metabolic disorder), Intercept	

INT-777 DEALS AND PATENTS

PATENTS

Patents by Parent Company Chart



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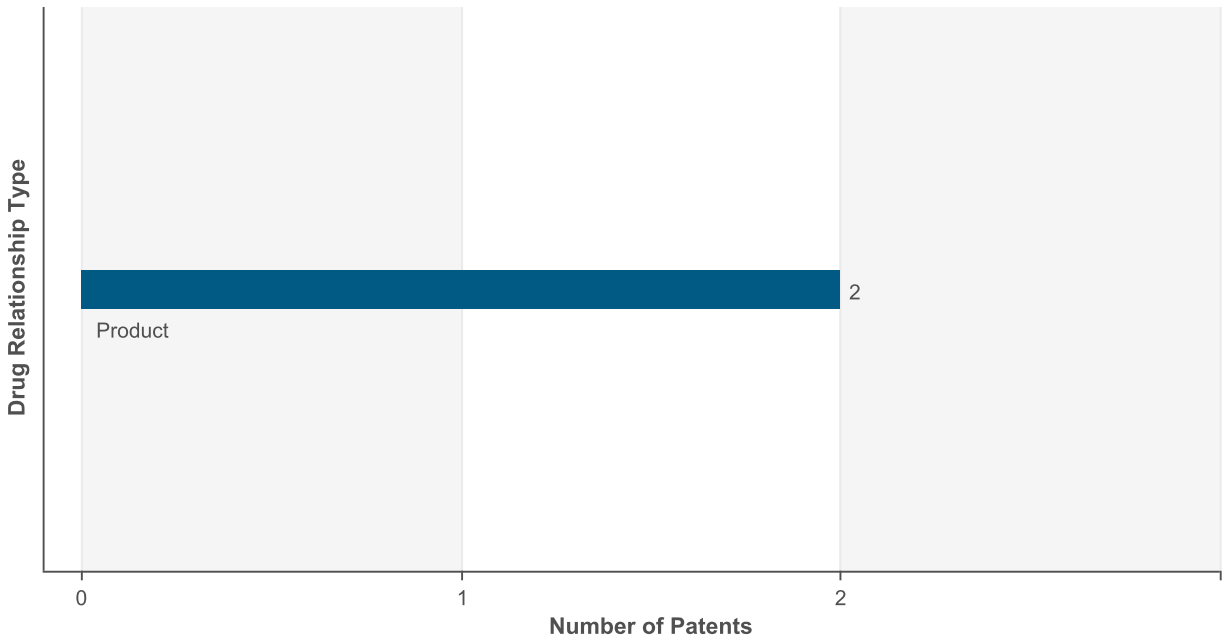
Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Genextra SpA	2	0	2

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Product	2

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