

# **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

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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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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, Non-insulin dependent diabetes, Diabetic nephropathy, Diarrhea, Fibrosis, Non-alcoholic steatohepatitis, Portal hypertension, Primary biliary cirrhosis, Gastrointestinal disease, Inflammatory 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, Farnesoid X receptor 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.

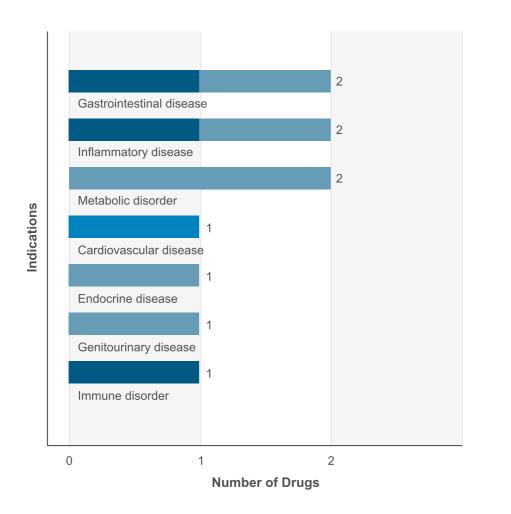
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## PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

## **Drugs by Indication**

Active Drugs by Indication Chart





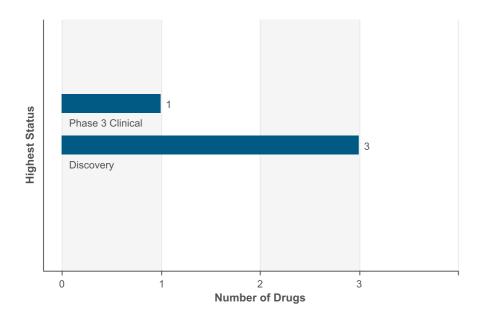


## Drugs by Indication Table

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



#### **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
Endocrine disease	0	2
Metabolic disorder	0	2
Inflammatory 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
Immune disorder	3	0	3
Neoplasm	3	0	3
Ocular disease	1	0	1



Metabolic disorder	9	0	9
Neurological disease	1	0	1
Cardiovascular disease	8	0	8
Endocrine disease	3	0	3
Genitourinary disease	7	0	7
Gastrointestinal disease	10	0	10
Nutritional disorder	5	0	5
Inflammatory disease	5	0	5

<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

#### obeticholic acid

#### obeticholic acid SNAPSHOT

Drug Nameobeticholic acidKey Synonymsobeticholic acidOriginator CompanyUniversita di PerugiaActive CompaniesIntercept Pharmaceuticals Inc;Dainippon Sumitomo Pharma Co LtdInactive CompaniesUniversita di PerugiaHighest StatusPhase 3 ClinicalActive IndicationsDiarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertensionTarget-based ActionsFarnesoid X receptor agonistOther ActionsBile acid modulator;Antihypertensive;AntidiarrhoealTechnologiesOral formulation;Small molecule therapeuticLast Change Date30-Nov-2012		
Originator Company Universita di Perugia Intercept Pharmaceuticals Inc;Dainippon Sumitomo Pharma Co Ltd Inactive Companies Universita di Perugia Highest Status Phase 3 Clinical  Active Indications Diarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertension  Target-based Actions Farnesoid X receptor agonist Other Actions Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies Oral formulation;Small molecule therapeutic	Drug Name	obeticholic acid
Active Companies  Intercept Pharmaceuticals Inc;Dainippon Sumitomo Pharma Co Ltd  Inactive Companies  Universita di Perugia  Highest Status  Phase 3 Clinical  Diarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertension  Target-based Actions  Farnesoid X receptor agonist  Other Actions  Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies  Oral formulation;Small molecule therapeutic	Key Synonyms	obeticholic acid
Inactive Companies  Universita di Perugia  Phase 3 Clinical  Active Indications  Diarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertension  Target-based Actions  Farnesoid X receptor agonist  Other Actions  Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies  Oral formulation;Small molecule therapeutic	Originator Company	Universita di Perugia
Highest Status  Phase 3 Clinical  Active Indications  Diarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertension  Target-based Actions  Farnesoid X receptor agonist  Other Actions  Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies  Oral formulation;Small molecule therapeutic	Active Companies	Intercept Pharmaceuticals Inc;Dainippon Sumitomo Pharma Co Ltd
Active Indications  Diarrhea;Liver disease;Primary biliary cirrhosis;Non-alcoholic steatohepatitis;Portal hypertension  Target-based Actions  Farnesoid X receptor agonist  Other Actions  Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies  Oral formulation;Small molecule therapeutic	Inactive Companies	Universita di Perugia
Target-based Actions Farnesoid X receptor agonist  Other Actions Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies Oral formulation;Small molecule therapeutic	Highest Status	Phase 3 Clinical
Other Actions  Bile acid modulator;Antihypertensive;Antidiarrhoeal  Technologies  Oral formulation;Small molecule therapeutic	Active Indications	
Technologies Oral formulation;Small molecule therapeutic	Target-based Actions	Farnesoid X receptor agonist
	Other Actions	Bile acid modulator;Antihypertensive;Antidiarrhoeal
Last Change Date 30-Nov-2012	Technologies	Oral formulation;Small molecule therapeutic
	Last Change Date	30-Nov-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 January 2012, a phase III PBC trial began in the US. In March 2011, a phase III trial was to be initiated in Europe. 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. At that time, the trial was expected to be completed in October 2012.

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** 



	1 11 41	0 1	5 1 1011	D 1
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

CAC Degistry Neurobers	Confidence Level
CAS Registry Number:	Confidence Level:
459789-99-2	2
HOW!!!	OH OH
Name	Туре
obeticholic acid	INN; USAN
INT-747	Research Code
6ECDCA	



#### obeticholic acid DRUG NAMES

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

## obeticholic acid CLINICAL TRIALS

# Trials by Phase and Condition Studied

	se 4 nical	Pha Clin		Pha Clin	se 2 lical		se 1 nical	Pha Unspe		То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Non-alco	holic steat	ohepatitis									
0	0	0	0	2	3	0	1	0	0	2	4
Primary b	oiliary cirrh	osis									
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 hy	pertension	l									
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 dise	Liver disease										
0	0	0	0	0	0	0	1	0	0	0	1



#### Total Trials by Phase and Status

	se 4 lical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All								
Total by	Phase an	d 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

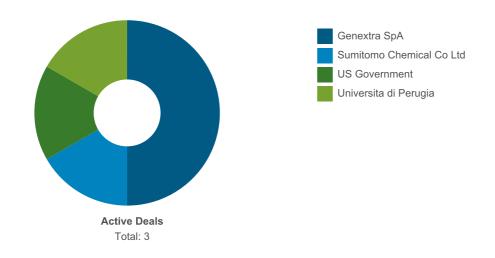
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1, 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

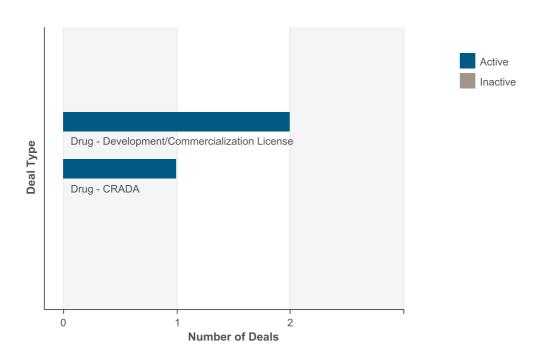




## **Deals by Parent Company Table**

Company Name	Prin Active	icipal Inactive	Par Active	tner Inactive	Total
Genextra SpA	2	0	1	0	3
US Government	0	0	1	0	1
Sumitomo Chemical Co Ltd	0	0	1	0	1
Universita di Perugia	1	0	0	0	1

## **Deals by Type Chart**

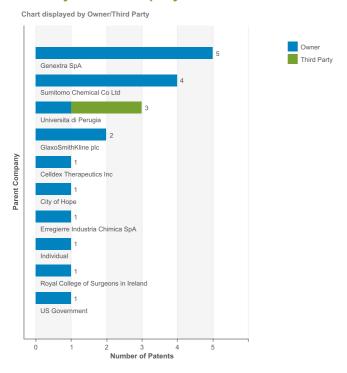


## **Deals by Type Table**

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

#### **PATENTS**

#### **Patents by Parent Company Chart**

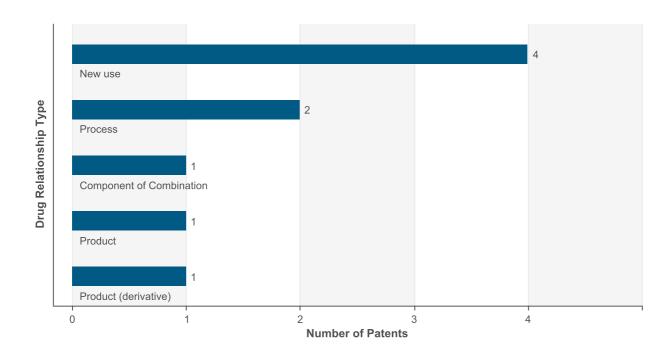


## **Patents by Parent Company Table**

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



## **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 (derivative)	1
Product	1



#### **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	Systemic formulation unspecified;Small molecule therapeutic
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	<b>Development Status</b>	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



## **INT-767 CHEMICAL STRUCTURES**

CAS Registry Number:	Confidence Level:
	4
	OH OH
Name	Туре
INT-767	Research Code

## **INT-767 DRUG NAMES**

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

## 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	Servier;Intercept Pharmaceuticals Inc
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	<b>Development Status</b>	Date
Intercept Pharmaceuticals Inc	Non-insulin dependent diabetes	US	Discovery	09-Aug-2011
Servier	Non-insulin dependent diabetes	France	Discovery	09-Aug-2011

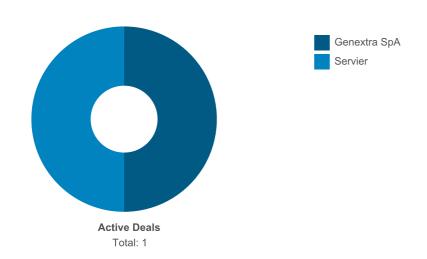
## TGR5 agonists (type 2 diabetes), Servier/ Intercept Pharmaceuticals DRUG NAMES

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



DEALS

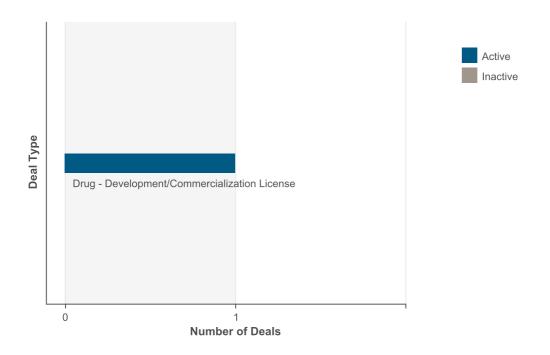
Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Genextra SpA	1	0	0	0	1
Servier	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

## **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	<b>Development Status</b>	Date
Intercept Pharmaceuticals Inc	Metabolic disorder	US	Discovery	17-Dec-2007

#### **INT-777 CHEMICAL STRUCTURES**

CAS Registry Number:	Confidence Level:
	3
HOWING H	он шин он
Name	Туре
INT-777	Research Code

#### **INT-777 DRUG NAMES**

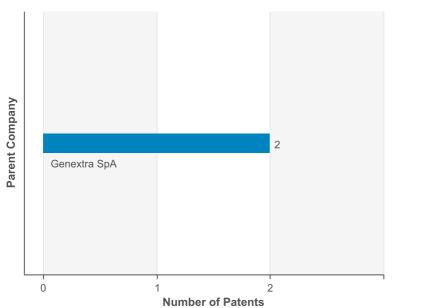
Names	Туре
TGR5 agonist (oral, metabolic disorder), Intercept	
INT-777	Research Code

## **INT-777 DEALS AND PATENTS**

## **PATENTS**

## **Patents by Parent Company Chart**

Chart displayed by Owner/Third Party



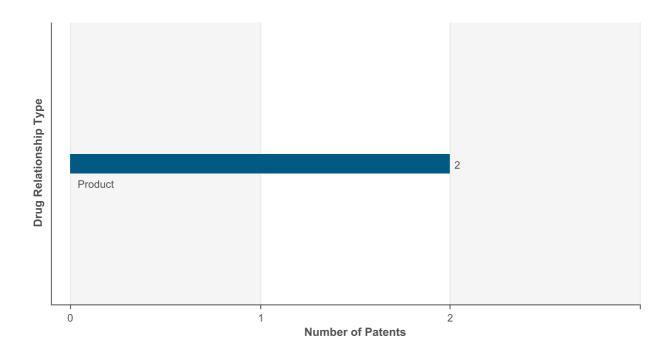




## **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
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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