IMS R&D Focus

Description

IMS R&D Focus provides both scientific and commercial development data for drugs from laboratory to international market launches. All stages of drug development, including biotechnological products, combinations, and new formulations can be monitored.

IMS R&D Focus is compiled from information provided directly by companies involved in R&D, interviews with key executives, official press releases and meetings. Additional sources include medical and clinical symposia, research conferences, scientific journals, trade journals and patents.

Subject Coverage

IMS R&D Focus provides comprehensive reviews and up-to-date news on drugs in development including full synonyms, licensing status, patent summary, development history, commercial potential, pre-clinical and clinical data, and commercial summaries.

Date Coverage

1994 to the present

Update Frequency

Weekly

Geographic Coverage

International

Document Types

Reports of drug development

Publisher

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ProQuest Dialog

IMS R&D Focus

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TI rivaroxaban

PD (Apr 2, 2014).

TX **Full text** Translate

GENERAL HISTORY - FULL REPORT

02 April 2014 : On 31 March 2014 Janssen reported that it has initiated additional trials of rivaroxaban (XARELTO) as part of a global cardiovascular research program, EXPLORER, in adults and children. These trials are being conducted in collaboration with its partner, Bayer. The MARINER trial will evaluate the safety and efficacy of rivaroxaban in reducing the risk of symptomatic deep vein thrombosis (DVT) and/or pulmonary embolism (PE) in medically ill patients. Approximately 8000 patients will be enrolled in at least 15 countries and will receive rivaroxaban or placebo once daily for up to 45 days following hospital discharge. The EINSTEIN JUNIOR program consists of several phase I, IIa, IIb and III trials and will assess the efficacy and safety of rivaroxaban for the treatment and secondary prevention of DVT and/or PE in children. The program will enroll at least 150 patients in 20 countries worldwide who will be dosed with rivaroxaban based on body weight and age. Enrollment is ongoing in a phase II trial in this program and a phase III trial is expected to begin in September 2014. Patient recruitment is also ongoing in another phase III trial (EINSTEIN CHOICE), under the EXPLORER program, comparing rivaroxaban with aspirin in the long-term, secondary prevention of symptomatic recurrent DVT and/or PE.Rivaroxaban, an oral factor Xa inhibitor, is available in most major markets worldwide for the prevention of venous thromboembolism in patients who have undergone elective total hip or total knee replacement surgery. The agent is also available in the USA, the EU and Japan for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, and in the EU and USA for the treatment and prevention of DVT and PE. Rivaroxaban is also available in the EU for secondary prevention of cardiovascular events following acute coronary syndrome (ACS). The agent is being co-developed by Janssen and Bayer under an agreement signed in October 2005; the product is marketed by Janssen in the USA and by Bayer outside the USA.

CURRENT DEVELOPMENT STATUS

Indication	Region	Report Event	Phase Change
cardiovascular disease	Worldwide	general	No Change

COMMERCIAL SUMMARY

Commercial overview

Overview

Bayer is developing an oral factor Xa inhibitor, rivaroxaban (XARELTO), as an antithrombotic agent. Rivaroxaban is available in most major markets worldwide for the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip or total knee replacement surgery. The agent is also available in the USA, the EU and Japan for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, and in the EU and the USA for the treatment and prevention of deep vein thrombosis (DVT) or pulmonary embolism (PE). In May 2013, the EMA approved rivaroxaban in combination with standard platelet therapy for secondary prevention following acute coronary syndrome (ACS). In December 2011, Janssen, a Johnson & Johnson company, submitted an sNDA to the US FDA for this indication; the US FDA issued a Complete Response letter in June 2012, and the company resubmitted the sNDA in September 2012. The FDA issued a second Complete Response letter in March 2013, and the sNDA was resubmitted in August 2013; in January 2014, the FDA's advisory committee voted not to recommend approval of rivaroxaban in this indication and issued a third Complete Response letter in February 2014. In May 2012, Janssen submitted an sNDA to the

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Regulatory progress

Acute coronary syndrome

USA

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Johnson & Johnson prevention of stent thrombosis.---Supplemental filing - May 2012. Janssen Research & Development, a Johnson & Johnson company, has submitted an sNDA to the US FDA seeking approval of rivaroxaban to reduce the risk of stent thrombosis in patients with acute coronary syndrome (ACS). The submission is based on data from the pivotal ATLAS ACS 2 TIMI 51 phase III trial of the agent (Janssen Research & Development, MAY 2012).---Submission withdrawn - Jul 2012. This sNDA is being withdrawn because it is contingent on the sNDA for rivaroxaban in the reduction of the risk of secondary cardiovascular events in patients with ACS, for which the US FDA issued a Complete Response letter in June 2012. Results from the ATLAS ACS 2 TIMI 51 trial support both sNDAs (Janssen Research & Development, JUL 2012).---Resubmission - Sep 2012. Janssen Research & Development has resubmitted the sNDA for rivaroxaban to reduce the risk of stent thrombosis in patients with ACS (Johnson & Johnson, SEP 2012).---Complete Response letter - Jun 2013. The US FDA has issued a Complete Response letter for this sNDA (Janssen Research & Development, JUN 2013).---Complete Response letter - Feb 2014. A Complete Response letter has been issued by the US FDA for this application (Johnson & Johnson, FEB 2014).

Johnson & Johnson.---Fast Track, USA (acute coronary syndrome) - Feb 2012. Rivaroxaban has been granted fast track designation by the US FDA for the treatment of acute coronary syndrome (Johnson & Johnson, FEB 2012).

Johnson & Johnson reduction of risk of thrombotic cardiovascular events.---Pre-registration - Dec 2011. Janssen Research & Development, a Johnson & Johnson company, has filed a supplemental NDA with the US FDA for approval of rivaroxaban use to reduce the risk of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS). The filing is supported by data from the ATLAS ACS 2-TIMI 51 pivotal trial (Janssen Research & Development, DEC 2011).---Priority Review - Feb 2012. This sNDA has been granted Priority Review by the US FDA (Janssen Research & Development, FEB 2012).---Not Recommended - May 2012. The US FDA's Cardiovascular and Renal Drugs Advisory Committee has recommended against approval of rivaroxaban, in combination with standard antiplatelet therapy, to reduce the risk of thrombotic cardiovascular events in patients with ACS (Janssen Research & Development, MAY 2012).---Complete Response letter - Jun 2012. The US FDA has issued a Complete Response letter to this sNDA. Janssen Research & Development is evaluating the letter and will respond to the FDA's questions (Janssen Research & Development, JUN 2012).---Update - Sep 2012. Janssen Research & Development has responded to the Complete Response letter from the US FDA. The response includes specific information requested by the FDA (Johnson & Johnson, SEP 2012).---Update - Sep 2012. As part of its complete response, Janssen Research & Development submitted data related to patients who had withdrawn from the ATLAS ACS 2 TIMI 51 trial (Janssen Research & Development, MAR 2013).---Complete Response letter - Mar 2013. The US FDA has issued a second Complete Response letter to this sNDA. Janssen Research & Development is evaluating the letter and will respond to the agency's questions (Janssen Research & Development, MAR 2013).---Resubmission - Aug 2013. The sNDA has been resubmitted to the US FDA (Janssen, JAN 2014).---Not Recommended - Jan 2014. The US FDA's Cardiovascular and Renal Drugs Advisory Committee has recommended against approval of rivaroxaban, in combination with standard antiplatelet therapy, to reduce the risk of thrombotic cardiovascular events in patients with ACS (Janssen, Bayer, JAN 2014).---Complete Response letter - Feb 2014. A Complete Response letter has been issued by the US FDA for this application (Johnson & Johnson, FEB 2014).

EU

Bayer.---Pre-registration - Dec 2011. Bayer has submitted a marketing authorization application to the EMA seeking approval for rivaroxaban in combination with standard platelet therapy for secondary prevention following acute coronary syndrome (ACS). The submission is supported by data from a pivotal phase III trial (ATLAS ACS 2-TIMI 51) of rivaroxaban in this indication (Bayer, DEC 2011).---Recommended - Mar 2013. The EMA's CHMP recommended approval of rivaroxaban 2.5 mg twice daily, in combination with standard antiplatelet therapy, for the prevention of atherothrombotic events after ACS in adult patients with elevated cardiac biomarkers (Bayer, MAR 2013).---Registered - May 2013. The EMA has approved rivaroxaban in this indication. The approval is based on data from the ATLAS ACS 2-TIMI 51 phase III trial of the agent in more than 15 500 patients (Bayer, MAY 2013).

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R&D progress

Stroke

Phase III, "NCT01674647; X-VeRT" (non-valvular atrial fibrillation), Bayer, Janssen, Worldwide.---DESIGN:Trial started - Oct 2012. A prospective, randomized, open-label, parallel-group, active-controlled, multicenter phase III trial has been conducted to assess the efficacy and safety of once-daily oral rivaroxaban compared with dose-adjusted oral vitamin K antagonists for the prevention of cardiovascular events in patients with non-valvular atrial fibrillation scheduled for cardioversion. The trial enrolled 1500 patients across 17 countries worldwide. The primary endpoint included a composite number of: stroke, transient ischemic attack, non-central nervous system systemic embolism, myocardial infarction and cardiovascular death. Source-http://www.janssenrnd.com/sites/default/files/pdf/Janssen_ACC%20Press%20Release_FINAL.PDF (Janssen, ClinicalTrials.gov, MAR 2014).---PROGRESS:Trial completed - Jan 2014. (ClinicalTrials.gov, MAR 2014).

Phase III, "NCT01729871; VENTURE-AF" (non-valvular atrial fibrillation), Janssen, Europe, USA.---DESIGN:Trial started - Feb 2013. An open-label, randomized, controlled, multicenter phase III trials has been started to evaluate the safety of rivaroxaban and uninterrupted vitamin K antagonist in adults with non-valvular atrial fibrillation who undergo catheter ablation. The trial will enroll up to 250 patients. The primary endpoint is incidence of post-procedure major bleeding events. Source-http://www.janssenrnd.com/sites/default/files/pdf/Janssen_ACC%20Press%20Release_FINAL.PDF (Janssen, ClinicalTrials.gov, MAR 2014).

Phase III, "NCT01830543; PIONEER AF-PCI", Bayer, Janssen, Worldwide.---DESIGN:Trial started - May 2013. An open-label, randomized, controlled, multicenter phase III has been initiated to assess the safety and efficacy of two treatment strategies of rivaroxaban and a dose-adjusted oral vitamin K antagonist treatment strategy, utilizing various combinations of dual antiplatelet therapy or low-dose aspirin or clopidogrel in patients with atrial fibrillation who undergo percutaneous coronary intervention. The trial will enroll 2100 patients worldwide. The primary endpoint is number of participants with clinically significant bleeding. Source-http://www.janssenrnd.com/sites/default/files/pdf/Janssen_ACC%20Press%20Release_FINAL.PDF (Janssen, ClinicalTrials.gov, MAR 2014).

Phase II, Bayer, Germany.---DESIGN:Trial started - Q2 2005. Bayer has initiated a German phase IIb trial of rivaroxaban in the prevention of stroke in patients with atrial fibrillation (Bayer, AUG 2005).

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Licensing/Partnering

Bayer, Janssen, Portola.---Portola enters into a clinical collaboration with Bayer and Janssen, Marketed - Feb 2014.Portola has signed a non-exclusive clinical collaboration agreement with Bayer and Janssen to conduct phase III registration trials of andexanet alfa in patients given rivaroxaban. The agreement will be effective through phase III evaluation and any potential regulatory approvals of andexanet alfa in the USA and the EU. Under the terms of the agreement, Portola will receive an upfront payment and is entitled to receive development- and regulatory-based milestone payments. Portola retains full global commercialization rights to andexanet alfa. Source-http://investors.portola.com/phoenix.zhtml?c=198136&p=irol-newsroomArticle&ID=1896088&highlight= (Janssen, MAR 2014; Portola, FEB 2014).

Bayer (Licensor), Almirall (Licensee).Spain ---Licensing agreement signed, Marketed - Feb 2012.Bayer and Almirall have signed an agreement for the co-promotion of rivaroxaban in Spain; the co-promotion will start in 2012 (Bayer, Almirall, FEB 2012).

Past Agreements.---Bayer and Ortho-McNeil, an affiliate of Johson & Johnson, have signed an agreement to jointly develop and market rivaroxaban for the prevention and treatment of thrombosis. Under the terms of the agreement, Ortho-McNeil will receive exclusive US marketing rights to the compound for the cardiology, primary care and hospital speciality markets. Bayer will retain an option to co-promote rivaroxaban in the hospital and speciality markets as well as marketing rights in countries outside the USA. In return, Ortho-McNeil will share global development costs and will pay Bayer an upfront payment as well as development-dependent milestone payments of approximately US$290 million. In addition, Ortho-McNeil will pay royalties of up to 30%, depending on sales thresholds, upon commercialization of the product in the USA (Bayer, Ortho-McNeil, OCT 2005).

Company predictions

Bayer - Jan 2013.---Bayer expects a decision on a regulatory filing in the EU seeking approval for the treatment of secondary prevention following acute coronary syndrome during early 2013 (Bayer, JAN 2013).

Bayer - Oct 2012.---Bayer expects approval of rivaroxaban in the EU for the treatment of pulmonary embolism and the prevention of recurrent deep vein thrombosis and pulmonary embolism in adults by end 2012 (Bayer, OCT 2012).

Analyst Predictions

Jefferies (13 Apr 2012): XARELTO (rivaroxaban), Bayer

Sales: EUR0 Billion in 2012, EUR1 Billion in 2013, EUR1 Billion in 2014, EUR1 Billion in 2015, EUR1 Billion in 2016 - year end December

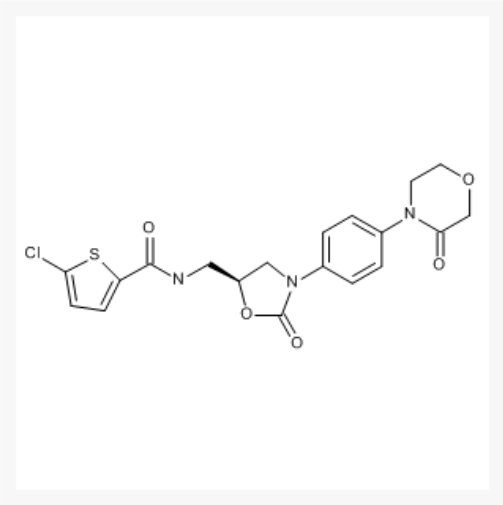
Jefferies (13 Apr 2012): XARELTO (rivaroxaban), Bayer

Jefferies predicts US regulatory decision in prevention of recurrent venous thromboembolism (VTE) fourth quarter 2012 and EU regulatory decision in the treatment of stroke prevention in atrial fibrillation (SPAF) second half 2012.

Jefferies (13 Jun 2012): XARELTO (rivaroxaban), Johnson & Johnson

Jefferies predicts a regulatory decision in the EU for approval of rivaroxaban for the treatment of acute coronary syndrome (ACS) and a regulatory decision in the USA for recurrent venous thromboembolism (VTE) prevention fourth quarter 2012.

Drawing or chemical structure



Chemical Name: 5-chloro-N-[[(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-5-oxazolidinyl]methyl]2-thiophenecarboxamide

Drug Development History

Event Date	Description
MAR 2014	EINSTEIN JUNIOR pediatric program
DATE UNKNOWN	EXPLORER global research program
FEB 2014	Bayer trial started (Phase III), Worldwide (deep vein thrombosis, pulmonary embolism) (long-term, secondary prevention of VTE)
FEB 2014	Johnson & Johnson Complete Response letter, USA (acute coronary syndrome) (reduction of risk of thrombotic cardiovascular events)
FEB 2014	Johnson & Johnson Complete Response letter, USA (acute coronary syndrome) (prevention of stent thrombosis)
FEB 2014	Portola enters into a clinical collaboration with Bayer and Janssen
JAN 2014	Johnson & Johnson not recommended for approval, USA (acute coronary syndrome) (reduction of risk of thrombotic cardiovascular events)
AUG 2013	Johnson & Johnson resubmitted for approval, USA (acute coronary syndrome) (reduction of risk of thrombotic cardiovascular events)
JUN 2013	Johnson & Johnson Complete Response letter, USA (acute coronary syndrome) (prevention of stent thrombosis)

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Drug Development Phases

Phase	Region	Indication
Marketed	USA	deep vein thrombosis
Marketed	USA	pulmonary embolism
Marketed	USA	stroke
Pre-registration	USA	acute coronary syndrome
Marketed	South Korea	thrombosis
Marketed	Japan	stroke
Marketed	EU	acute coronary syndrome
Marketed	EU	deep vein thrombosis
Marketed	EU	pulmonary embolism
Marketed	EU	stroke
Marketed	EU	thrombosis
Marketed	Canada	thrombosis
Marketed	Australia	thrombosis
Marketed	China	thrombosis
Marketed	Latin America	thrombosis
Marketed	Russia	thrombosis
Marketed	Singapore	thrombosis
Marketed	South Africa	thrombosis
Marketed	United Arab Emirates	thrombosis
Phase III	Worldwide	acute coronary syndrome

PATENT SUMMARY

Product (Bayer): US 03/153610 2003, priority DE 19962924 1999. Equivalents identified.

Indexing (details) Cite

SUBST

Substance — Substance: 5-chloro-N-[[(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-5-oxazolidinyl]methyl]2-thiophenecarboxamide;

RN

CAS: 366789-02-8

GN

Generic name: 5-chloro-N-[[(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-5-oxazolidinyl]methyl]2-thiophenecarboxamide

DN

Drug name: rivaroxaban

TN

Trade name: XARELTO

LAB

Laboratory code: BAY 597939, BAY 59-7939

RO

Route of administration: oral

MEC

Mechanism of action: protease inhibitor, serine protease inhibitor, blood clotting factor Xa inhibitor

TC

Therapeutic class: B1F: Direct Factor Xa Inhibitors

IND

Indication:
acute coronary syndrome
cardiovascular disease
cerebrovascular disease
deep vein thrombosis
peripheral vascular disease
pulmonary embolism
stroke
thrombosis

DST

Drug status: Active

CO

Company information:
Name: Bayer (Germany)
Role: Licensor
Parent: Bayer

		Name: Almirall (Spain) Role: Licensee Parent: Almirall Region: Spain
DOR		Name: Janssen (USA) Role: Licensee Parent: Johnson & Johnson Region: USA
LCO	**Originator**	Bayer (Germany). Role: Licensor. Parent: Bayer (Germany).
PHS	**Phase**	Marketed (80) in USA. Indication: deep vein thrombosis. Marketed (80) in USA. Indication: pulmonary embolism. Marketed (80) in USA. Indication: stroke. Pre-registration (60) in USA. Indication: acute coronary syndrome. Marketed (80) in South Korea. Indication: thrombosis. Marketed (80) in Japan. Indication: stroke. Marketed (80) in EU. Indication: acute coronary syndrome. Marketed (80) in EU. Indication: deep vein thrombosis. Marketed (80) in EU. Indication: pulmonary embolism. Marketed (80) in EU. Indication: stroke. Marketed (80) in EU. Indication: thrombosis. Marketed (80) in Canada. Indication: thrombosis. Marketed (80) in Australia. Indication: thrombosis. Marketed (80) in China. Indication: thrombosis. Marketed (80) in Latin America. Indication: thrombosis. Marketed (80) in Russia. Indication: thrombosis. Marketed (80) in Singapore. Indication: thrombosis. Marketed (80) in South Africa. Indication: thrombosis. Marketed (80) in United Arab Emirates. Indication: thrombosis. Phase III (50) in Worldwide. Indication: acute coronary syndrome.
HP	**Highest phase**	Marketed (80)
HI	**Development history**	MAR 2014 EINSTEIN JUNIOR pediatric program. DATE UNKNOWN EXPLORER global research program. FEB 2014 Bayer trial started (Phase III), Worldwide (deep vein thrombosis, pulmonary embolism) (long-term, secondary prevention of VTE). FEB 2014 Johnson & Johnson Complete Response letter, USA (acute coronary syndrome) (reduction of risk of thrombotic cardiovascular events).

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PAT	**Patent information**	Patent assignee: Bayer
LA	**Language**	English
DTYPE	**Document type**	Report
PSTYPE	**Publication type**	Report
PD	**Publication date**	Apr 2, 2014
DSTAT	**Document status**	MajorUpdate
	Source attribution	IMS R&D Focus, © Publisher specific
AN	**Accession number**	2015916
	Document URL	http://search.proquest.com/professional/docview/577337283?accountid=137296
FAV	**First available**	2010-07-13
UD	**Updates**	2012-06-29 2012-07-06 2012-07-13 2012-08-31 2012-09-07 2012-09-14 2012-10-26 2012-11-09 2012-11-23 2013-01-25 2013-03-01 2013-03-08 2013-04-01 2013-05-31 2013-07-05 2013-08-09 2013-10-25 2014-01-30 2014-02-21 2014-04-04
	Database	IMS R&D Focus (1994 - current)

SEARCH FIELDS

You can use field codes on the Basic Search, Advanced Search, and Command Line Search pages to limit searches to specific fields. The table below lists the field codes for this file.

Field Name	Field Code	Example	Description and Notes
Accession number	AN	an(2015916)	A unique document identification number assigned by the information provider.
All fields (except full text)	ALL	all("prevention of venous thromboembolism")	Searches all fields *except* the full text.
All fields + text	--	"prevention of venous thromboembolism"	Searches all fields including the full text.
CAS® Registry Number	RN	rn(366789-02-8)	Also searchable using the Substance field code (SUBST).
Classification[1]	TC SUB	tc(B1F) tc(direct factors Xa inhibitors) sub(direct factors Xa inhibitors)	"TC" searches the classification code and name. "SUB" searches classification name only.
Company	CO	co(bayer)	CO searches Company, Parent, Originator, and Licensee.
Country of launch/development	CLD	cld(germany)	Displayed in the "DEVELOPMENT PHASE" section of the text
Development history (including patent events)	HI	hi("Einstein junior" LNK "global research program") hi("priority product patent application")	
Document status	DSTAT	dstat(new) dstat(majorupdate) dstat(minorupdate)	
Document text	TX	tx("global cardiovascular research program")	
Document title	TI	ti(rivaroxaban)	Usually the generic name of the drug.
Title only	TIO	tio(rivaroxaban)	The name of the drug. (Same as TI in this database)
Document type	DTYPE	dtype(report)	All documents in IMS R&D Focus are Reports.
Drug name	DN	dn(rivaroxaban)	The generic name of the drug
Drug status	ST	st(active) st(inactive)	States whether the drug is in active development or not
First available	FAV	fav(2010-07-13)	Indicates the first time the record was loaded onto PQD. It will not change however many times the record is subsequently reloaded, as long as the accession number does not change.
From database[2]	FDB	co(janssen) AND fdb(IMSRANDDFOCUS) co(janssen) AND fdb(1007820)	Useful in multi-file searches to isolate records from a single file. FDB cannot be searched on its own; specify at least one search term then AND it with FDB.

[1] A Lookup/Browse feature is available for this field in the Advanced Search dropdown or in Browse Fields.
[2] Click the "Field codes" hyperlink at the top right of the Advanced search page. Click "Search syntax and field codes" then click on "FDB command" to get a list of database names and codes that can be searched with FDB.

Field Name	Field Code	Example	Description and Notes
Generic name	GN	gn(posaconazole)	
Highest phase	HP	hp(marketed)	The highest phase of development reached by the drug anywhere in the world
Indication[1]	IND	ind(thrombosis)	
Laboratory code	LAB	lab("BAY 597939")	
Language	LA	la(english)	All documents are in English.
Licensee	LCO	lco(almirall)	
Licensing availability	ALIC	alic(usa) alic(worldwide)	
Mechanism of action[1]	MEC	mec("protease inhibitor")	
Origin of substance	OS	os("chemical synthesis")	
Originator	DOR	dor(bayer)	
Patent event date	HI	hi(2010)	Displays with "Development history" in Document View.
Patent assignee	PA	pa(bayer)	Displays with "Patent information" in Document View.
Patent information	PAT	pat(bayer)	Includes Patent Assignee and Patent Summary.
Phase	PHS	phs("phase iii" LNK worldwide)	Includes the Phase, Region, and Indication of the drug in development. Place LNK or -- between "Phase" and "Region" and again between "Region" and "Indication" to link all terms accurately.
Publication date	PD	pd(20140402) pd(20130101-20131231)	Date range searching is supported.
Publication title	PUB	pub(ims r&d focus)	All documents are from IMS R&D Focus
Publication type	PSTYPE	pstype(report)	All documents in IMS R&D Focus are the same type – report.
Publication year	YR	yr(2014) yr(2013-2014)	The publication year displays in "Publication date". Date range searching is supported.
Region	RG	rg(worldwide)	Region in which the drug has reached the stage of development noted in the 'Drug Development Phases' table.
Route of administration	RO	ro(oral)	
Substance	SUBST	subst(aripiprazole) subst(abilify) subst(129722-12-9)	Includes Chemical Name, Trade Name, Generic Name, and CAS Registry Number.
Therapeutic classification	TC SUB	tc(B1F) tc(direct factors Xa inhibitors) sub(direct factors Xa inhibitors)	"TC" searches the classification code and name. "SUB" searches classification name only.
Trade name Trade name - drug	TN TNDRUG	tn(xarelto) tndrug(xarelto)	

Field Name	Field Code	Example	Description and Notes
Updated	UD	ud(2014-04-04)	Date that documents were added or revised in ProQuest Dialog, to incorporate changes by an information provider.

In addition to ***Search Fields***, other tools available for searching are ***Limit Options***, ***Browse Fields***, and ***"Narrow Results By" Limiters***. Each is listed separately below. Some data can be searched using more than one tool.

Limit Options

Limit options are quick and easy ways of searching certain common concepts*.* Check boxes are available for:

Active development, Development ceased, Available for licensing, Major change to record in this update, Drugs with a tradename, Documents with images

Short lists of choices are available for:

Phase, Highest phase, Drug status, Route of administration, Origin of substance

Date limiters are available in which you can select single dates or date ranges for **Updated** and **Patent event date.**

Browse Fields

You can browse the contents of certain fields by using Look Up lists. These are particularly useful to validate spellings or the presence of specific data. Terms found in the course of browsing may be selected and automatically added to the Advanced Search form. Look Up lists are available in the fields drop-down an din the search options for:

Classifications, Mechanism of action

And in the fields drop-down only for **Companies, Indications**

"Narrow Results By" Limiters

When results of a search are presented, the results display is accompanied by a list of "Narrow results by" options shown on the right-hand panel. Click on any of these options and you will see a ranked list showing the most frequently occurring terms in your results. Click on the term to apply it to ("narrow") your search results. "Narrow results by" limiters in IMS R&D Focus include:

Classification, Highest phase, Company, Publication date, Mechanism of action, Indication

Notes

Excel Custom Export Fields

If you choose to export your data in Excel (XLS) you have the option to use a custom format to output only the fields you need. PQD shows ALL fields for ALL databases in the custom pick list – not just the ones that are appropriate to this database. The following lists only those fields that may appear in the *IMS R&D Focus* database.

Field Name	Detail
Accession Number	Provider's unique record identifier
Article Type	Same for all records
CAS Registry Number	CAS Registry Number
Company Information	Supports One-to-Many; the following fields will also be output if you select *Multiple rows per item by: Company Information*
• Company Information – Name	
• Company Information – Type	One of two values: Originator or Licensor
• Company Information – Role	Further detail on the role the company plays in the development or marketing of the drug

• Company Information – Country/Region	
• Company Information – Parent	The parent company name and the country in which they're based
Database	Same for all records
Document Status	
Document Type	Same for all records
Document URL	
Drug Name	See Title
Drug Status	
Drug Synonym	
First Available	
Generic Name	
Indication	
Language	
Language Of Summary	
Licensing Information	
Mechanism Of Action	
Patent Assignee	
Phase Of Development	Supports One-to-Many; the following fields will also be output if you select *Multiple rows per item by: Phase Of Development*
• Phase Of Development – Phase	
• Phase Of Development – Country/Region	
• Phase Of Development – Indication	
• Phase Of Development – Route Of Administration	Not populated for *IMS R&D Focus*
• Phase Of Development – Formulation	Not populated for *IMS R&D Focus*
• Phase Of Development – On Fast Track	Not populated for *IMS R&D Focus*
• Phase Of Development – Qualifiers And Comments	Not populated for *IMS R&D Focus*
Phase Of Development (Highest)	
Publication Date	
Publication Title	Same for all records
Publication Type	Same for all records
Publication Year	
Route Of Administration	
Source Attribution	Same for all records
Source Type	Same for all records
Store ID	PQD's internal unique record identifier
Substance	
Therapeutic Class (EPhMRA)	
Title	The name of the drug
Tradename	
Updates	

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