

Cortellis使用手冊

2017. 12



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認識Cortellis

Cortellis醫藥情報的綜合資料庫，以藥品為中心提供從研發、臨床試驗、上市註冊、交易及法規等綜合情報

法規
(Regulatory)

交易
(Deals)

會議
(Conference)

專利 (Patent)

論文
(Literature)

臨床試驗
(Clinical Trials)

藥品報告 (Drug Report)

研發公司/機構
(Company)

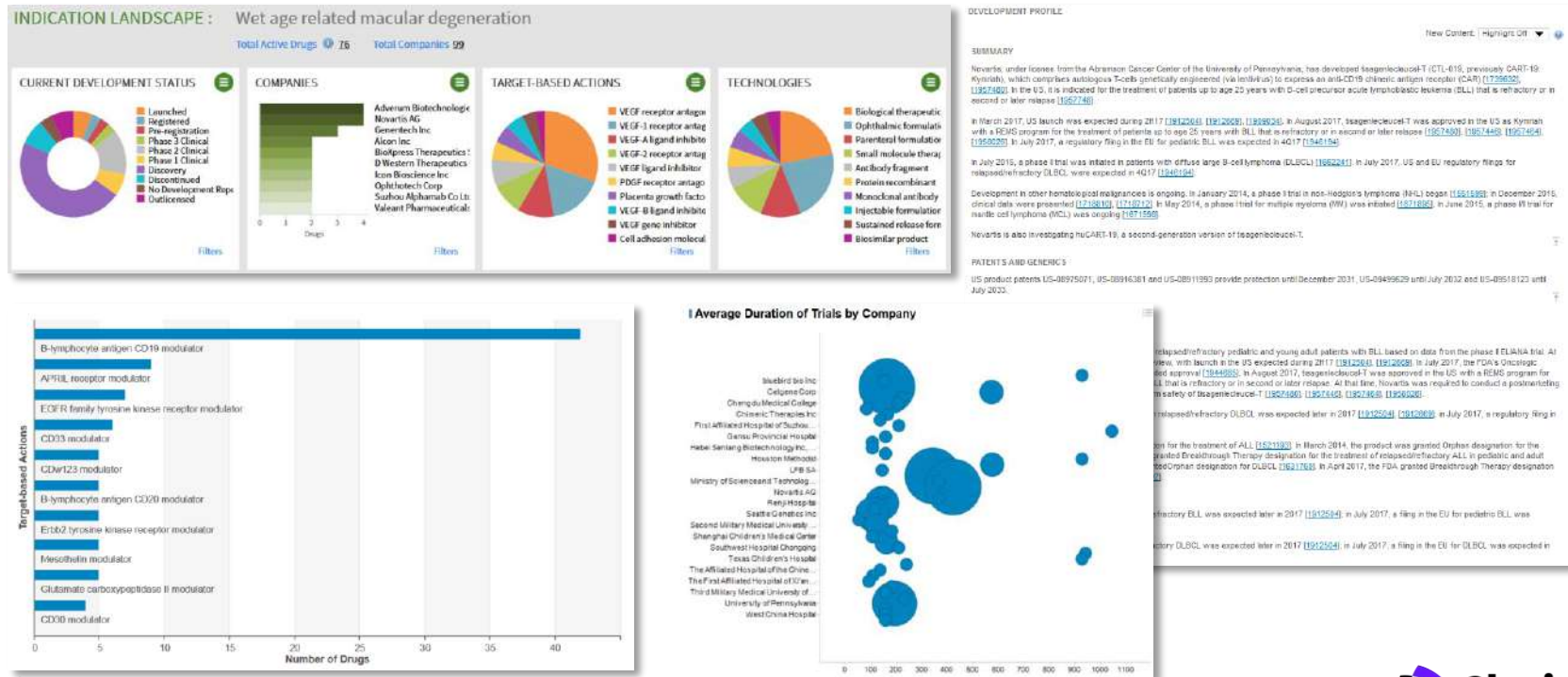
新聞報導 (Press
Release)

疾病綜述*
(Disease Briefing)

券商報告*
(Broker Research)

電話會議逐字稿*
(Event Transcript)

Cortellis提供可溯源的藥品研發情報及分析圖表，供您即時瞭解藥品研發動態



DEVELOPMENT PROFILE

SUMMARY

Novartis, under license from the Abramson Cancer Center of the University of Pennsylvania, has developed isageniciceptin-T (CTL-019, previously CART-19; Kynriah), which comprises autologous T-cells genetically engineered (via lentivirus) to express an anti-CD19 chimeric antigen receptor (CAR) [1759620]. [1527400]. In the US, it is indicated for the treatment of patients up to age 25 years with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse [162746].

In March 2017, US launch was expected during 2017 [1912063], [1912063]. In August 2017, isageniciceptin-T was approved in the US as Kynriah with a REMS program for the treatment of patients up to age 25 years with ALL that is refractory or in second or later relapse [1527400], [1917440], [1927464]. [1950020]. In July 2017, a regulatory filing in the EU for pediatric ALL was expected in 4Q17 [194104].

In July 2016, a phase I trial was initiated in patients with diffuse large B-cell lymphoma (DLBCL) [1622411]. In July 2017, US and EU regulatory filings for relapsed/refractory DLBCL were expected in 4Q17 [194104].

Development in other hematological malignancies is ongoing. In January 2014, a phase I trial in non-Hodgkin's lymphoma (NHL) began [1641909]. In December 2016, clinical data were presented [170810], [170912]. In May 2014, a phase I trial for multiple myeloma (MM) was initiated [1671869]. In June 2015, a phase II trial for acute lymphoma (ALL) was ongoing [1671599].

Novartis is also investigating hucART-18, a second-generation version of isageniciceptin-T.

PATENT \$ AND GENERIC \$

US product patents US-86975071, US-86916361 and US-86911993 provide protection until December 2031, US-86996229 until July 2032 and US-86918123 until July 2033.

Target-based Actions

Target-based Action	Number of Drugs
B-lymphocyte antigen CD19 modulator	42
APRIL receptor modulator	10
ECDFR family tyrosine kinase receptor modulator	8
CD33 modulator	7
CDw123 modulator	6
B-lymphocyte antigen CD20 modulator	5
ErbB2 tyrosine kinase receptor modulator	4
Mesothelin modulator	3
Glutamate carboxypeptidase II modulator	2
CD30 modulator	1

Average Duration of Trials by Company

- Bluebird bio Inc.
- Cellgene Corp.
- Chongqing Medical College
- Chronic Therapeutics Inc.
- First Affiliated Hospital of Soochow ...
- Genex Provinces Hospital
- Hubei Sanyang Biotechnology Inc. ...
- Hexacon Healthcare
- UFB SA
- Ministry of Science and Technol...
- Hipocrite AG
- Rajiv Hospital
- Saath e Genetec Inc.
- Second Military Medical University ...
- Shanghai Children's Medical Center
- Southeast Hospital Chongqing
- Texas Children's Hospital
- The Affiliated Hospital of the Chine...
- The First Affiliated Hospital of GZ...
- The Third Military Medical University of...
- University of Pennsylvania
- West China Hospital

relapsed/refractory pediatric and young adult patients with ALL based on data from the phase I ELIANA trial. At review, with launch in the US expected during 2017 [1912063], [1912063]. In July 2017, the FDA's Oncologic and approval [1640005]. In August 2017, isageniciceptin-T was approved in the US with a REMS program for ALL that is refractory or in second or later relapse. At that time, Novartis was required to conduct a postmarketing safety study of isageniciceptin-T [1927460], [1927460], [1927460], [1950020].

relapsed/refractory DLBCL was expected later in 2017 [192504], [192504]. In July 2017, a regulatory filing in

on for the treatment of ALL [1621930]. In March 2014, the product was granted Orphan designation for the granted Breakthrough Therapy designation for the treatment of relapsed/refractory ALL in pediatric and adult and Orphan designation for DLBCL [1621763]. In April 2017, the FDA granted Breakthrough Therapy designation

refractory ALL was expected later in 2017 [192504]. In July 2017, a filing in the EU for pediatric ALL was

DLBCL was expected later in 2017 [192504]. In July 2017, a filing in the EU for DLBCL was expected in

All ▾

Search Cortellis



個人設定及登出

Advanced search | Structure search

 Full text. Index

檢索功能區:

快速檢索 (Quick Search)
結構式檢索 (Structure Search)
進階檢索 (Advanced Search)

Cortellis涵蓋:

Competitive Intelligence (競爭情報): 藥品研發pipeline及市場動態監控
Clinical Trials Intelligence (臨床情報): 臨床試驗規劃, 降低試驗風險
Deals Intelligence (交易情報): 交易授權benchmark及價值評估
Regulatory Intelligence (法規情報): 依各國上市法規指引及規劃上市路徑
Disease Briefings (疾病綜述): 疾病背景及臨床應用評估

Live chat

Competitive Intelligence



Clinical Trials Intelligence



Deals Intelligence



Regulatory Intelligence



Disease Briefings



News



All

Search Cortellis



瀏覽(Explore):

不需檢索直接進入相應的報告或分析內容，
包含臨床試驗*、全球藥品/醫材法規**及疾
病綜述(Disease Briefing***)

*需訂閱Clinical Trials Intelligence

**需訂閱Cortellis Regulatory Intelligence

***需訂閱疾病綜述

Live chat

Deals Intelligence

Regulatory Intelligence

Disease Briefings

News

帳戶設定、檢索紀錄、登出

設定 (Setting)

- 使用者資訊(My Account):
- 內容設定(My Content)
- 使用者喜好(My Preference)

檢索 (Search)

- 檢索及通知(Search and Alert)
- 檢索歷史紀錄 (Search History)

登出

All ▾ Search Cortellis

Advanced search | Structure search

Help

客戶技術支援(Customer Care)

訓練資源: (Training Resources):

- 學習中心(learning center): 提供Cortellis 入門指南
- 線上說明書 (online user guide)
- 訓練課程(public training): 需註冊並預約線上課程

知識庫(Knowledge Base): 連結至Cortellis 用戶論壇及給予Cortellis 建議

Live chat

Competitive Intelligence

學習中心

線上說明書

News

點選回到首頁

Advanced search | Structure search

瀏覽(Explore):

不需檢索直接進入相應的報告或分析內容，
包含全球藥品/醫材法規*及疾病綜述**

*需訂閱Cortellis Regulatory Intelligence

**需訂閱疾病綜述

Live chat

Competitive Intelligence

Clinical

即時交談(Live Chat):
即時與Cortellis 客服線上提問

Deals In

Regulatory Intelligence

Disease Briefings

News

調整模組順序或展開各模組內容:

↓ : 該模組向下移動

↑ : 該模組向上移動

+ : 展開內容

競爭情報首頁入口

藥品佈告欄:

最新一周研發階段更新的藥品列表

研發藥品總覽:

點選圖示連結相應藥品報告

分析:

競爭全景概覽(Competitive Landscape Viewer)

點選查看所有藥品、公司、專利、文獻、券商報告

The screenshot displays the Cortellis interface with several key components:

- Navigation Panel (Left):** Includes buttons for 'Drugs', 'Companies', 'Patents', 'Literature', and 'Broker research'.
- Drugs Filter (Top):** Shows 'From 13/01/2018' and 'To 20/01/2018'. A 'Status' dropdown is set to 'Launched'.
- Drug List (Middle):** A list of drugs including 'rituximab biosimilar, Sandoz', 'L-glutamine (oral, sickle cell anemia/sl...', and 'melatonin (controlled release, insomnia)...'. A link 'View all 7 Launched Drugs' is visible.
- Donut Chart (Right):** A donut chart showing the distribution of drugs by status: Pre-Clinical (orange), Clinical (purple), and Approved (green).
- Analysis Sidebar (Far Right):** Titled 'Analysis', it contains links for 'Competitive landscape viewer', 'Competitive intelligence matrix', 'Virtual merger', and 'Intellectual property landscape'. A descriptive paragraph states: 'Launch the competitive landscape viewer to monitor a portfolio via a one click visualization tool, bringing the power of all Cortellis competitive intelligence content into a series of interactive dashboards'. A 'Competitive landscape viewer' button is at the bottom.

臨床情報首頁入口

Clinical Trials Intelligence

點選查看所有臨床試驗報告

Report Type	Results	Filter: Last 30 days	Filter: Last 30 days	Filter: Last 30 days	Filter: Last 30 days	Filter: Last 30 days
231856 Clinical Trial results						
Show selected only	Title	Condition	Patient Segment	Biomarkers	Interventions	Phase
Clinical Trials (231856)	Phase 3 Study of the Oncology Medication in Relapsed/Refractory CLL	Filters: (0)	Filters: (0)	Filters: (0)	mgmgzmlzab alone	Phase 3 Clinical
Refine Search						
Search within Results:						
Search						
▼ Condition						
<input type="checkbox"/> Pain (10592)						
<input type="checkbox"/> Non-insulin-dependent diabetes (1126)						
<input type="checkbox"/> Breast tumor (1094)						
Show all filters						
▶ Patient Segment						

View all

Clinical trials

Clinical trials

View all Clinical trials information



分析：
臨床試驗時程及試驗中心分析

Analysis

[Clinical trials timeline](#)

Launch an interactive visualization of clinical trials timelines around a condition and recruitment status

Condition

Recruitment status

Analyze

交易情報首頁入口

Deals Intelligence



點選查看所有交易報告

Report Type	Results	Sort by	Most Recent Last Date	View	Filter	Reset	Last 60
Deal Title	Principal Company	Partner Company	Agreement Type	Deal Asset Type	Deal Transaction Type		
Regeneron and Decibel Therapeutics Inc. announce a collaboration to develop and commercialize Regeneron's first-in-class, oral, small molecule, JAK2 inhibitor, regalizumab, for the treatment of myelodysplastic syndromes (MDS).	Regeneron Pharmaceuticals Inc.	Decibel Therapeutics	Drug - Drug Discovery/Design	Drug - Drug Discovery Technology	Collaboration (Shared responsibilities)		
Levi's Pharmaceuticals Australia to use BiZ's Boston platform for antibody discovery projects.	Berkeley Lights Inc.	Levi's Pharmaceuticals Australia Pty Ltd	Technology - Other Proprietary	Drug Discovery Technology	Basic License (Licensee takes over)		
Emerald acquires majority stake in Vero Pharmaceuticals.	Vero Pharmaceuticals Inc.	Emerald Health Therapeutics Inc.	Company - M&A (in whole or part)	Capital (Equity/Loans/Equity In/ Royalty Buyout)	Equity/Equity Option (SOP Stake - Standalone)		

Deals

View all Deals information, formerly known as Recap



View all

Deals

疾病綜述首頁入口

Disease Briefings

點選查看所有疾病綜述內容

158 Disease Briefings

DISEASE BRIEFINGS

Expand all

<input type="checkbox"/> NEWLY REPUBLISHED (1)	<input type="checkbox"/> Musculoskeletal and Connective Tissue Disorders (12)
<input type="checkbox"/> Autoimmune Disorders (13)	<input type="checkbox"/> Neurological Disorders (22)
<input type="checkbox"/> Bioterrorism (3)	<input type="checkbox"/> Pain (4)
<input type="checkbox"/> Cancer (23)	<input type="checkbox"/> Poisoning (1)
<input type="checkbox"/> Cardiovascular Disorders (9)	<input type="checkbox"/> Psychiatric Disorders (11)
<input type="checkbox"/> Critical Care Medicine (4)	<input type="checkbox"/> Rare Diseases (28)
<input type="checkbox"/> Dermatological Disorders (12)	<input type="checkbox"/> Renal Disorders (2)
<input type="checkbox"/> Endocrine Disorders (8)	<input type="checkbox"/> Reproductive Health (4)
<input type="checkbox"/> Eye Disorders (5)	<input type="checkbox"/> Respiratory Disorders (18)
<input type="checkbox"/> Gastrointestinal Disorders (18)	<input type="checkbox"/> Substance Abuse and Dependence (4)
<input type="checkbox"/> Genetic Disorders (12)	<input type="checkbox"/> Women's Health (11)
<input type="checkbox"/> Genitourinary Disorders (7)	
<input type="checkbox"/> Hematologic Diseases (8)	
<input type="checkbox"/> Immunological Disorders (3)	
<input type="checkbox"/> Infections (35)	
<input type="checkbox"/> Men's Health (4)	
<input type="checkbox"/> Metabolic Diseases (11)	

Disease briefings

Browse all content related to
Disease briefings



Search

在Cortellis裡檢索

檢索

Cortellis

快速檢索:

在此輸入藥名、公司名、適應症、標靶、技術...關鍵字



進階檢索

組合一種以上的檢索條件或索引

結構式檢索:

繪製化學結構用於檢索

Tina Chao | Help

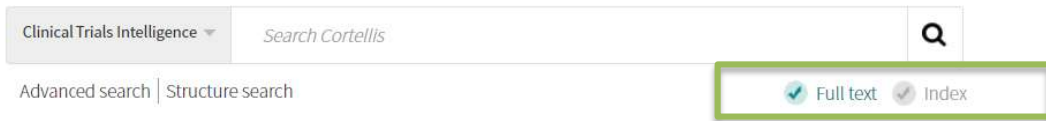


全文檢索及標籤檢索

Cortellis

Explore ▾

Tina Chao | Help



全文檢索

(Full-text search)

在Cortellis大多數的文件中檢視符合您的搜索條件的關鍵字並呈現其結果。

然而，全文檢索不包括藥品報告中的發展階段(development status) 和最高階段 (highest status)

索引檢索

(Index search)

檢索範圍限縮在以下已索引的內容:

- 藥品名稱(Drug names)
- 公司/機構名稱 (Company names)
- 標靶 (Action)
- 適應症 (Indication)
- 技術 (Technology)

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全文檢索及索引檢索-以藥品報告為例

藥品報告			
分頁	欄位	全文檢索	索引檢索
快照 (Snapshot)	Drug Name	√	√
	Other Drug Names	√	√
	Originator Company (and Ancestor)	√	√
	Active Companies (and Ancestor)	√	√
	Inactive Companies (and Ancestor)	√	√
	Active Indication (and Ancestor)	√	√
	Inactive Indications (and Ancestor)	√	√
	Target-based Actions (and Ancestor)	√	√
	Other Actions (and Ancestor)	√	√
	Regulatory Designations	√	√
	Technologies (and Ancestor)	√	√
研發概況 (Development Profile)	Development Profile Summary	√	
	Development Profile Other Fields	√	
文獻探討 (Literature Review)	Literature Review	√	
藥品名稱 (Drug Names)	Drug Names	√	√
SWOT分析 (SWOT Analysis)	SWOT Analysis	√	
銷售及預測 (Sales and Forecasts)	Commentary	√	
	Drugs Marketers (and Ancestor)	√	√
資料來源 (Sources)	Sources	√	
未顯示於藥品報告	Drug ID	√	√

結構式檢索*

*檢索範圍: 藥品報告(Drug Reports)、論文報告 (Literature Reports)、專利報告 (Patent Reports) 或會議報告 (Conference Presentations)

Cortellis

Clinical Trials Intelligence Search Cortellis

Advanced search **Structure search**

複製藥品報告裡的結構式或自行繪製

Structure search

Exact match | Flexible | Similarity | Substructure

Molecular Weight <-

Copy Structure | Paste Structure | Clear Structure

dotmatics

Explore

Tina Chao | Help

Clarivate
Analytics

點選此處展開結構式繪製工具

dotmatics

Cortellis
Powering Life Science

te

結構式檢索(續)

Structure search

Exact match | Flexible | Similarity | Substructure

Molecular Weight

<=

Copy Structure | Paste Structure | Clear Structure

Exact match

與檢索對話框中所示的結構完全符合

Similarity

比對相似結構

預設: 相似度80%，使用者可自訂相似度在60%-100%之間。

Flexible match

比對相同結構的立體異構物(stereoisomers)、互變異構物(tautomers)、鹽類(salts)以及電荷異構物(charge variants)

Substructure

- 1) 與檢索對話框中所示的結構完全符合; 或
- 2) 將對話框裡的結構做為子結構(substructure) 與更大的結構式比對

進階檢索

Cortellis

Competitive Intelligence ▾

Search Cortellis



Explore ▾

Tina Chao | Help



Full text Index

< Back | Forward >

Advanced Search

Advanced Search - Drugs

Search Strategy (non-editable)

根據報告類型*，選擇對應的分頁

Drugs

Patents

Literature

Clinical Trials

Regulatory

Deals

Structure Search ▾

Any Action

AND ▾

Current Development Status ▾

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*分頁選項視使用者訂閱內容而呈現

進階檢索-以藥品報告為例

Advanced Search - Drugs

Search Strategy (non-editable) 

Drugs Patents 

Select 

AND  Any Action 

AND  Select 

Add an [additional search field](#)

Structure Search 

Reset **SEARCH**

下拉式選單，可選擇不同的欄位及組合檢索條件


- Select
- Active Companies
- Inactive Companies
- Originator Company
- Active Indications
- Inactive Indications
- Any Action
- Technologies
- EphMRA Codes
- Other Drug Names
- Highest Status
- Highest Status at Termination
-
- First Launched Status
- Regulatory Designations
- Added Date
-
- Current Development Status**
- Development Profile
- Any Text

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進階檢索-以藥品報告為例(續)


Advanced Search - Drugs


Search Strategy (non-editable) 


Drugs Patents Literature Clinical Trials Regulatory Deals

Structure Search 

Select

AND  Any Action

AND  Select

Add an additional search field 

Reset **SEARCH**

點選展開索引清單

以AND 或 OR 或 NOT結合不同檢索條件

進階檢索-以藥品報告為例(續)

ADVANCED SEARCH - ANY ACTION

programmed cell death protein 1 Look up

Select from those listed below

Hierarchy Look-up List

輸入關鍵字查詢相應的索引標籤

- Antimicrobial (10150)
- Blood system agent (2617)
- CNS modulator (10271)
- Cardiovascular agent (7762)
- Cell control agent (23196)
- Cell modulator (7513)
- Dermatological agent (1992)
- Diagnostic agent (1092)
- Gastrointestinal system agent (1378)
- Gene target (1357)
- Genetic modulator (3485)
- Immunomodulator (19941)
- Musculoskeletal system modulator (1031)
- Ophthalmological agent (1236)
- Other actions (13822)
- Pathway modulator (12851)
- Protein target (40157)
- Renal system agent (425)
- Reproductive system modulator (265)

Defence protein modulator (364)

Enzyme modulator (16569)

Protein ligand (3195)

Receptor modulator (17053)

Regulatory protein modulator (4821)

Programmed cell death protein modulator (106)

- Programmed cell death protein 1 modulator (104)
 - Programmed cell death protein 1 stimulator (1)
 - Programmed cell death protein 1 inhibitor (98)
- Programmed cell death protein 2 modulator (105)
 - Programmed cell death protein 2 stimulator (1)
 - Programmed cell death protein 2 inhibitor (98)
- Programmed cell death protein 3 modulator (106)
 - Programmed cell death protein 3 stimulator (1)
 - Programmed cell death protein 3 inhibitor (98)
- Programmed cell death protein 4 modulator (107)
 - Programmed cell death protein 4 stimulator (1)
 - Programmed cell death protein 4 inhibitor (98)
- Programmed cell death protein 5 modulator (108)
 - Programmed cell death protein 5 stimulator (1)
 - Programmed cell death protein 5 inhibitor (98)
- Programmed cell death protein 6 modulator (109)
 - Programmed cell death protein 6 stimulator (1)
 - Programmed cell death protein 6 inhibitor (98)
- Programmed cell death protein 7 modulator (110)
 - Programmed cell death protein 7 stimulator (1)
 - Programmed cell death protein 7 inhibitor (98)
- Programmed cell death protein 8 modulator (111)
 - Programmed cell death protein 8 stimulator (1)
 - Programmed cell death protein 8 inhibitor (98)
- Programmed cell death protein 9 modulator (112)
 - Programmed cell death protein 9 stimulator (1)
 - Programmed cell death protein 9 inhibitor (98)
- Programmed cell death protein 10 modulator (113)
 - Programmed cell death protein 10 stimulator (1)
 - Programmed cell death protein 10 inhibitor (98)

點選  加入要檢索的索引標籤，點選Apply 完成選擇

[註] 若選擇2個(含)以上的索引標籤，不同索引標籤會以OR 連結，例如：

Any Action ▼ Programmed cell death protein 1 stimulator OR Programmed cell death protein 1 inhibitor

Selected terms

Programmed cell death protein 1 stimulator

Programmed cell death protein 1 inhibitor

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arivate alytics

Cancel Clear All Apply

Competitive Landscape Viewer

競爭全景概覽

進入CLV: Competitive Intelligence→Competitive Landscape Viewer

Competitive Intelligence

View all

Drugs

Companies

Patents

Literature

Broker research

Patents gazette

[Latest](#) | [By date](#) | [Alert](#)

Week 47 2017

- 40 New Compounds
- 193 New Uses, Formulations and Methods of Treatment
- 23 Chemical Processes and Combinatorial Technology
- 128 Biotechnology
- 34 Devices and Equipment
- 273 European and US Granted Patents
- 4 UK Initial A0 Applications

Active drugs coverage by highest status

- Pre-Clinical
- Clinical
- Approved



點選進入CLV

[Competitive intelligence matrix](#) | [Virtual merger](#) | [Intellectual property landscape](#)

Launch the competitive landscape viewer to monitor a portfolio via a one click visualization tool, bringing the power of all Cortellis competitive intelligence content into a series of interactive dashboards

[Competitive landscape viewer](#)

選擇適應症、標靶、技術或公司，輸入關鍵字以展現相應競爭概況

Cortellis Competitive Intelligence Search Cortellis

Advanced search

< Back | Forward >

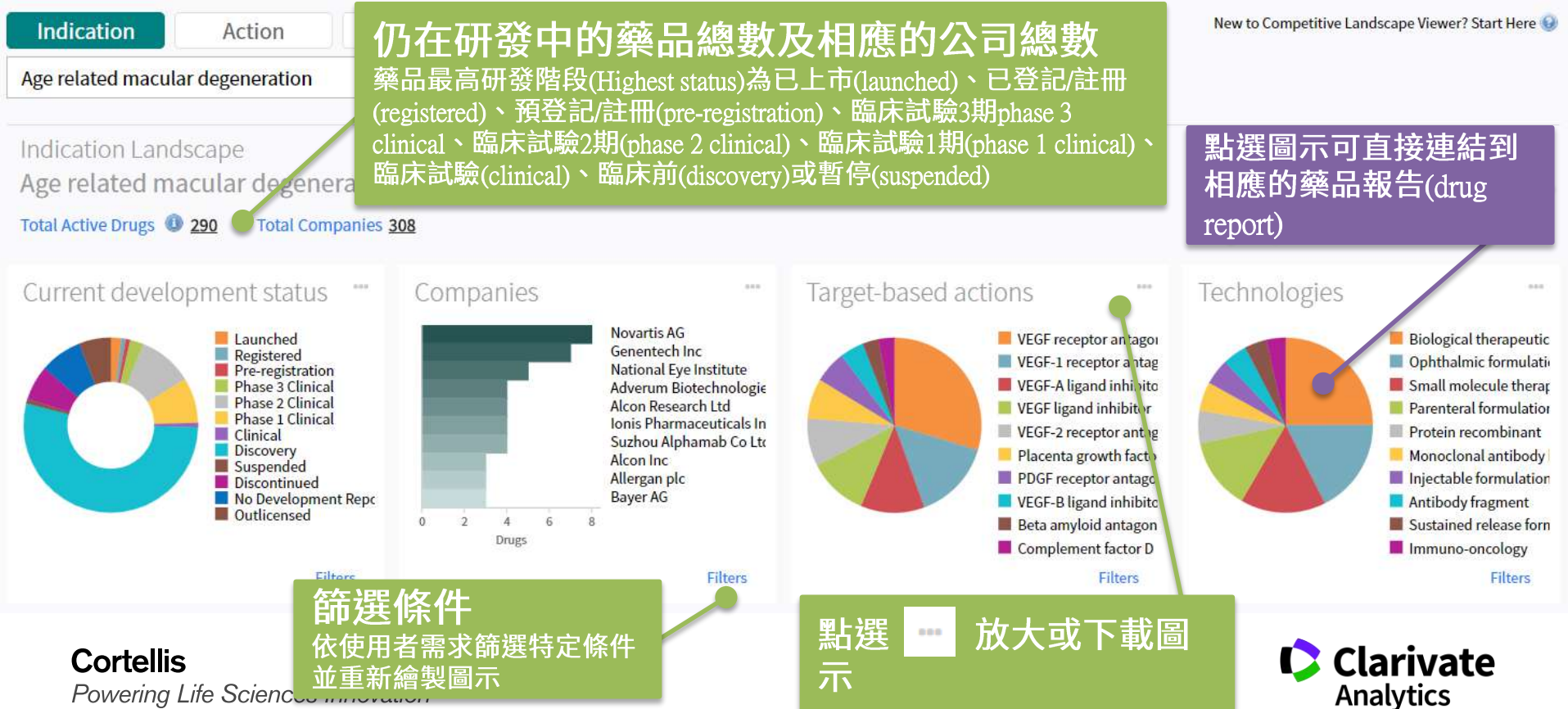
Indication Action Technology Company

macular degeneration Look up

- Age related macular degeneration
- Dry age related macular degeneration
- Macular degeneration
- Wet age related macular degeneration

針對適應症、標靶、技術或公司，輸入相應的關鍵字，點選Look up
以老年性黃斑部退化(age-related macular degeneration)為例，按下look up後即提供相應的適應症名稱供使用者點選

概覽同適應症、標靶、技術或公司的競爭全景



依您的需求篩選符合特定條件的藥品並重新檢視競爭全景

Indication

Macular degenerati

Indication Land

Macular degen

Total Active Drugs

Current develo

Look up

Target-based actions

Technologies

Filters

Filters

VEGF receptor antagon (40)

VEGF-1 receptor antagon (20)

VEGF-A ligand inhibitor (16)

VEGF ligand inhibitor (15)

VEGF-2 receptor antagonist (12)

Placenta growth factor ligand inhibitor (10)

PDGF receptor antagonist (8)

VEGF-B ligand inhibitor (6)

VEGF gene inhibitor (5)

Beta amyloid antagonist (4)

Complement factor D inhibitor (4)

PDGF receptor beta antagonist (4)

Protein tyrosine kinase inhibitor (4)

CCR3 chemokine antagonist (3)

VEGF receptor antagon

VEGF-1 receptor antag

Advanced gly

Amyloid prote

C-type lectin c

Cathelicidin in

CD11b antago

Complement Factor in

Hepatocyte growth fac

L-Selectin antagoni

Biological therapeutic

Small molecule therap

formulation

ic formulati

combinant

ragment

product

Immuno-oncology

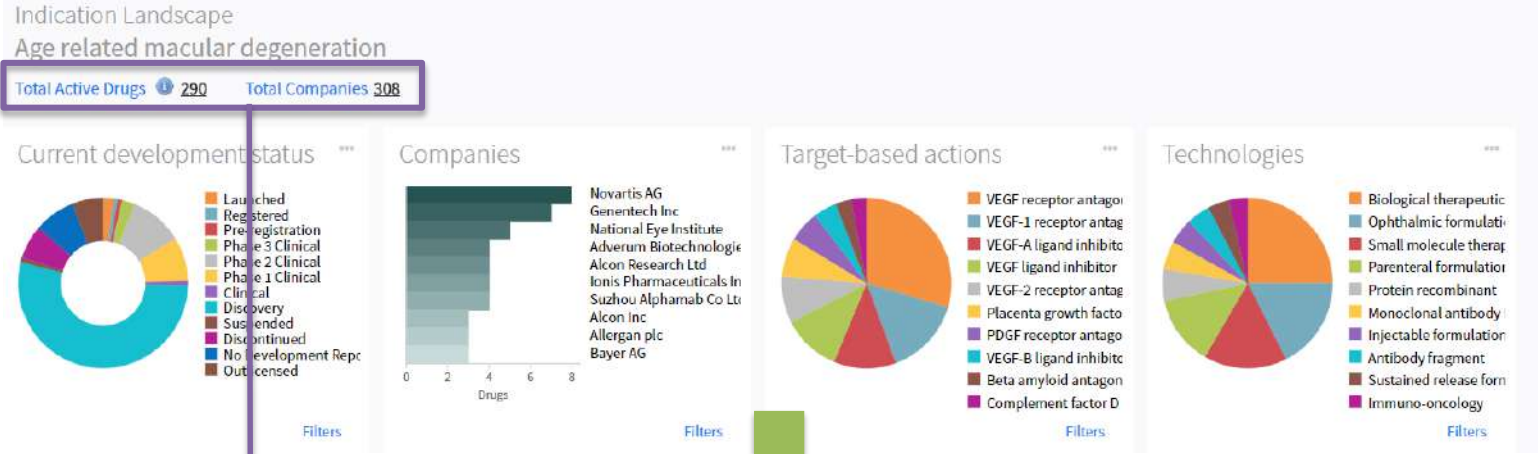
Monoclonal antibody

Oligosaccharide

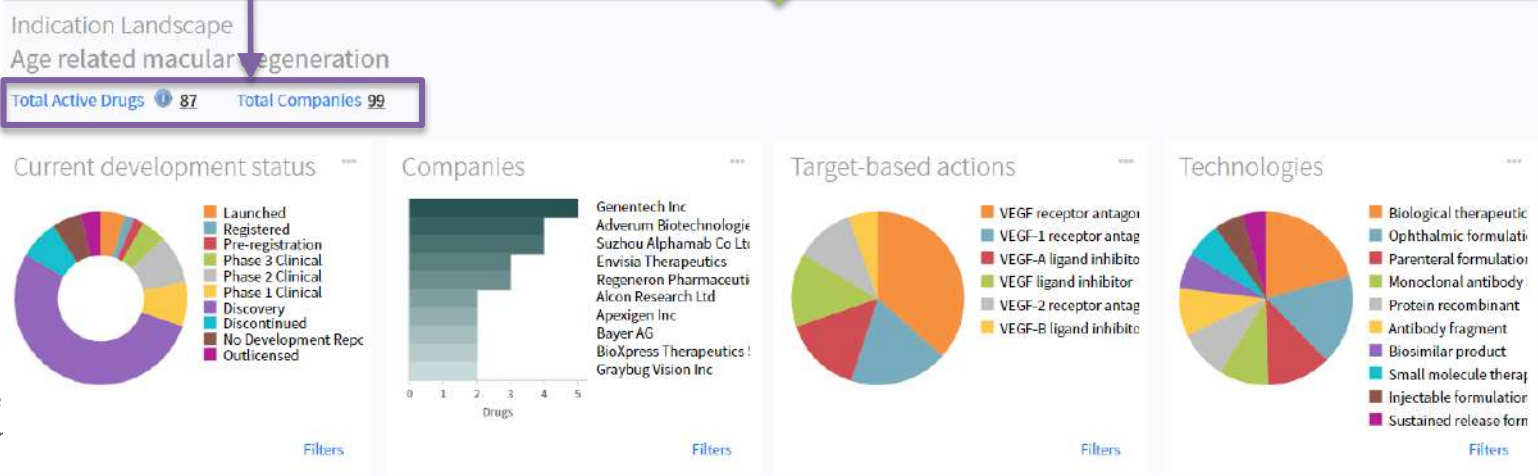
依使用者需求勾選後，
按下Apply更新CLV

篩選條件
依使用者需求篩選特定條件
並重新繪製圖示

篩選前



篩選後



Corte
Powerir

ivate
tics

全球發展概況

Country of development

Drugs 0 160



點選  下載單張圖示

Country of development

Top five

US (180)
Japan (27)
South Korea (23)
China (22)
Australia (18)

Filters

在各國的研發數量投入
依數量排序

Corporate headquarters

Top five

US (169)
Japan (20)
South Korea (19)
Switzerland (18)
China (16)

Filters

研發藥品的公司/機構
總部所在國家
依數量排序

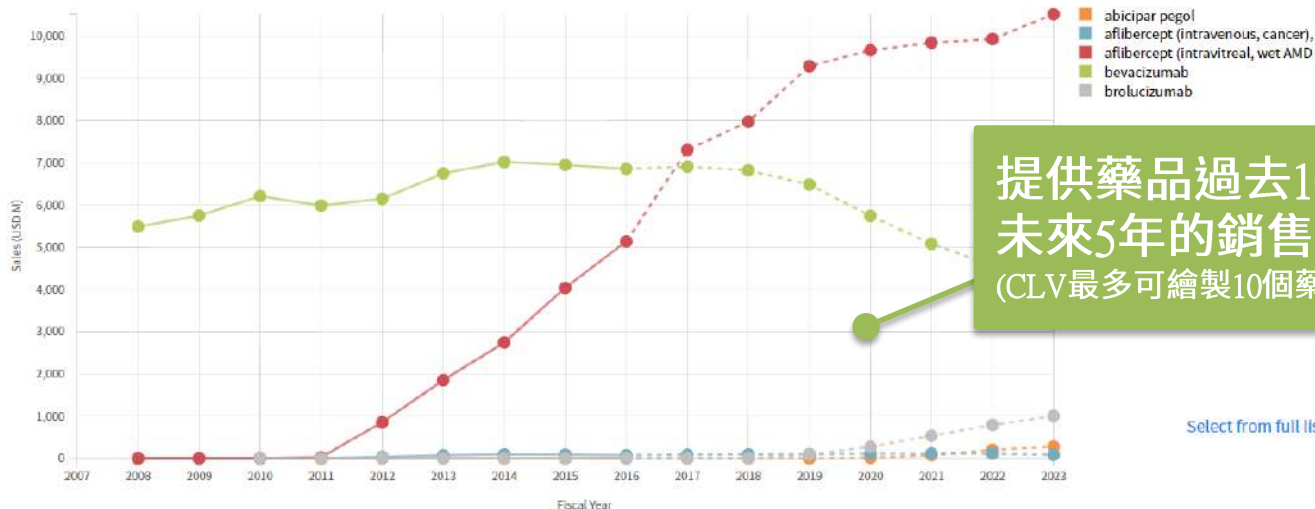
藥品銷售額及預測銷售額

Drug Sales And Forecasts

[22 Drugs with Sales and Forecasts Data](#)

Total reported and consensus forecast sales

點選  下載單張圖示



提供藥品過去10年銷售額及
未來5年的銷售額
(CLV最多可繪製10個藥品的銷售趨勢圖)

[Select from full list of drugs](#)

交易全景總覽

藥品相應的交易總數

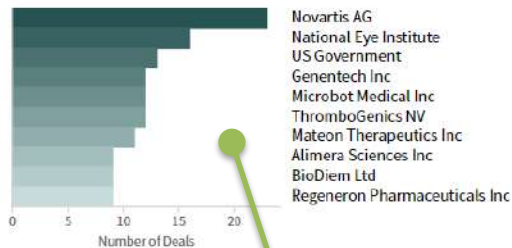
點選可直接連結交易報告(drug report)

Deals

406 Deals linked to 290 Selected Drugs

點選  下載單張圖示

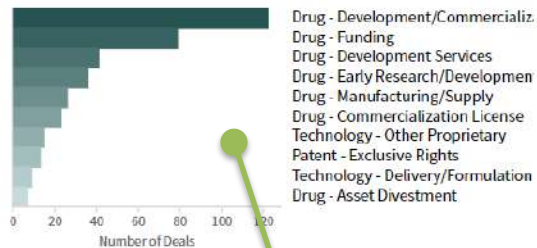
Company



Filters

交易涉及的公司
(依數量排序)

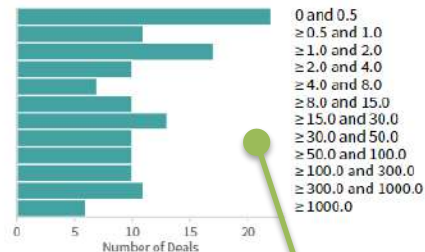
Deal type



Filters

交易類型
(依數量排序)

Current projected value (USD M)



Filters

交易金額
(依金額區間排序)

臨床試驗總覽

藥品相應的臨床試驗總數
點選可直接連結臨床試驗報告(clinical trials report)

勾選即顯示正在進行中的
臨床試驗
(執行階段為:招募中(recruiting)或尚未開始招募(Not recruiting yet))

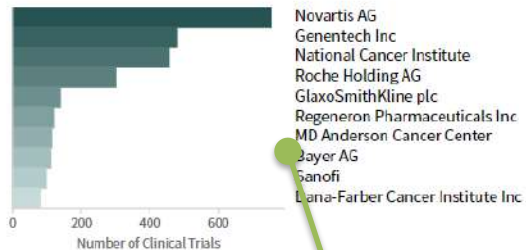
Clinical Trials

[6039 Clinical Trials linked to 290 Selected Drugs](#)

點選  下載單張圖示

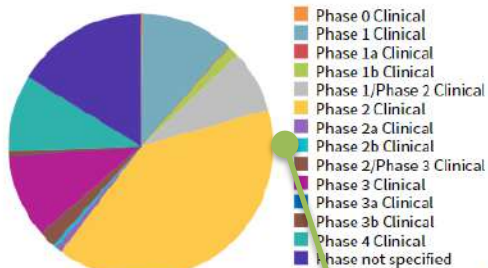
Ongoing only ⓘ

Company



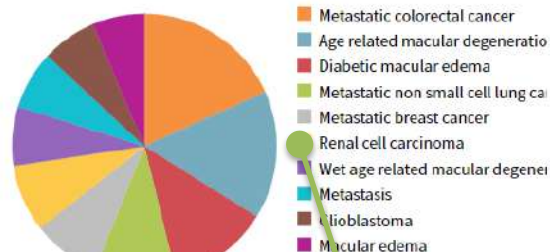
執行臨床試驗的公司
(依數量排序)

Phase



臨床試驗分期

Condition



臨床試驗涉及的適應症

專利全景總覽

藥品相應的專利總數

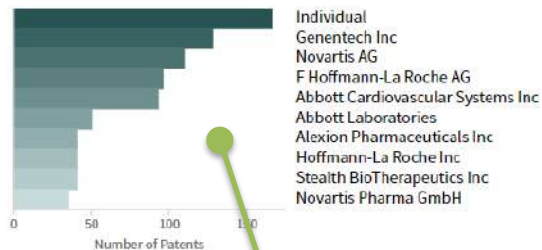
點選可直接連結專利報告(patent report)

Patents

[1719 Patents linked to 290 Selected Drugs](#)

點選  下載單張圖示

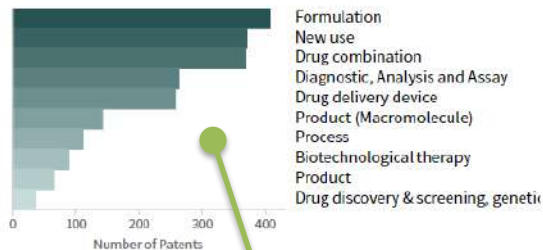
Owner companies



Filters

專利所有權人/公司
(依數量排序)

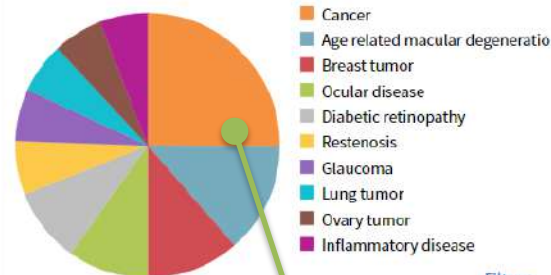
Patent type



Filters

專利類型
(依數量排序)

Indications



Filters

專利涉及的適應症

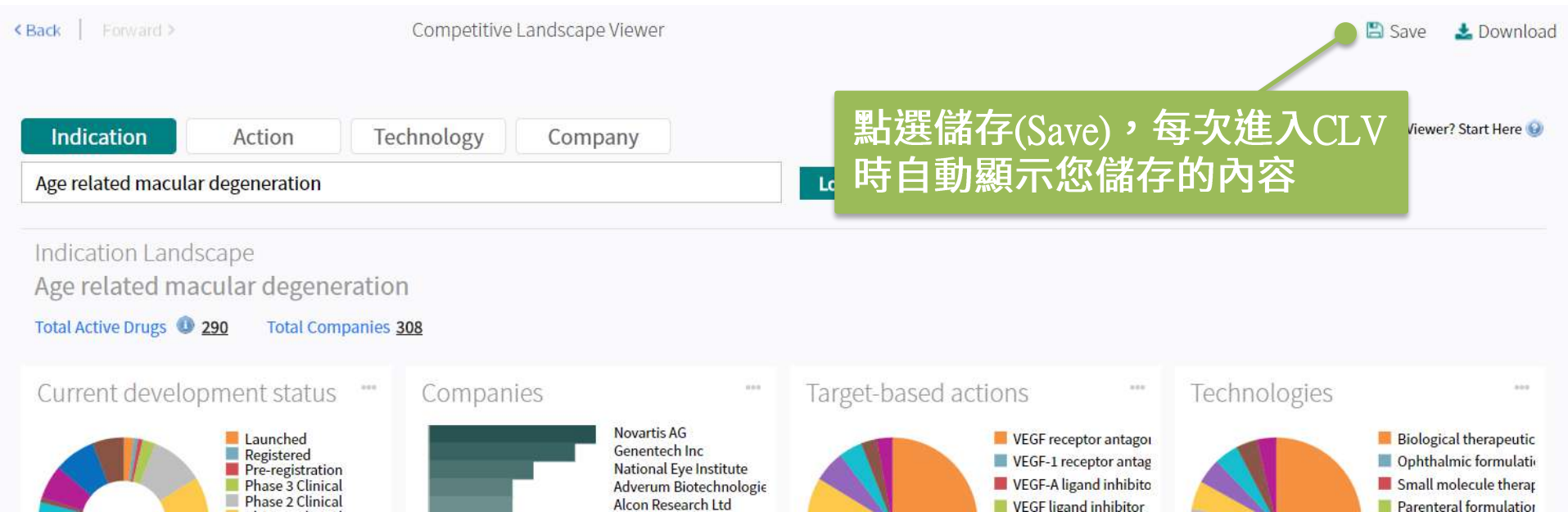
Cortelli

Powering Life Sciences Innovation

Analytics

下載競爭全景概覽圖示

儲存競爭全景概覽



點選儲存(Save)，每次進入CLV時自動顯示您儲存的內容

下載競爭全景圖示

Competitive Landscape Viewer

Save Download

Indication Action

Age related macular degeneration

Indication Landscape
Age related macular degeneration

Total Active Drugs 290 Total Competitors

Current development status

- Launched
- Registered
- Pre-registration
- Phase 3 Clinical
- Phase 2 Clinical

Technologies

- Biological therapeutic
- Ophthalmic formulation
- Small molecule therapy
- Parenteral formulation

1. Choose Document Format

STEP 1 of 2 - CHOOSE THE DOCUMENT FORMAT

- Microsoft PowerPoint
- Adobe PDF

Cancel Next

點選下載(Download)，將CLV圖
示下載為Power Point或PDF，點
選Next
(以下以Power Point格式為例)

下載競爭全景圖示(續)

Competitive Landscape Viewer

Back Forward Save Export

Indication Action

Wet age related macular dege

INDICATION LANDSCAPE

CURRENT DEVELOPMENT STAGE

Launch
Registe
Pre-reg
Phase

DOWNLOAD

1. Choose Document Format 2. Select Content

STEP 2 of 2 - SELECT CONTENT

Available content

Drug Sales And Forecasts
Deals
Clinical Trials
Patents

Add >
Add All >>
< Remove
<< Remove All

Selected content

Drugs
Select Available
Current development status
Companies
Target-based actions

指定下載的圖表後按下
Download
點選要下載的圖表並點選Add 或Add All加入所有圖表;

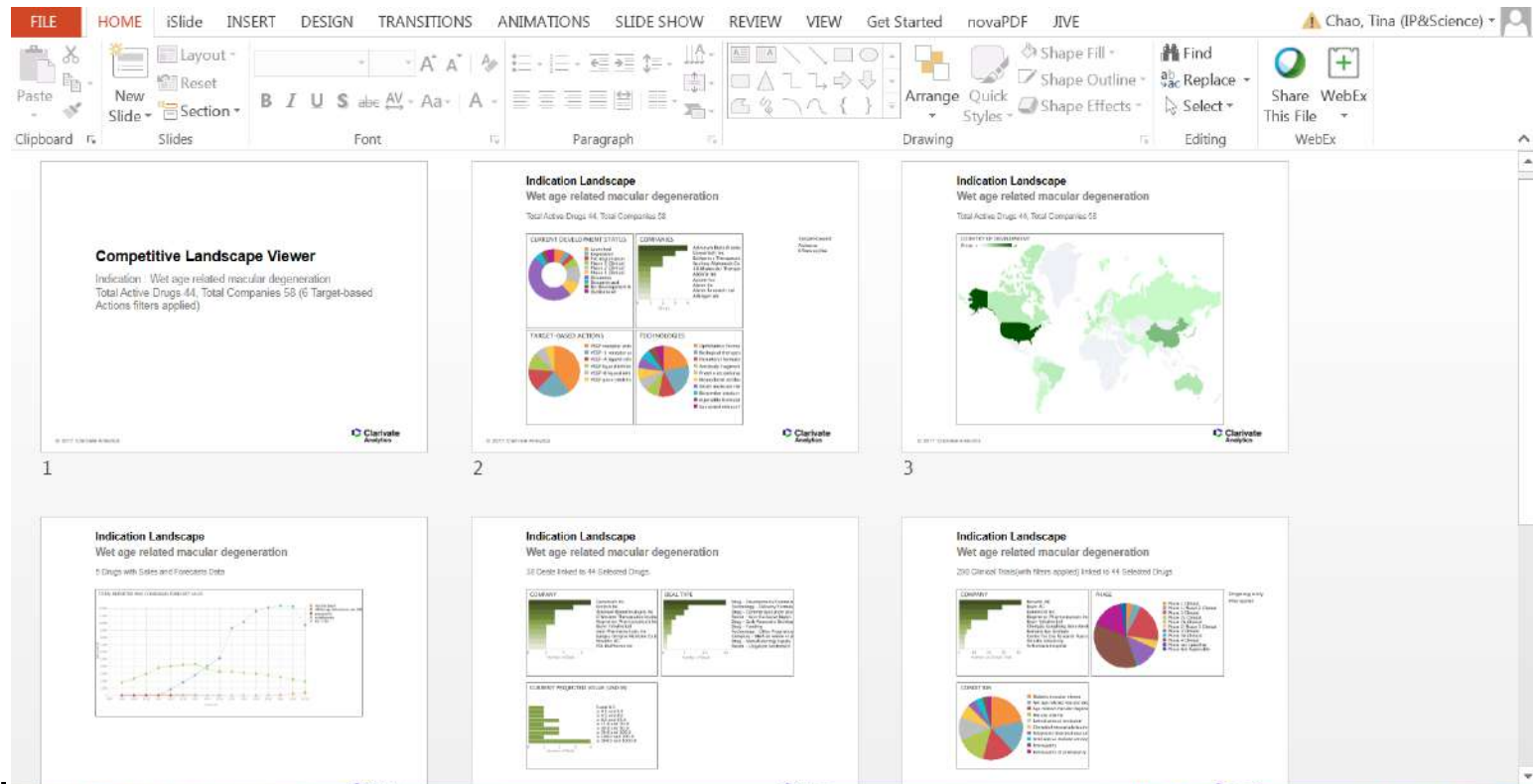
Cancel Previous Download

New to Competitive Landscape Viewer? Start Here

TECHNOLOGIES

Ophthalmic formulati
Biological therapeutic
Parenteral formulatio

下載競爭全景圖示為Power Point或PDF



Disease Briefings

疾病綜述

疾病綜述 (Disease Briefings)

提供**158種疾病***(涵蓋20個治療領域)的情報，包含:

- 病因
- 發病率/流行率
- 診斷
- 預防
- 治療: 治療類型、標靶(target)及相應的藥品研發pipeline
- 已上市的藥品清單

每份報告另提供相關的輔助材料，如詞彙表(glossary)，多媒體插圖列表和建議閱讀。

*統計至2017.12為止

1. 使用Quick Search, 再點選左側Disease Briefing

The screenshot displays the Cortellis search interface. At the top left is the Cortellis logo. A search bar contains the query "non-small-cell lung cancer" and is highlighted with a purple box. To the right of the search bar are options for "Advanced search" and "Structure search", and checkboxes for "Full text" and "Index". Further right, there is an "Explore" dropdown menu, the user name "Tina Chao", a "Help" link, and the Clarivate Analytics logo.

Below the search bar, the page shows "Search Results" with a "Download" button. It indicates "6 results found for 'non-small-cell lung cancer'". A table of results is displayed with columns for "Report Type", "Results", and "View". The "Disease Briefings (6)" category is highlighted with a purple box. The results include:

- Bioactives (1698)**: [Lung Cancer](#)
- Broker Research (40558)**: that cell growth exceeds cell death. Cancer cells are abnormal cells that outlive healthy cells, dividing without the normal control mechanisms and accumulating into a mass...b> cell lung cancer (NSCLC) and small cell lung cancer (SCLC...other parts of the body (van Meerbeeck, J.P. et al (2011)). Several risk factors for lung cancer have been
- Companies (1478)**: [Prostate Cancer](#)
- Conferences (2400)**
- Deals (1862)**
- Disease Briefings (6)**: that cell growth exceeds cell death. Cancer cells are abnormal cells that outlive healthy cells, dividing without the normal control mechanisms and accumulating into a...of prostate cancers originate (Lee, C.H. et al (2011)). Prostate cancer may remain confined to the prostate gland for long periods of time, in some cases indefinitely...Prostate cancer may also spread through the vascular system to other sites including lung, lymph nodes, liver and, rarely, brain. I
- Drugs (3848)**
- Event Transcripts (7700)**: [Nicotine Addiction](#)

2. 自清單中選擇 Explore→Disease Briefings

Cortellis

All ▾ "non-small-cell lung cancer" 🔍 **Explore ▾**

Clinical Trials Intelligence >

Competitive Intelligence >

Deals Intelligence >

Disease Briefings >

Regulatory Intelligence >

News >

Disease briefings

Browse all content related to Disease briefings



點選

Tina Chao | Help

 Clarivate
Analytics

Cortellis
Powering Life Sciences Innovation

 Clarivate
Analytics

2. 自清單中選擇 Explore→Disease Briefings

DISEASE BRIEFINGS

[Expand all](#)

- [Autoimmune Disorders \(13\)](#)
- [Bioterrorism \(3\)](#)
- [Cancer \(23\)](#)
- [Cardiovascular Disorders \(9\)](#)
- [Critical Care Medicine \(4\)](#)
- [Dermatological Disorders \(12\)](#)
- [Endocrine Disorders \(8\)](#)
- [Eye Disorders \(5\)](#)
- [Gastrointestinal Disorders \(18\)](#)
- [Genetic Disorders \(12\)](#)
- [Genitourinary Disorders \(7\)](#)
- [Hematologic Diseases \(8\)](#)
- [Immunological Disorders \(3\)](#)
- [Infections \(34\)](#)
- [Men's Health \(4\)](#)
- [Metabolic Diseases \(11\)](#)
- [Musculoskeletal and Connective Tissue Disorders \(12\)](#)
- [Neurological Disorders \(22\)](#)
- [Pain \(4\)](#)
- [Poisoning \(1\)](#)
- [Psychiatric Disorders \(11\)](#)
- [Rare Diseases \(28\)](#)
- [Renal Disorders \(2\)](#)
- [Reproductive Health \(4\)](#)
- [Respiratory Disorders \(18\)](#)
- [Substance Abuse and Dependence \(4\)](#)
- [Women's Health \(11\)](#)

點選可展開下階清單

158 Disease Briefings

DISEASE BRIEFINGS

[Expand all](#)

- [NEWLY REPUBLISHED \(1\)](#)
- [Autoimmune Disorders \(13\)](#)
- [Bioterrorism \(3\)](#)
- [Cancer \(23\)](#)
 - [Bladder Cancer](#)
 - [Breast Cancer](#)
 - [Cervical Cancer](#)
 - [Colorectal Cancer](#)
 - [Cutaneous T-Cell Lymphoma](#)
 - [Endometrial Cancer](#)
 - [Gastric Cancer](#)
 - [Head & Neck Cancer](#)
 - [Hepatocellular Carcinoma](#)
 - [Hodgkin's Lymphoma](#)
 - [Human T-Cell Leukemia Viruses \(HTLVs\)](#)

點擊疾病名稱打開個別疾病綜述報告

疾病綜述提供的內容

< Back | Forward > Disease Briefing Report

Nonalcoholic Fatty Liver Disease

Disease Briefing	Highlight Search Terms & Synonyms < Previous Next >
Latest Headlines	DISEASE BRIEFINGS
Multimedia	Expand all
Glossary	FACTS ABOUT NONALCOHOLIC FATTY LIVER DISEASE
Suggested Reading	Pathophysiology
Related Information	Risk Factors
Sources	Genetics
	Epidemiology
	Morbidity and Mortality
	Cost
	DIAGNOSIS
	Staging and Grading
	Differential Diagnosis
	PREVENTION
	TREATMENT
	Lifestyle Modification

疾病的背景介紹:

病理生理學(pathophysiology)/ 分類(Classification)
 致病因子(risk factor)
 流行病學(Epidemiology): 發生率及盛行率
 發病率(morbidity) 和死亡率(mortality)
 成本(cost): 社會成本及治療費用

診斷

匯整目前診斷疾病的概況

預防

匯整目前預防疾病的概況

治療

匯整目前治療的概況，包含手術、藥物治療標靶及相應pipeline

疾病綜述提供的內容(續)

< Back | Forward >

Nonalcoholic Fatty Liver Disease

- Disease Briefing
- Latest Headlines
- Multimedia
- Glossary
- Suggested Reading
- Related Information
- Sources

建議閱讀(suggested reading)

提供相關文章、臨床治療指引或網站

SUGGESTED READING

RELATED ARTICLES

- [The burden of liver disease in Europe - A review of available epidemiological data \(European Association for the Study of the Liver, 2013\)](#)

GUIDELINES

- [EASL-EASD-EASO clinical practice guidelines for the management of non-alcoholic fatty liver disease \(European Association for the Study of the Liver/European Association for the Study of Diabetes/European Association for the Study of Obesity, 2016\)](#)
- [Guidelines for liver transplantation for patients with non-alcoholic steatohepatitis \(British Society of Gastroenterology, British Association for the Study of the Liver, NHS Blood and Transplant, 2012\)](#)
- [KASL clinical practice guidelines: Management of nonalcoholic fatty liver disease \(Korean Association for the Study of the Liver, December 2013\)](#)
- [Non-alcoholic fatty liver disease \(NAFLD\): Assessment and management \(National Institute for Health and Care Excellence, July 2016\)](#)
- [Practice guidelines for the diagnosis and management of nonalcoholic fatty liver disease. A decalogue from the Italian Association for the Study of the Liver \(AISF\) Expert Committee \(2010\)](#)
- [The diagnosis and management of non-alcoholic fatty liver disease: Practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association \(2012\)](#)
- [World Gastroenterology Organisation global guidelines: Nonalcoholic fatty liver disease and nonalcoholic steatohepatitis \(World Gastroenterology Organisation, 2014\)](#)

RELATED WEBSITES

PREVENTION

TREATMENT

- Lifestyle Modification

Results

檢視您的檢索結果



依檢索條件找到的報告數量

- 預設顯示藥品報告(drug report)
- 點選切換報告分頁

712 results found for "non-small-cell lung cancer"

1 2 3 4 5 6 7 8 9 Next Last

Report Type	Results	Per page: 50	Sort by: Relevance	Descending	Order Columns	View
Show selected only	<input checked="" type="checkbox"/> Drug Name		Highest Status	<input checked="" type="checkbox"/> Active Companies	<input checked="" type="checkbox"/> Active Indications	<input checked="" type="checkbox"/> Total Reported Sales 2016 (USD M)
Bioactives (1049)	<input checked="" type="checkbox"/> mutant EGFR inhibitor (NSCLC), Amgen		No Development Reported	<input checked="" type="checkbox"/> Filters: [0]	<input checked="" type="checkbox"/> Filters: [0]	<input checked="" type="checkbox"/> Total Forecast Sales 2022 (USD M)
Broker Research (39987)	<input checked="" type="checkbox"/> IF1A1 gene activator (NSCLC), NCI		No Development Reported			
Clinical Trials (6983)	<input checked="" type="checkbox"/> cytolytic bradykinin inhibitors (NSCLC)		Discovery	University of Colorado	Non-small-cell lung	
Companies (1032)						
Conferences (1932)						
Deals (1764)						
Disease Briefings (6)						
Drugs (712)						
Event Transcripts (2799)						
Literature (11460)						

排序您的檢索結果

可供排序的選項包含:

- Relevance
- Last Change Date
- Highest Phase
- Drug Name
- Total Reported Sales 2016 (USD M)
- Total Forecast Sales 2022 (USD M)
- Added Date

點選藥品名稱可以直接進入對應的藥物報告

調整表格順序

可供排序的內容包括:

ORDER COLUMNS

Select a column, then use the Move buttons to position the column in the results table

Column
Drug Name (fixed column)
Highest Status
Active Companies
Active Indications
Total Reported Sales 2016
Total Forecast Sales 2022
Originator Company
Target-based Actions
Technologies

move up move

Reset Cancel **Apply**

Save to Preferences

點選要排序的欄位

Move up 向前

Move down 向後

選擇Apply完成設定或Save to preference固定顯示順序

游標向右拉動檢視更多表格內容

< Back Analyze Save and Alert Download

1 2 3 4 5 6 7 8 9 Next Last

Order Columns

Active Companies	Active Indications	Total Reported Sales 2016 (USD M)	Total Forecast Sales 2022 (USD M)
Filters: [0]	Filters: [0]	Filters: [0]	Filters: [0]

University of Colorado System; University of Colorado Technology Transfer Office

Venture Funding (0)

712 results found for "non-small-cell lung cancer"

1 2 3 4 5 6 7 8 9 Next Last

Report Type

Show select

Bioactives

Broker Res
(39987)

Clinical Tri

Companie

Conferenc

Deals (176

Disease Br

Drugs (712

Event Tran
(2799)

Literature (11466)

Patents (3959)

Press Releases (2810)

Regulatory (0)

Venture Funding (0)

檢視檢索結果呈現方式:



表格

(table view) (預設)

列表呈現報告裡已索引的重要內容，例如藥品名稱、目前研發公司、標靶、技術、年銷售額...等



列表

(list view)

簡要呈現檢索的結果，並重點標示文句中的檢索關鍵字



目前研發階段

(current development status view)

檢視目前藥品在各國的研發階段
*僅在藥物報告提供此種檢視方式

排序

(rank by view)

提供簡單圖表依所選條件排序

[cytolytic bradykinin inhibitors \(NSCLC\), University of Colorado System](#)

Discovery

University of Colorado System; University of Colorado Technology Transfer Office

Non-small-cell lung cancer

< Back | Forward >

Search Results

Analyze

Save and Alert

Download

712 results found for "non-small-cell lung cancer"

1 2 3 4 5 6 7 8 9 Next Last

Report Type

Show select

Bioactives

Broker Res
(39987)

Clinical Tri

Companie

Conferenc

Deals (176

Disease Br

Drugs (712

Event Tran
(2799)

Literature

Patents (39

Press Rele

Regulatory

Venture Fu

下載您的檢索結果

選擇下載的格式及內容

DOWNLOAD
DOWNLOAD

1. Document Type

2. Document Format

3. Delivery Format

4. Download Files

CHOOSE THE DOCUMENT TYPE

You have 712 records selected.

Results

- Microsoft Excel
- Microsoft Excel (unformatted) ⓘ
- SD File
- ISIS for Excel
- BizInt

Reports

- PDF
- Microsoft Word

1. Document Type

2. Document Format

3. Delivery Format

4. Download Files

CHOOSE THE DOCUMENT FORMAT

- Results Table
- Current Development Status Results
- Complete Current and Historical Development Status Results
- Customized Results

Cancel Previous Download

報告類型 (Report Type)

報告類型	說明	備註
券商研究報告 (Broker Research Report)	生命科學產業相關的券商研究報告	需訂購Broker research 模組
臨床試驗報告 (Clinical Trial Report)	臨床試驗內容(臨床試驗分期、納入/排除條件、試驗指標、地點)及結果*	*需視是否公布試驗結果且可取得
公司報告(Company Report)	收錄參與藥物研發或專利的藥廠、生技公司、大學或政府機構	
會議報告 (Conference Report)	Cortellis編輯團隊參與國際重要會議並摘錄會議重點	
交易報告 (Deal Report)	收錄藥品相關交易的內容、交易條件(簽約金、里程碑金)、合作進度、合約..併購**等訊息	*合約視可取得而定，且需訂購Cortellis Deals Intelligence (CDI) *併購交易內容需訂購CDI
疾病綜述(Disease Briefing Report)	提供藥品相關的病理、發病率、流行率、診斷、治療及治療疾病相關藥物pipeline等綜合評述	需訂購Disease Briefings模組
藥品報告(Drug Report)	個別藥品研發相關科學、專利、市場及財務...等綜合情報	

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報告類型 (續)

報告類型	說明	備註
電話會議逐字稿(Event Transcript Report)*	提供製藥公司電話會議或網路會議的會議內容逐字稿	需訂購Event Transcript模組
文獻報告(Literature Report)	超過200萬筆選自超過900種期刊的藥物專題摘要及索引，最早可追溯至1964年	
專利報告(Patent Report)	提供全球藥品相關的專利內容及重點摘要及專利說明書	
新聞報導 (Press Release)	選自製藥產業發佈的新聞及摘錄與藥品研發的重要訊息	
法規報告(Regulatory Report)	提供全球製藥/醫療器材相關法規情報	需訂購Cortellis Regulatory Intelligence
風險投資(Venture funding)	投資生命科學產業的風險投資公司重要信息	需訂購Venture Funding模組

Drug Report

藥品報告

藥品報告快照(Snapshot)

提供藥品上位摘要訊息，包括藥品名稱、研發公司、最高研發階段、適應症、作用標靶、技術及報告更新日期

藥品名稱

regorafenib

Snapshot	Highlight	Search Terms & Synonyms	< Previous	Next >
Latest Press Releases	SNAPSHOT View equivalent Bioactive(s) in Cortellis			
Latest Event Transcripts	Drug Name	regorafenib		
Broker Research Reports	Other Drug Names	DAST inhibitor (cancer), Bayer, BAY-01-1557; dual acting kinase inhibitor (cancer), Bayer; dual acting multikinase inhibitor (cancer), Bayer; dual acting signal transduction inhibitor (cancer), Bayer; DAST (cancer), Bayer; regorafenib; DAST inhibitor; BAY-73-4506; Stivarga; Ruoro-sorafenib		
Development Profile	Originator Company	Bayer AG		
Literature Review	Active Companies	Bayer AG ; Bayer Yakuhin Ltd ; H Lee Moffitt Cancer Center and Research Institute		
Development Status	Inactive Companies			
Regulatory Designations	Highest Phase	Launched (Metastatic colorectal cancer - US - Sep-2012)		
Chemical Structures	Regulatory Designations	Fast Track ; Orphan Drug ; Priority Review		
Drug Names	Active Indications	Esophagus tumor; Stomach tumor; Biliary cancer; Cholangiocarcinoma; Hepatocellular carcinoma; Pancreas tumor; Adenoid tumor; Gastrointestinal stromal tumor; Soft tissue sarcoma; Metastatic colorectal cancer; Solid tumor View Epidemiology in IPD		
Sales and Forecasts	Inactive indications	Non-small-cell lung cancer; Renal cell carcinoma; Fallopian tube cancer; Peritoneal tumor; Ovary tumor; Colorectal tumor View Epidemiology in IPD		
Clinical Trials	Target-based Actions	Raf 1 protein kinase inhibitor; Raf B protein kinase inhibitor; VEGF-3 receptor antagonist; VEGF-2 receptor antagonist; VEGF-1 receptor antagonist; Tek tyrosine kinase receptor inhibitor; Tie tyrosine kinase receptor inhibitor; RET tyrosine kinase receptor family inhibitor; Kit tyrosine kinase inhibitor; FGF receptor antagonist; PDGF receptor beta modulator; Caspase-9 stimulator; Caspase-3 stimulator		
Deals and Patents	Other Actions	Synergist; Anticancer; Anticancer protein kinase inhibitor; Angiogenesis inhibitor		
SWOT Analysis	Technologies	Oral formulation; Tablet formulation; Film coating; Small molecule therapeutic		
Change History	EphMRA Codes			
Sources	Last Change Date	05-Oct-2017		
	Added Date	14-Dec-2006		

點選連結至公司報告
(Company Report)

點選切換
分頁

點選至IPD
(流行病學資料庫)
(另開視窗)

Last Change Date: 最近一次更新的日期
Add Date: 藥品加入Cortellis的日期

藥品報告快照(續)

regorafenib

Snapshot	Highlight	Search Terms & Synonyms	< Previous	Next >
Latest Press Releases	SNAPSHOT View equivalent Bioactive(s) in Cortellis for DR0 (0)			
Latest Event Transcripts	Drug Name	regorafenib		
Broker Research Reports	Other Drug Names	DAST inhibitor (cancer), Bayer; BAY-01-1557; dual act (cancer), Bayer; dual acting signal transduction inhibi BAY-73-4506; Stivarga; fluoro-sorafenib		
Development Profile	Originator Company	Bayer AG		
Literature Review	Active Companies	Bayer AG ; Bayer Yakuhin Ltd ; H Lee Moffitt Cancer Ce		
Development Status	Inactive Companies			
Regulatory Designations	Highest Phase	Launched (Metastatic colorectal cancer - US - Sep-2		
Chemical Structures	Regulatory Designations	Fast Track ; Orphan Drug ; Priority Review		
Drug Names	Active Indications	Esophagus tumor; Stomach tumor; Biliary cancer; Chole Gastrointestinal stromal tumor; Soft tissue sarcoma; M		
Sales and Forecasts	Inactive Indications	Non-small-cell lung cancer; Renal cell carcinoma; Fallo		
Clinical Trials	Target-based Actions	Raf 1 protein kinase inhibitor; Raf B protein kinase inh receptor antagonist; Tek tyrosine kinase receptor inhibi family inhibitor; Kit tyrosine kinase inhibitor; FGF recep Caspase-3 stimulator		
Deals and Patents	Other Actions	Synergist; Anticancer; Anticancer protein kinase inhibitor; Angiogenesis inhibitor		
SWOT Analysis	Technologies	Oral formulation; Tablet formulation; Film coating; Small molecule therapeutic		
Change History	EphMRA Codes			
Sources	Last Change Date	05-Oct-2017		
	Added Date	14-Dec-2006		

目前研發公司(Active Company)
在研發階段(Development status)分頁中，列名在目前研發階段的公司。

歷史研發公司(In-active Company)
在研發階段分頁中，列名在歷史研發階段(historical development status)的公司。

初始研發公司(Originator Company)
最早開始研發的公司

藥品報告快照(續)

regorafenib

Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms	< Previous Next >
Latest Press Releases	SNAPSHOT View equivalent Bioactive(s) in Cortellis for DR1 (0)	
Latest Event Transcripts	Drug Name	regorafenib
Broker Research Reports	Other Drug Names	DAST inhibitor (cancer), Bayer; BAY-01-1557; dual act (cancer), Bayer; dual acting signal transduction inhibi BAY-73-4506; Stivarga; fluoro-sorafenib
Development Profile	Originator Company	Bayer AG
Literature Review	Active Companies	Bayer AG ; Bayer Yakuhin Ltd ; H Lee Moffitt Cancer Ce
Development Status	Inactive Companies	
Regulatory Designations	Highest Phase	Launched (Metastatic colorectal cancer - US - Sep-2012)
Chemical Structures	Regulatory Designations	Fast Track ; Orphan Drug ; Priority Review
Drug Names	Active Indications	Esophagus tumor; Stomach tumor; Biliary cancer; Cholangiocarcinoma; Hepatocellular carcinoma; Pancreas tumor; Adenoid tumor; Gastrointestinal stromal tumor; Soft tissue sarcoma; Metastatic colorectal cancer; Solid tumor View Epidemiology in IPD
Sales and Forecasts	Inactive Indications	Non-small-cell lung cancer; Renal cell carcinoma; Fallopian tube cancer; Peritoneal tumor; Ovary tumor; Colorectal tumor View Epidemiology in IPD
Clinical Trials	Target-based Actions	Raf 1 protein kinase inhibitor; Raf B protein kinase inhibitor; VEGF-3 receptor antagonist; VEGF-2 receptor antagonist; VEGF-1 receptor antagonist; Tek tyrosine kinase receptor inhibitor; Tie tyrosine kinase receptor inhibitor; RET tyrosine kinase receptor family inhibitor; Kit tyrosine kinase inhibitor; FGF receptor antagonist; PDGF receptor beta modulator; Caspase-9 stimulator; Caspase-3 stimulator
Deals and Patents	Other Actions	Synergist; Anticancer; Anticancer protein kinase inhibitor; Angiogenesis inhibitor
SWOT Analysis	Technologies	Oral formulation; Tablet formulation; Film coating; Small molecule therapeutic
Change History	EphMRA Codes	
Sources	Last Change Date	05-Oct-2017
	Added Date	14-Dec-2006

研發中適應症(Active Indication)

在研發階段頁中，列名在目前研發階段的適應症。

已停止研發的適應症(In-active Indication)

在研發階段分頁中，列名在歷史研發階段的適應症。

藥品報告快照(續)-最高研發階段(highest status)

當一個藥品在一個以上的國家(適應症或公司)有不同的研發階段時，最高研發階段是依據藥品報告(Drug report)裡的目前研發階段列表中，列出最高的研發階段；若藥品已上市，則另標示首次上市的國家、適應症及上市時間。

CURRENT DEVELOPMENT STATUS

Companies	Indication	Country	Status	Date	Source
Bayer AG	Hepatocellular carcinoma	EU	Registered	07-Aug-2017	[1951323]
Bayer AG	Hepatocellular carcinoma	Japan	Launched	26-Jun-2017	[1940964]
Bayer AG	Hepatocellular carcinoma [C01]	US	Launched	27-Apr-2017	[1922189]
Bayer AG	Hepatocellular carcinoma	China	Pre-registration	27-Apr-2017	[1922189]
Bayer AG	Peritoneal tumor	US	Discontinued	31-Dec-2016	[1612733]
Bayer AG	Ovary tumor	US	Discontinued	31-Dec-2016	[1612733]
Bayer AG	Fallopian tube cancer	US	Discontinued	31-Dec-2016	[1612733]
Bayer AG	Esophagus tumor	South Korea	Discovery	13-May-2010	[1779187]
Bayer AG	Esophagus tumor	Taiwan	Discovery	13-May-2010	[1779187]
Bayer AG	Stomach tumor	South Korea	Discovery	13-May-2010	[1779187]

SNAPSHOT

View equivalent Bioactive(s) in Cortellis for DRI (0)

Drug Name	regorafenib
Other Drug Names	DAST inhibitor (cancer), Bayer; BAY-81-1557, dual acting kinase inhibitor (cancer), Bayer; dual acting multikinase inhibitor (cancer), Bayer; dual acting signal transduction inhibitor (cancer), Bayer; DAST (cancer), Bayer; regorafenib, DAST inhibitor, BAY-73-4506, Sivarga; Iluro-sorafenib
Originator Company	Bayer AG
Active Companies	Bayer AG , Bayer Yakuin Ltd , H Lee Moffitt Cancer Center and Research Institute
Inactive Companies	
Highest Phase	Launched (Metastatic colorectal cancer - US - Sep-2012)
Regulatory Designations	Fast Track , Orphan Drug , Priority Review
Active Indications	Esophagus tumor; Stomach tumor; Biliary cancer; Cholangiocarcinoma; Hepatocellular carcinoma; Pancreas tumor; Adenoid tumor; Gastrointestinal stromal tumor; Soft tissue sarcoma; Metastatic colorectal cancer; Solid tumor View Epidemiology in IPD
Inactive Indications	Non-small-cell lung cancer; Renal cell carcinoma; Fallopian tube cancer; Peritoneal tumor; Ovary tumor; Colorectal tumor View Epidemiology in IPD
Target-based Actions	Raf 1 protein kinase inhibitor; Raf B protein kinase inhibitor; VEGF-3 receptor antagonist; VEGF-2 receptor antagonist; VEGF-1 receptor antagonist; Tek tyrosine kinase receptor inhibitor; Tie tyrosine kinase receptor inhibitor; RET tyrosine kinase receptor family inhibitor; Kit tyrosine kinase inhibitor; FGF receptor antagonist; PDGF receptor beta modulator; Caspase-9 stimulator; Caspase-3 stimulator
Other Actions	Anticancer protein kinase inhibitor; Angiogenesis inhibitor; Synergist; Anticancer
Technologies	Oral formulation; Tablet formulation; Film coating; Small molecule therapeutic

研發概況 (Development Profile)

研發概況紀錄藥品研發過程的重要情報，包括: 重點訊息(Summary)、專利及學名藥(Patent & Generics)、法規/查驗登記(Regulatory)、上市後 (Postmarketing)、上市前(Premarketing)、臨床前(Preclinical)及補充資料(Additional Information)。

研發概況 (Development Profile)

regorafenib

Snapshot **Highlight** Search Terms & Synonyms < Previous Next >

Latest Press Releases **DEVELOPMENT PROFILE**

Latest Event Transcripts New Content: Highlight Off

Broker Research Reports

Development Profile

- Summary
- Patents & Generics
- Regulatory
- Postmarketing
- Premarketing
- Preclinical
- Additional Information

Literature Review

Development Status

Regulatory Designations

Chemical Structures

Drug Names

Sales and Forecasts

Clinical Trials

SUMMARY

Bayer has developed and launched regorafenib (BAY-73-4500, fuoro-sorafenib, Stivarga), a lead dual-acting VEGFR 1 to 3, TIE, KIT, RET, BRAF, CRAF, PDGFR, and FGFFR inhibitor and caspase-3 and -9 stimulator. The product is indicated in the US, EU and Japan for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy, and for the treatment of metastatic or unresectable gastroesophageal stromal tumors (GIST) in patients who have been previously treated with imatinib and sunitinib [1327170], [1581203], [1941222], [1951323], [1951324], [1951325], [1951326], [1951327], [1951328], [1951329], [1951330], [1951331], [1951332], [1951333], [1951334], [1951335], [1951336], [1951337], [1951338], [1951339], [1951340], [1951341], [1951342], [1951343], [1951344], [1951345], [1951346], [1951347], [1951348], [1951349], [1951350], [1951351], [1951352], [1951353], [1951354], [1951355], [1951356], [1951357], [1951358], [1951359], [1951360], [1951361], [1951362], [1951363], [1951364], [1951365], [1951366], [1951367], [1951368], 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[1951915], [1951916], [1951917], [1951918], [1951919], [1951920], [1951921], [1951922], [1951923], [1951924], [1951925], [1951926], [1951927], [1951928], [1951929], [1951930], [1951931], [1951932], [1951933], [1951934], [1951935], [1951936], [1951937], [1951938], [1951939], [1951940], [1951941], [1951942], [1951943], [1951944], [1951945], [1951946], [1951947], [1951948], [1951949], [1951950], [1951951], [1951952], [1951953], [1951954], [1951955], [1951956], [1951957], [1951958], [1951959], [1951960], [1951961], [1951962], [1951963], [1951964], [1951965], [1951966], [1951967], [1951968], [1951969], [1951970], [1951971], [1951972], [1951973], [1951974], [1951975], [1951976], [1951977], [1951978], [1951979], [1951980], [1951981], [1951982], [1951983], [1951984], [1951985], [1951986], [1951987], [1951988], [1951989], [1951990], [1951991], [1951992], [1951993], [1951994], [1951995], [1951996], [1951997], [1951998], [1951999], [1952000].

OTHER PUBLICATION

2013May
Japanese prescribing information: Stivarga (regorafenib) tablets 40 mg
Drug datasheet website

Source ID: 1941222

文獻回顧 (Literature Review)

文獻綜述由產業專家或學術界的科學家撰寫，它參考了現有的文獻並匯整該些文獻對此藥品在科學或商業利益上的重點提示。

regorafenib

Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms < Previous Next >
Latest Press Releases	LITERATURE REVIEW
Latest Event Transcripts	Marlo Blazer & Tanios Bekaii-Saab, The Ohio State University - Arthur James Cancer Hospital, Columbus, OH
Broker Research Reports	Submission date: 10 January 2011 Publication date: 15 March 2011
Development Profile	ABSTRACT
Literature Review	Regorafenib is a multikinase inhibitor of angiogenesis and tumor proliferation pathways, currently under development. In cellular assays, regorafenib was a potent inhibitor of VEGFR-2, -3 and PDGFR-beta. Regorafenib also inhibited endothelial cells and human aortic smooth muscle cells in vitro. In vivo, treatment with regorafenib resulted in various tumors, with decreased tumor microvasculature in xenograft models of human colorectal tumor and glioblastoma. Regorafenib exhibited promising disease control rates in pretreated patients with various solid tumors. Several trials are currently underway to evaluate the potential role of regorafenib in malignancies including advanced renal cell cancer, metastatic colorectal cancer and carcinoma. Results from these trials may help to clarify the role regorafenib will play in a market where oral multikinase inhibitors and several other such agents are at various stages of active clinical development.
Development Status	INTRODUCTION
Regulatory Designations	Angiogenesis is an essential component of tumor growth, migration and metastasis [1163756]. The VEGF family of cytokines is known to play a stimulatory role in angiogenesis [1163757], and targeting the VEGF receptor can improve therapeutic outcome in several solid tumor types, including metastatic colorectal cancer (CRC), renal cell carcinoma (RCC) and hepatocellular cancer (HCC). EGFR, PDGFR and receptor tyrosine kinases (RTKs) are also known to play a role in the regulation of growth, differentiation and angiogenesis of cells; aberrant activation or overexpression of these signaling pathways can lead to tumor growth, angiogenesis and metastasis, making these entities a valid target for cancer therapy [538172], [1167116].
Chemical Structures	CRC is the third most common cancer in women and the fourth most common in men [1164918]. In 2007, there were nearly 1.2 million new diagnoses expected worldwide and approximately 630,000 deaths [1164916]. At diagnosis, 19% of patients will have metastatic disease and 37% will have regional/nodal disease [1164918]. Current therapies combining cytotoxic agents with agents that target either angiogenesis or the EGFR have resulted in improved outcome in patients with metastatic disease [895739], [1163762]. Bevacizumab is a mAb that binds to and inhibits the VEGF receptor and improves the overall survival of patients with metastatic CRC when combined with irinotecan-based chemotherapy [462953], [955736]. EGFR is expressed on cells of epithelial origin, including liver, skin and gastrointestinal tract [462953], [1163763]. Ligand-binding activation of the EGFR pathway leads to a signaling cascade including the activation of the Ras/Raf/MAPK pathway that ultimately drives cell proliferation, differentiation, migration, gene transcription and cell immortality [1124047], [1163911], [1163913]. Both cetuximab and panitumumab, mAbs that target the EGFR receptor, improve the outcome of patients with metastatic CRC [895739], [1163762]; however, both agents are ineffective in tumors that harbor a mutation in the K-RAS oncogene, which is present in ~ 40% of all patients [846626], [895363], [1163914]. Therefore, improved therapeutic options which can overcome this constitutive gain-in-function mutation are necessary.
Drug Names	
Sales and Forecasts	
Clinical Trials	
Deals and Patents	
SWOT Analysis	
Change History	
Sources	

點選顯示資料來源

SERIAL PUBLICATION

20101291245255
Regorafenib (BAY 73-4506): A new oral multikinase inhibitor of angiogenic, stromal, and oncogenic receptor tyrosine kinases with potent preclinical antitumor activity
International Journal of Cancer
Wilhelm SM, Dumas J, Adnane L, Lynch M, Carter CA, Schütz G, Thierauch KH, Zopf D
Source ID: 1167122

文獻回顧
(Literature Review)

研發階段(Development Status)

研發階段列表整理在各國研發進度，分別列出研發公司、適應症、國家、階段及資料來源。

regorafenib

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Latest Press Releases **CURRENT DEVELOPMENT STATUS**

Latest Event Transcripts

Broker Research Reports

Development Profile

Literature Review

Development Status

- Current
- Historical

Regulatory Designations

Structures

Recasts

Deals and Patents

SWOT Analysis

Companies	Indication	Country	Status	Date	Source
Bayer AG	Solid tumor	Japan	Phase 1 Clinical	31-Jul-2009	[1024200]
Bayer AG	Metastatic colorectal cancer	Israel	Phase 3 Clinical	07-May-2010	[1095817]
Bayer AG	Metastatic colorectal cancer	Argentina	Phase 3 Clinical	07-May-2010	[1095817]
Bayer AG	Metastatic colorectal cancer	Brazil	Phase 3 Clinical	07-May-2010	[1095817]
Bayer AG	Metastatic colorectal cancer	Turkey	Phase 3 Clinical	07-May-2010	[1095817]
Bayer AG	Gastrointestinal stromal tumor	Far East	Phase 3 Clinical	10-Jan-2011	[1150148]
Bayer AG	Gastrointestinal stromal tumor	China	Discovery	17-Jun-2011	[1397415]
Bayer AG	Metastatic colorectal cancer	Far East	Phase 3 Clinical	18-May-2012	[1576979]
Bayer AG	Metastatic colorectal cancer [FT]	US	Launched	28-Sep-2012	[1345349]
Bayer AG	Gastrointestinal stromal tumor [OD]	US	Launched	28-Feb-2013	[1397139]

研發階段
(Development Status)

點選顯示資料來源

CORPORATE PUBLICATION

02-Jun-2009
Investor Handout : Meet Management 2009
Company Presentation
Bayer AG
Source ID: 1024200

研發階段(續)

研發階段列表整理在各國研發進度，分別列出研發公司、適應症、國家、階段及資料來源。

regorafenib

Snapshot Highlight Search Terms & Synonyms < Previous Next >

Latest Press Releases CURRENT DEVELOPMENT STATUS

	Companies	Indication	Country	Status	Date
Latest Event Transcripts	Bayer AG	Solid tumor	Japan	Phase 1 Clinical	31-Jul-2009
Broker Research Reports	Bayer AG	Metastatic colorectal cancer	Israel	Phase 3 Clinical	07-May-2010
Development Profile	Bayer AG	Metastatic colorectal cancer	Argentina	Phase 3 Clinical	07-May-2010
Literature Review	Bayer AG	Metastatic colorectal cancer	Brazil	Phase 3 Clinical	07-May-2010
Development Status	Bayer AG	Metastatic colorectal cancer	Turkey	Phase 3 Clinical	07-May-2010
	Bayer AG	Gastrointestinal stromal tumor	Far East	Phase 3 Clinical	10-Jan-2011
Current	Bayer AG	Gastrointestinal stromal tumor	China	Discovery	17-Jun-2011
	Bayer AG	Metastatic colorectal cancer	Far East	Phase 3 Clinical	18-May-2012
	Bayer AG	Metastatic colorectal cancer	US	Launched	28-Sep-2012
Sales and Forecasts	Bayer AG	Gastrointestinal stromal tumor	US	Launched	28-Feb-2013
Clinical Trials					
Deals and Patents					
SWOT Analysis					

點選直接連結相應的特殊審查
(Regulatory Designation)記錄

點選後可以條件篩選，點選Apply顯示相應內容。

STATUS

Sort

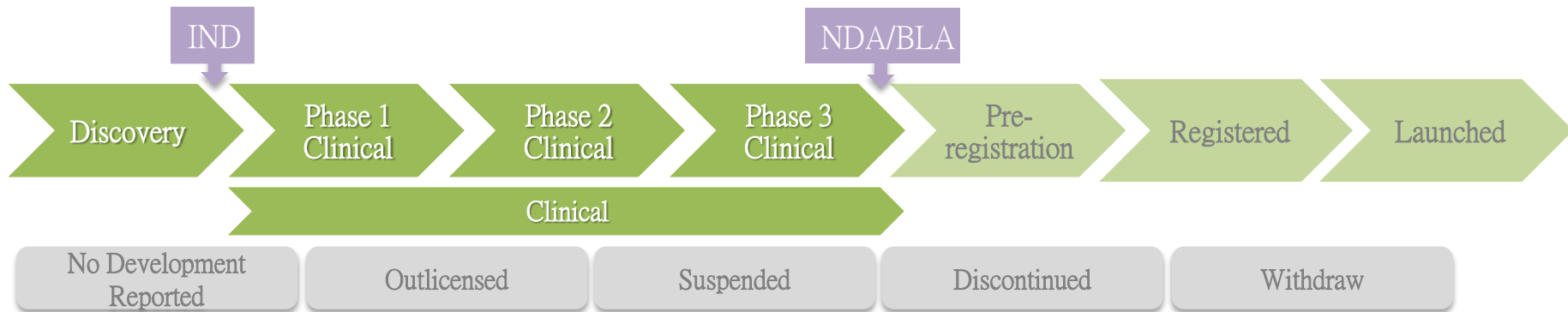
Ascending
 Descending

Filter

Select All
 No Development Reported
 Discontinued
 Discovery
 Phase 1 Clinical
 Phase 2 Clinical
 Phase 3 Clinical
 Pre-registration
 Registered

Cancel Apply

研發階段(development status)的定義及分類



Discovery

包含藥品探索及臨床前。臨床前指的是體內(in vivo)實驗，動物實驗開始。

Clinical

藥品目前的研發階段是未知分期的臨床試驗。

Phase 1 Clinical

初步研究確定藥品在人體中的代謝和藥理作用、增加劑量相關的副作用以及開始獲得早期有效性的證據; 通常試驗對象是健康受試者。

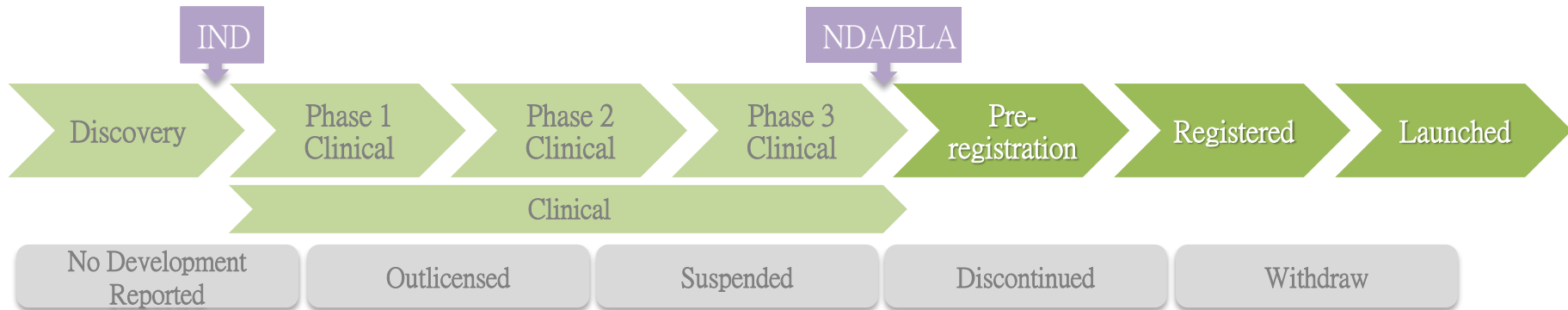
Phase 2 Clinical

進行對照的臨床研究，以評估藥品對於特定適應症患者的有效性，並已經開始確認常見的短期副作用和風險。

Phase 3 Clinical

在取得初步證據證實藥效後放大對照或非對照的臨床試驗。旨在收集更多的訊息來評估藥品整體以及提供仿單所需的風險效益的基礎。

研發階段的定義及分類(續)



Launched

藥品已上市

Registered

藥品已取得上市許可，然而尚未在市場上流通

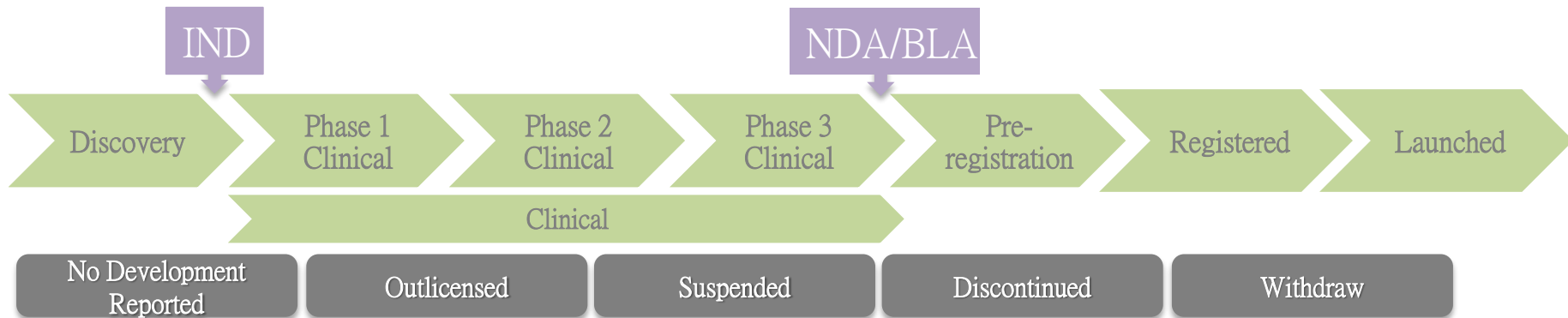
Pre-registration

新藥申請已送件，等待查驗登記

Cortellis

Powering Life Sciences Innovation

研發階段的定義及分類(續)



No Development Reported

關於此藥品的研發報導已18個月沒有變化。

Outlicensed

藥品開發的權利已轉讓給被授權人(不論被授權人是已知或是推測)，而對於原開發公司/機構不再具有商業利益

Suspended

藥品的研發暫時停止但未中止，例如由於試驗中出現副作用、公司現金周轉或待戰略調整

Discontinued

藥品的研發在送交特定適應症的查驗登記後中止，或在送交後未獲得上市許可。

Withdrawn

藥品許可證被撤銷及下市

法規認證(Regulatory Designation)

法規認證列表整理如孤兒藥(orphan drug)、優先審查(priority review)、快速審查(fast track)…等特殊審查機制的內容，包含在認證路徑、適應症、申請公司、國家、狀態及資料來源。

regorafenib

Snapshot		Highlight <input type="checkbox"/> Search Terms & Synonyms < Previous Next >																																							
Latest Press Releases		FAST TRACK																																							
Latest Event Transcripts		<table border="1"> <thead> <tr> <th>Indication</th> <th>Awarded Indication</th> <th>Company</th> <th>Country</th> <th>Status</th> <th>Type</th> <th>Date</th> <th>Source</th> </tr> </thead> <tbody> <tr> <td>Metastatic colorectal cancer</td> <td>Treatment of metastatic colorectal cancer (CRC)</td> <td>Bayer AG</td> <td>US</td> <td>Granted</td> <td>Treatment</td> <td>20-Dec-2011</td> <td>1250167</td> </tr> </tbody> </table>								Indication	Awarded Indication	Company	Country	Status	Type	Date	Source	Metastatic colorectal cancer	Treatment of metastatic colorectal cancer (CRC)	Bayer AG	US	Granted	Treatment	20-Dec-2011	1250167																
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Sources																																									

點選後可以條件篩選，點選 Apply 顯示相應內容。

點選顯示資料來源

PRESS RELEASE

20-Dec-2011
Bayer: Four potential blockbusters in the Pharma pipeline
 Bayer AG
 Source ID: 1250167

[View full report](#)

化學結構式(Chemical Structure)

提供小分子藥品的結構式、研發代號或名稱，信心分級(依公開資料的來源評分)

regorafenib

Snapshot **Highlight** Search Terms & Synonyms < Previous Next >

Latest Press Releases **CHEMICAL STRUCTURES**

Latest Event Transcripts CAS Registry Number 755037-03-7 Confidence Level 2

Broker Research Reports

Development Profile

Literature Review

Development Status

Regulatory Designations

Chemical Structures

Drug Names

Sales and Forecasts

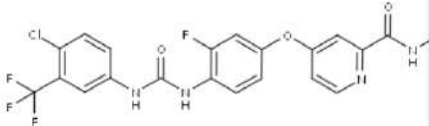
Clinical Trials

Deals and Patents

SWOT Analysis

Change History

Sources



Name	Agreement
regorafenib	USAN, INN
BAY-73-4506	Research Co
Stivarga	Trade Name
fluoro-sorafenib	

信心分級(Confidence Level)

Level 1: 經美國化學文摘社(Cheical Abstract Service) 或研發公司確認結構。

Level 2: 結構來自Merck Index、世界衛生組織(WHO)或美國藥名選定委員會(USAN council)公佈的資料。

Level 3: 結構來自有同儕審查機制的(peer-review)的期刊。

Level 4: 結構來自非同儕審查機制的出版品，例如會議講義(handout)、新聞稿或非研發公司官網的內容。

Level 5: 結構來自學術會議的手寫筆記或專利，經Cortellis編輯比對研發公司發佈的公開訊息而提供。

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藥品名稱(Drug names)

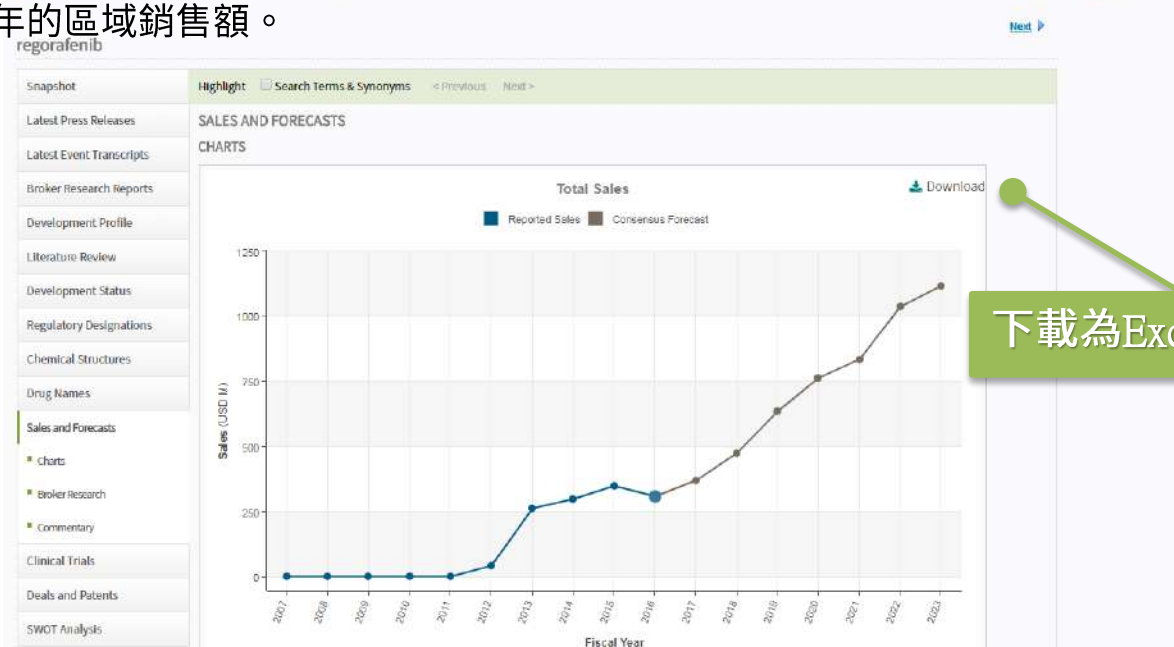
列表提供藥品研發歷程中的研發代號、USAN命名、國際非專利藥品名稱(INN)、商品名(Trade name)

regorafenib

Snapshot	Highlight	<input type="checkbox"/> Search Terms & Synonyms	< Previous	Next >
Latest Press Releases	DRUG NAMES			
Latest Event Transcripts	Names	Agreement Type		
Broker Research Reports	DAST inhibitor (cancer), Bayer			
Development Profile	BAY-81-1557	Research Code		
Literature Review	dual acting kinase inhibitor (cancer), Bayer			
Development Status	dual acting multikinase inhibitor (cancer), Bayer			
Regulatory Designations	dual acting signal transduction inhibitor (cancer), Bayer			
Chemical Structures	DAST (cancer), Bayer			
Drug Names	regorafenib	USAN , INN		
Sales and Forecasts	DAST inhibitor			
Clinical Trials	BAY-73-4506	Research Code		
Deals and Patents	Stivarga	Trade Name		
SWOT Analysis				
Change History				
Sources				

銷售及預測(Sales and Forecast)

銷售及預測提供來自藥品收入及策略評論。依藥品上市公司公告的銷售額(reported sales)及共識銷售預測(Consensus Forecast Sales)提供歷年/未來銷售趨勢圖和券商對該藥品的銷售預測。並依藥品上市公司公告的區域顯示前一年的區域銷售額。



下載為Excel文件

銷售及預測(續)

摘錄券商報告中對該藥品的銷售預測，依年度、券商名稱、券商報告日期列表。策略評論包括共識銷售訊息，年度銷售報導，區域發展和經銷權以及共識預測摘要。

BROKER RESEARCH

2017	2018	2019	2020	2021	2022	2023
Region	Franchise	Broker name		Date	Value (USD million)	Consensus (USD million)
Bayer AG						
WW	Anticancer multitargeted protein kinase inhibitors	Undisclosed		01-Aug-2017	366.18	368.9
		Undisclosed		05-Jul-2017	318.89	
		DZ Bank		16-May-2017	340.92	
						Total 368.9

Due to the use of embargoed data, the number of analysts that comprise the Consensus value may differ from the number of listed Bro

COMMENTARY

Consensus Sales Information

Consensus forecast data, where available, are presented for Bayer AG.

Reported Annual Sales

Sales for regorafenib (Stivarga) reported by Bayer for 2016 were EUR 275.0 million (\$307.1 million), representing a year-on-year decrease of 12.1% on 2015 [[1902853](#)].

Reported Quarterly Sales

Sales for regorafenib (Stivarga) reported by Bayer for 3Q 2016 were EUR 64.0 million (\$69.6 million) [[1868701](#)]. Sales for regorafenib (Stivarga) reported by Bayer for 4Q 2016 were EUR 77.0 million (\$81.4 million) [[1902853](#)]. Sales for regorafenib (Stivarga) reported by Bayer for 1Q 2017 were EUR 75.0 million (\$81.8 million) [[1922811](#)]. Sales for regorafenib (Stivarga) reported by Bayer for 2Q 2017 were EUR 83.0 million (\$97.1 million) [[1949655](#)].

Regional Development and Marketing Rights

Bayer holds exclusive worldwide rights, although rights were the subject of a lawsuit between Onyx and Bayer, as the drug closely resembles Nexavar [[1172389](#)]. In October 2011, Onyx and Bayer settled the lawsuit, the terms of which granted Onyx US copromotion rights to regorafenib for cancer, with a 20% royalty on sales; Bayer

點選顯示資料來源

CORPORATE PUBLICATION

26-Oct-2016
Bayer Q3 interim report
 Company Presentation
 Bayer AG
 Source ID: 1868027

臨床試驗(Clinical Trials)

列出了所有以該藥品為主要治療(Primary intervention)用藥的臨床試驗，依適應症及臨床分期顯示統計結果。

regorafenib

Snapshot Highlight Search Terms & Synonyms < Previous Next >

Latest Press Releases CLINICAL TRIALS

Latest Event Transcripts TRIALS BY PHASE AND CONDITION STUDIED

Condition Studied	Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All
	Esophagus tumor	0	0	0	1	1	2	0	3	0	0	1
Rectal tumor	0	0	0	0	0	1	0	0	0	0	0	1
Metastosa	0	1	0	1	4	6	1	3	1	1	6	14
Neuroendocrine tumor	0	0	0	0	1	1	0	0	0	0	1	1
Small-cell lung cancer	0	0	0	0	0	0	0	1	0	0	0	1
Non-small-cell lung cancer	0	0	0	0	2	2	0	4	0	0	0	6
Stomach tumor	0	0	0	1	0	1	0	3	0	0	0	4
Myelodysplastic syndrome	0	0	0	0	0	0	1	1	0	0	0	2
Gastrointestinal tumor	0	0	0	0	1	1	0	0	0	0	1	1
Biliary cancer	0	0	0	0	1	1	1	4	0	0	2	5

Click here to expand more content

TOTAL TRIALS BY PHASE AND STATUS

Total by Phase and Status	Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All	Ongoing	All
	6	9	3	12	36	74	13	33	1	13	61	141

Click here to view all clinical trials as a results table

點選展開更多內容

點選查看臨床試驗報告

臨床試驗(續)

列出了所有以該藥品為主要治療(Primary intervention)用藥的臨床試驗，列表顯示適應症，病患分組、生物標記、臨床分期、評估指標(及指標類型)、試驗中心總數、試驗狀態、試驗結果...等資訊。

148 trial results for 'regorafenib' drug report

Results Per page: 50 Sort by: Relevance Descending Order Columns View

Title	Condition	Patient Segment	Biomarker	Interventions	Phase
Regorafenib in Subjects With Gastrointestinal Stromal Tumors (GIST) who have Progressed after Standard Therapy (Managed Access Program)	Gastrointestinal stromal tumor	Gastrointestinal stromal tumor - Subjects with Advanced/Metastatic GIST; Gastrointestinal stromal tumor - Subjects with Treatment Resistant Disease - Subjects with progression or intolerance to imatinib;		regorafenib alone	Phase not specified
Regorafenib in Subjects With Gastrointestinal Stromal Tumors (GIST) Who Have Progressed After Standard Therapy	Gastrointestinal stromal tumor	Gastrointestinal stromal tumor - Subjects with Advanced/Metastatic GIST; Gastrointestinal stromal		regorafenib alone	Phase 3 Clinical
CONCUR: Asian Subjects With Metastatic Colorectal Cancer Treated With Regorafenib or Placebo After Failure of Standard Therapy	Metastatic colorectal cancer	Colorectal tumor - Subjects with Colon Cancer; Colorectal tumor - Subjects with Rectal Cancer; Colorectal tumor - Subjects with TNM stage IV/Metastatic /Advanced Colorectal Cancer; Colorectal tumor -	Alanine transaminase ; Aspartate aminotransferase ; B-Raf proto-oncogene serine/threonine-protein kinase ; Circulating tumor DNA ; GTPase KRas ; GTPase NRas ; Lipase ; Phosphatidylinositol-	best supportive care alone; regorafenib alone	Phase 3 Clinical
CONSIGN: Regorafenib in Subjects With Metastatic Colorectal Cancer (CRC) Who Have Progressed After Standard Therapy	Metastatic colorectal cancer	Colorectal tumor - Subjects with Colon Cancer; Colorectal tumor - Subjects with Rectal Cancer; Colorectal tumor - Subjects with TNM stage IV/Metastatic /Advanced Colorectal Cancer; Colorectal tumor -	Alanine transaminase ; Aspartate aminotransferase ; Bilirubin ; GTPase KRas	regorafenib alone	Phase 3b Clinical

點選查看個別臨床試驗報告

臨床試驗(續)-臨床試驗報告

表列該臨床試驗的關鍵訊息，包含：試驗結果*、是否達成評估指標*、適應症，病患分組、生物標記、臨床分期、評估指標(及指標類型)、試驗中心總數、試驗狀態...等資訊

◀ Prev Next ▶

Patients With Metastatic Colorectal Cancer Treated With Regorafenib or Placebo After Failure of Standard Therapy

Snapshot	Highlight <input type="checkbox"/>	Search Terms & Synonyms	< Previous	Next >
Protocol & Results	SNAPSHOT			Results Available Yes Endpoints Met Yes Results Available Yes Endpoints Met Yes
Subjects & Measurements	Title Patients With Metastatic Colorectal Cancer Treated With Regorafenib or Placebo After Failure of Standard Therapy			
Contacts & Sites	Scientific Title A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Regorafenib Plus Best Standard of Care for Patients With Metastatic Colorectal Cancer (CRC) Who Have Progressed After Standard Therapy			
Change History	Identifiers 14387; NCT01103323; 2009-012787-14; JapicCTI-101325; BAY 73-4506 / 14387; CTR20090012787			
Sources	Condition Metastatic colorectal cancer			
	Cellular tumor antigen p53; Adenomatous polyposis coli protein; GTPase KRas;			
	Interventions regorafenib , alone			
	Active Controls			
	Phase Phase 3 Clinical			
	Recruitment Status Completed			
	Sites 174			
	Sponsor Only Bayer AG			
	Collaborator Only			
	Organization Type Company			
	Action FGF receptor antagonist; Kit tyrosine kinase inhibitor; RET tyrosine kinase receptor family inhibitor; TIE tyrosine kinase receptor inhibitor; Tek tyrosine kinase receptor inhibitor; VEGF-1 receptor antagonist; VEGF-2 receptor antagonist; VEGF-3 receptor antagonist; Raf B protein kinase inhibitor; Raf 1 protein kinase inhibitor; PDGF receptor beta modulator; Caspase-3 stimulator; Caspase-9 stimulator			

點選分頁檢視內容

試驗結果及是否達成評估
指標*

*需訂購 Cortellis Trials Intelligence 模組且需視是否公布試驗結果且可取得

交易和專利(Deals and Patents)

提供與藥品相關的交易和專利數量的圖示或列表

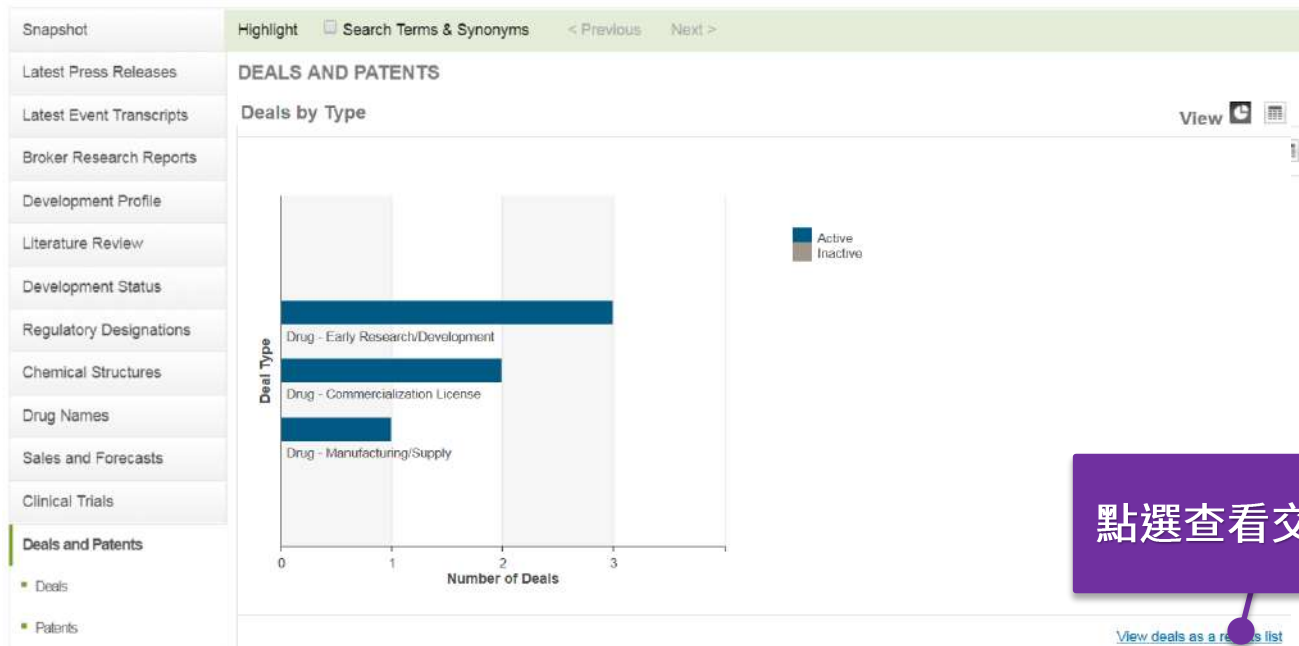
regorafenib



交易和專利(續)-交易

提供與藥品相關的交易和專利數量的圖示或列表

regorafenib



點選查看交易報告列表

交易和專利(續)-交易報告(Deal Report)

提供與藥品相關的交易和專利數量的圖示或列表

6 deal results for 'regorafenib' drug report

Results Per page : 50 Sort by: Most Recent Event Date Order Columns EFR Analyser View

Deal Title	Principal Company	Partner Company	Agreement Type	Deal Asset Type	Deal Transaction Type
<input checked="" type="checkbox"/>	Filters : [0]	Filters : [0]	Filters : [0]		
<input checked="" type="checkbox"/> NSABP and Bayer to Investigate Stivarga as adjuvant therapy against colon cancer	NSABP Foundation Inc	Bayer AG	Drug - Early Research/Development	Product(s) only	Research-Only
<input checked="" type="checkbox"/> Service agreement to provide specialty pharmacy services for Bayer's Nexavar (sorafenib) and Stivarga (regorafenib)	Advanced Care Scripts	Bayer AG	Drug - Early Research/Development	Other Services	
<input checked="" type="checkbox"/> Biologics to distribute Bayer's Nexavar and Stivarga	Biologics Inc	Bayer AG	Drug - Manufacturing/Supply	Product(s) only	Distribution

C

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交易和專利(續)-交易報告(續)

提供與藥品相關的交易情報，包含交易雙方、交易類型*、交易標的、交易狀態、財務條件**、原始合約***

Settlement of regorafenib litigation for 20% royalties and U.S. co-promotion rights, and Nexavar royalty buyout in Japan

Snapshot	Highlight	<input type="checkbox"/> Search Terms & Synonyms	< Previous	Next >
Drugs	SNAPSHOT			
Patents	Deal Title	Settlement of regorafenib litigation for 20% royalties and U.S. co-promotion rights, and Nexavar royalty buyout in Japan		
Contract	Principal Company	Onyx Pharmaceuticals Inc (US)		
Events	Partner Company	Bayer HealthCare AG (Germany)		
Financial	Agreement Type	Drug - Commercialization License		
Mergers & Acquisition	Deal Asset Type	Intellectual Property Only		
	Deal Transaction Type	Settlement		
	Deal Status	Active		
	Territories	World		
	Total projected value (Current-USD M)	Unknown		
	Total projected value (At Signing-USD M)	Unknown		
	Total Paid (USD M)	Unknown		
	Therapy Area	Cancer		
	Indications	Cancer(Primary)		

點選分頁檢視內容

*若需含M&A交易，需訂購Cortellis Deals Intelligence (CDI) 模組
 **需視是否公開財務條件且可取得
 *** 需訂購 CDI模組

交易和專利(續)-專利

提供與藥品相關的交易和專利數量的圖示或列表



交易和專利(續)-專利報告(Patent Report)

提供與藥品相關的專利情報，包含申請人/所有權人、專利類型、適應症、化學結構式、編輯重點摘要(editorial abstract)、技術類型、專利家族、預估到期日*、專利原文PDF

64 patent results for 'regorafenib' drug report

Report Type: Patents (64)

Results Per page: 50 Sort by: Last Change Date Order Columns: View

Patent Number	Title	Owner Companies	Indications	Target-based Actions	Structure
WO-2011128261	Process for the preparation of 4-[4-((4-chloro-3-(trifluoromethyl)phenylamino)carbonyl)amino]-3-fluorophenyl]-N-methylpyridine-2-carboxamide	Bayer AG, Bayer Corp, Bayer HealthCare AG, Bayer Healthcare LLC, Bayer Schering Pharma AG	Adenoid tumor; Cancer; Esophagus tumor; Fallopian tube cancer; Gastrointestinal stromal tumor; Leukemia; Lymphoma; Neoplasm; Non-small-cell lung cancer; Pancreas tumor; Peritoneal tumor;	Caspase-9 stimulator; Caspase-3 stimulator; Tek tyrosine kinase receptor inhibitor; Kit tyrosine kinase inhibitor; Raf 1 protein kinase inhibitor; RET tyrosine kinase receptor family inhibitor; FGF receptor	
WO-20171151044	regorafenib or regorafenib and a phosphoramidate prodrug of troxacitabine		Angiosarcoma; Hepatocellular carcinoma; Liver tumor; Metastatic liver cancer	PDGF receptor beta antagonist; Raf B protein kinase inhibitor; VEGF-1 receptor antagonist; VEGF-3 receptor antagonist; VEGF-2 receptor antagonist; Flt3 tyrosine kinase inhibitor; Kt tyrosine kinase inhibitor;	
CN-106880607	An oral cavity disintegrating tablet containing regorafenib and preparation method thereof	PKU Care Pharmaceutical R&D Center; PKU HealthCare Corp Ltd; Peking University Founder Group Corp	Cancer	Caspase-9 stimulator; Kit tyrosine kinase inhibitor; RET tyrosine kinase receptor family inhibitor; VEGF receptor antagonist; Raf 1 protein kinase inhibitor; PDGF receptor beta modulator; FGF receptor	
WO-2016051422	Process for the preparation of 4-[4-((4-chloro-3-(trifluoromethyl)phenyl)carbamoyl)amino]-3-fluorophenyl]-N-methylpyridine-2-carboxamide and its polymorphs thereof	MSN Laboratories Ltd	Gastrointestinal stromal tumor; Metastatic colorectal cancer	VEGF-2 receptor antagonist; Kit tyrosine kinase inhibitor; PDGF receptor beta modulator; VEGF-3 receptor antagonist; Tek tyrosine kinase receptor inhibitor; Raf 1 protein kinase inhibitor; VEGF-1 receptor antagonist;	

Owner Companies: Bayer HealthCare AG (14) Bayer Healthcare LLC (13) Bayer Corp (8) [Show all filters](#)

Third Party Companies

Company Relationships

Drugs

Drug Relationships

點選查看專利內容

*限已核准的專利

交易和專利(續)-專利報告(續)

提供與藥品相關的專利情報，包含申請人/所有權人、專利類型、適應症、化學結構式、編輯重點摘要、技術類型、專利家族、預估到期日*、專利原文PDF

WO-2011128261

Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms < Previous Next >
Companies and Drugs	SNAPSHOT
Editorial Abstract	Patent Number WO-2011128261
Chemical Structures	Title Process for the preparation of 4-{4-[(4-chloro-3-(trifluoromethyl)-phenylamino)carbonyl]amino}-3-fluorophenyl-N-methylpyridine-2-carboxamide, its salts and monohydrate
Claims	Original Assignee Bayer Pharma Aktiengesellschaft
Documents and Status	Inventor Abstract The present invention relates to a process for preparing 4-{4-[(4-chloro-3-(trifluoromethyl)-phenylamino)carbonyl]amino}-3-fluorophenyl-N-methylpyridine-2-carboxamide, its salts and monohydrate.
Expiry	Patent Type Process; Formulation
	Indications Esophagus tumor; Non-small-cell lung cancer; Stomach tumor; Renal cell carcinoma; Sarcoma; Leukemia; Lymphoma; Fallopian tube cancer; Neoplasm; Pancreas tumor; Peritoneal tumor; Adenoid tumor; Gastrointestinal stromal tumor; Cancer; Solid tumor; Ovary tumor
	Target-based Actions VEGF receptor antagonist; Tek tyrosine kinase receptor inhibitor; Caspase-3 stimulator; Kit tyrosine kinase inhibitor; Caspase-9 stimulator; Raf 1 protein kinase inhibitor; Raf protein kinase inhibitor; Raf B protein kinase inhibitor; PDGF receptor beta modulator; RET tyrosine kinase receptor family inhibitor; Tie tyrosine kinase receptor inhibitor; FGF receptor antagonist
	Other Actions Angiogenesis inhibitor
	Technologies Condensational synthesis; Hydrolytic synthesis; Salt synthesis; Synthetic method
	Inventors Reise, Joachim; Gottfried, Michael; Wichmann, Saskia; Logers, Michael; Stehl, Juergen; Hellmann, Werner
	IPC Codes C07D 3/81; C07D 213/02; C07D 213/01; A61K 31/4412; C07B 1/04; A61K 31/44; C07D 3/02; A61P 5/00; A61K 4/35; C07B 3/00; C07D 213/53; A61K 1/44; A61P 35/00; A61P 35/02; A61K 31/435
	Manual Codes B07-D04B (Pyridine (optionally substituted) production); B14-H01 (Anticancer general and other)
	First Estimated Expiry in Family 23-Mar-2031 Argentina AR-00081060
	First Publication in Family 20-Oct-2011 WO-2011128261-A1

點選分頁檢視內容

*限已核准的專利

SWOT 分析(SWOT Analysis)

條列藥品的優勢(Strength)、劣勢(Weakness)、機會(Opportunity)及威脅(Threat)等分析意見。

regorafenib

Snapshot Highlight Search Terms & Synonyms < Previous Next >

Latest Press Releases

Latest Event Transcripts

Broker Research Reports

Development Profile

Literature Review

Development Status

Regulatory Designations

Chemical Structures

Drug Names

Sales and Forecasts

Clinical Trials

Deals and Patents

SWOT Analysis

Change History

Sources

SWOT ANALYSIS

Anticancer multitargeted protein kinase inhibitors

Strengths

- Improved overall survival by 29% in patients with metastatic colorectal cancer (CRC; 6.4 versus 5 months), according to data from the phase III CORRECT study [\[1255650\]](#)
- Improved survival was seen in both KRAS wild-type and KRAS-mutated CRC tumors [\[1588336\]](#)
- Improved progression-free survival (PFS) in previously treated patients with gastrointestinal stromal tumors (GIST) from 0.9 to 5.8 months in the phase III GRID trial [\[1297065\]](#)
- First therapy to demonstrate a survival benefit over best supportive care in second-line hepatocellular carcinoma (HCC) patients in the phase III RESORCE trial; improved overall survival by 2.8 months (10.6 versus 7.8 months) for a 38% reduction in risk of death; PFS also favored Stivarga (3.1 versus 1.5 months), as did overall response rate (10.6 versus 4.1%) [\[1779224\]](#), [\[1922189\]](#)

Weaknesses

- Restricted to third-line use in CRC following treatment with chemotherapy; an anti-VEGF applicable [\[1327170\]](#)
- Deterioration in patients' quality of life and no difference between Stivarga and placebo in study in CRC [\[1588336\]](#)
- Non-significant difference versus placebo for second-line CRC; Stivarga had a median PFS and overall survival of 6.14 and 13.2 months, respectively, compared with 5.29 and 12.0 months, respectively, for placebo [\[1805892\]](#)
- Also restricted to third-line use in GIST [\[1327170\]](#)
- There was no difference in overall survival seen in the GRID study in GIST [\[1343176\]](#)

Opportunities

- Differentiation based on the drug's profile, as it targets cell proliferation and tumor vasculature [\[1024200\]](#), [\[1949099\]](#)
- Immediate uptake in metastatic CRC which has progressed after all approved treatments, where there is a lack of valid clinical management options; this is particularly relevant for patients with KRAS mutations who are non-responsive to anti-EGFR therapies [\[1588336\]](#)
- Move upstream in CRC treatment protocols; a phase III trial (ARGO) in the adjuvant setting in patients with Stage III disease is ongoing [\[1768320\]](#)

Threats

- The toxicity profile could be prohibitive, particularly without molecular markers to identify patients who would see compelling improvements in survival which would justify the side effects [\[1024200\]](#), [\[1006986\]](#), [\[1588336\]](#)
- Innovations in the management of metastatic CRC with new chemotherapeutics and targeted therapies and their introduction into clinical practice has led to significant improvement in outcomes in metastatic CRC, and provided a range of first- and second-line options [\[1588464\]](#), [\[1706422\]](#)
- Avastin remains dominant, and other options include Erbitux, Vectibix, Cyramza and Zaltrap. Generic chemotherapy options

點選顯示資料來源

OTHER PUBLICATION

2012September
US drug datasheet: highlights of prescribing information - Stivarga (regorafenib)tablets
 Drug datasheet website
 Bayer AG
 Source ID: 1327170

Save and Alert

儲存及通知

儲存您的檢索條件或報告及定期監控您的檢索結果

Cortellis All ▾ "non-small-cell lung cancer" 🔍 Explore ▾ Tina Chao | Help **Clarivate Analytics**

Advanced search | Structure search 🗑️ Full text 🗑️ Index

< Back | Forward > Search Results Analyze Save and Alert Download

712 results found for "non-small-cell lung cancer" 1 2 3 4 5 6 7 8 9 Next ▶ Last ⏪

Report Type Show selected only

Bioactives (1049)
 Broker Research (39987)
 Clinical Trials (6983)
 Companies (1032)
 Conferences (1932)
 Deals (1764)
 Disease Briefings (6)
Drugs (712)
 Event Transcripts (2799)
 Literature (11466)

Results Per page: 50 Sort by: Relevance Descending Order Columns

Drug Name	Highest Status	Filters: [0]		
<input checked="" type="checkbox"/> mutant EGFR inhibitor (NSCLC, Amgen)	No Development Reported			
<input checked="" type="checkbox"/> LFLAI gene activator (NSCLC, NCI)	No Development Reported			
<input checked="" type="checkbox"/> cytolytic bradykinin inhibitors (NSCLC)	Discovery	University of Colorado	Non-small-cell lung	

儲存及通知

儲存您的檢索條件、檢索結果裡相應的報告以及更新通知(包含篩選條件):

1. 儲存您的檢索條件及定期監控您的檢索結果;
2. 儲存您的檢索報告及定期監控檢索報告的更新。

1. 儲存您的檢索條件及定期監控您的檢索結果

The screenshot shows a software interface with a navigation bar at the top containing 'Back', 'Forward', 'Analyze', 'Save and Alert', and 'Export' buttons. A central dialog box is open, titled '儲存及通知' (Save and Alert), with the subtitle '儲存您的檢索條件、檢索結果裡相應的報告以及更新通知' (Save your search conditions, corresponding reports in search results, and update notifications). The dialog box contains six options arranged in a 2x3 grid:

- Save search query (represented by a floppy disk icon)
- Alert on search query (represented by an envelope icon with a green arrow)
- Save and alert on search query (represented by a floppy disk and envelope icon with a green arrow)
- Save reports (represented by a stack of papers and a floppy disk icon)
- Alert on reports (represented by a stack of papers and an envelope icon with a green arrow)
- Save and alert on reports (represented by a stack of papers, a floppy disk, and an envelope icon with a green arrow)

A 'Cancel' button is located at the bottom right of the dialog box. Three callout boxes provide additional context for the options:

- 儲存您的檢索條件(search query)**: Points to the 'Save search query' option.
- 通知您的檢索結果有新的更新(alert on search query)**: Points to the 'Alert on search query' option.
- 儲存您的檢索條件，並在檢索結果有更新時通知**: Points to the 'Save and alert on search query' option.

2. 儲存您的檢索報告及定期監控檢索報告的更新


Cortellis All ▾ "non-small-cell lung cancer" 🔍 Explore ▾ Tina Chao | Help **Clarivate Analytics**

儲存及通知
儲存您的檢索條件、檢索結果裡相應的報告以及更新通知


SAVE SEARCH AND/OR ALERT

Choose if you would like to save the search query or reports, create an alert, or save and alert combined; based on the search query (including filters) or reports in the results list


Save search query




Alert on search query




Save and alert on search query




Save reports



Alert on reports



Save and alert on reports



Save and Alert Download

1 2 3 4 5 6 7 8 9 Next Last

View

Sales Total Forecast Sales 2022 (USD M) Filters : [0]

儲存檢索結果裡的報告

檢索報告有更新時通知
(Alert on report)

儲存您選取的報告，並在
報告有更新時通知

儲存檢索條件及更新通知-設定

Step 1 Step 2 Step 3 Step 4

REPORTS ALERT

Enter a preferred name, or just click Next to use the display name.

Name

"non-small-cell lung cancer" **命名您的檢索條件或報告**

Includes

712 Report(s)

回到上一頁 下一步

Cancel Previous Next

儲存檢索條件及更新通知-設定(續)

Step 1 Step 2 Step 3 Step 4

The alerts notifications inform you about records that are new or that are removed from your search results set over time. To additionally include records that are updated, please select the 'Reasons for Update'!

Alert updates...

Select all

- Chemistry
- Development Profile
- Development Status
- Drug Name
- Index

Alert me if there are no updates

回到上一頁 下一步

Cancel Previous Next

勾選更新條件

沒更新也要通知

儲存檢索條件及更新通知-設定(續)

Step 1 Step 2 **Step 3** Step 4

FORMAT, START DATE AND FREQUENCY

Choose your preferred alert format and how often.

Email format

HTML

Text

Start date of alert

Earliest available date (02-Dec-2017)

Specify date

Frequency

Daily ▾

Share

I would like to share this alert with colleagues

設定郵件格式

設定通知郵件起始日

**設定通知頻率
(每日、每日、每月)**

也要通知同事

回到上一頁

下一步

Previous Next

儲存檢索條件及更新通知-設定(續)

Step 1 Step 2 Step 3 **Step 4**

SHARE ALERT

Choose if you would like to share your alerts with colleagues.

Notify

Me and colleagues

Colleagues

Email

"tina.chao@clarivate.com"

Colleagues

Please separate email addresses using a semi-colon (;)

通知郵件收件人:

1. 帳號使用人及同事
2. 只通知同事

同事的email, 不同email用分號(;)隔開

回到上一頁 完成設定

Cancel Previous Create

Cortellis Regulatory Weekly Alert

法規更新通知

每周法規更新通知*

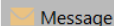


Mon 9/11/2017 9:31 AM

Cortellis Alerts <cortellis.alerts@clarivate.com>

Cortellis Regulatory Intelligence Weekly Alert - Drugs and Biologics & Medical Devices and IVDs - Volume 2017 - 37

To



Message



Cortellis Weekly Alert - Drugs and Biologics & Medical Devices and IVDs - 2017 Volume 37.html (774 KB)

Dear *Cortellis Regulatory Intelligence User*,

Please find attached our **Weekly Alert - Drugs and Biologics & Medical Devices and IVDs**, 2017 Volume 37 of 04-Sep-2017 - 08-Sep-2017.

The *Cortellis Regulatory Intelligence Weekly Alert* provides you with a survey of the Global Regulatory Landscape by highlighting the latest documents added to *Cortellis Regulatory Intelligence*.

The Cortellis Regulatory Intelligence Team

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FDA諮詢委員會會前通知(Adcomm Advance)*

在美國FDA諮詢委員會會議開始之前，以email寄送給您的即將舉行的會議的單頁概述

 Tue 9/12/2017 10:28 PM
Cortellis Alerts <cortellis.alerts@clarivate.com>
AdComm Advance - Drugs and Biologics - Shingrix an Adjuvanted Shingles Vaccine to Be Reviewed

To

Message  Shingrix an Adjuvanted Shingles Vaccine to Be Reviewed.pdf (273 KB)

AdComm Advance
Know before you go

 **Clarivate Analytics**

IDRAC 258411

Dear *Cortellis Regulatory Intelligence - Drugs and Biologics User*,

The **AdComm Advance - Drugs and Biologics** is attached to provide a pre committee.

The Cortellis Regulatory Intelligence Team

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Meeting Schedule*
September 13, 2017
8:30 a.m. – 5:00 p.m.

Federal Register Announcement
August 7, 2017
(IDRAC 256695)
(Vol. 82, No. 150)

Meeting Documents

Vaccines and Related Biological Products Advisory Committee
Shingrix, an Adjuvanted Shingles Vaccine, to Be Reviewed

Meeting Overview

At this meeting, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet to discuss recommendations on the safety and effectiveness of Shingrix (varicella zoster vaccine [recombinant], adjuvanted), a proposed vaccine to prevent shingles in patients aged ≥50 years, manufactured by GlaxoSmithKline Biologicals. Caused by the varicella zoster virus [VZV], a herpes zoster virus, shingles is also referred to as herpes zoster.

second available vaccine approved to prevent shingles. In 2006, the FDA approved the first shingles vaccine, [Zostavax](#) (IDRAC 256627) (zoster vaccine, live), by Merck Sharp & Dohme Corp, prepared from a strain of live, attenuated VZV, for the prevention of shingles in patients aged ≥50 years.

According to the sponsor, Shingrix would provide a reduced overall incidence of post-herpetic neuralgia (PHN) in patients with shingles and could potentially offer higher and longer-term protection.

If approved, Shingrix would be the first non-live adjuvanted vaccine and the

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Clarivate Analytics

FDA諮詢委員會公告(Adcomm Bulletin)*

美國FDA諮詢委員會會議結束後，以email寄送給您最新的投票結果及會議中討論的法規問題或背景

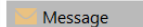


Thu 9/14/2017 4:23 AM

Cortellis Alerts <cortellis.alerts@clarivate.com>

AdComm Bulletin - Drugs and Biologics - GSK Biologicals Adjuvanted Shingles Vaccine S

To



Message

GSK Biologicals Adjuvanted Shingles Vaccine Shingrix Earns Full Support.pdf (331 KB)

Dear *Cortellis Regulatory Intelligence - Drugs and Biologics User*,

Today's *AdComm Bulletin - Drugs and Biologics* is attached.

This FDA Advisory Committee Meeting Summary is also available from *Cortellis Regulatory Intelligence*

The Cortellis Regulatory Intelligence Team

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AdComm Bulletin

Read it first. Read it fast.

The latest developments from US FDA drug and biologic advisory committee meetings.

**Today's
Headline:
GSK's
Adjuvanted
Shingles
Vaccine,
Shingrix, Earns
Full Support**

Decision/Voting

IDRAC 258413



September 13, 2017

Meeting Begin Time: 8:30 a.m. | End Time: 2:12 p.m.

IN THIS ISSUE

**Vaccines and Related Biological Products
Advisory Committee Meeting**

[AdComm Profiles and Voting Histories](#)
(IDRAC 175864)

Subject: Recommendations on the safety and effectiveness of Shingrix (varicella zoster vaccine [recombinant], adjuvanted), a proposed vaccine against infection caused by shingles (also known as the varicella zoster virus [VZV], a herpes zoster virus), in patients aged ≥50 years, manufactured by GlaxoSmithKline Biologicals.

Announced in the Federal Register
[August 7, 2017](#) (IDRAC 256695)
(Volume 82, Number 150)



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每周法規更新通知*(續)

2017, Volume 48 of Monday 20 November to Friday 24 November 2017

International (1)	USA (161)	Canada (11)
EUROPE European Union (104) Austria Belgium (1) Bulgaria (1) Croatia (3) Cyprus Czech Republic (1) Denmark (4) Estonia	Finland (1) France (23) Germany (1) Greece Hungary Iceland Ireland (12) Italy (1) Latvia	Lithuania Luxembourg Mexico Poland Portugal Romania (1) Russian Federation (1)
ASIA - PACIFIC Asean Australia (12) China (23) Hong Kong	India (13) Indonesia Japan (9) Malaysia (1)	New Zealand Philippines Singapore (4) South Korea (4)
LATIN AMERICA Mercosur SICA Argentina	Brazil (2) Chile Colombia (2)	Costa Rica Guatemala Mexico
AFRICA - MIDDLE EAST Gulf Cooperation Council Algeria (2) Egypt (5) Iraq	Israel Jordan (1) Kenya Lebanon (2)	Morocco Nigeria (1) Saudi Arabia (2) South Africa (1)
		Switzerland (11) Turkey (1) Ukraine United Kingdom (3)
		Taiwan (2) Thailand (4) Vietnam (1)
		Panama (1) Peru (3) Venezuela
		Tunisia (1) United Arab Emirates

最近一周內有法規情報更新
(以超連結標示)



科睿唯安



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聯繫窗口：

Jack Lee 李旻哲
Account Manager, Academic Taiwan
Phone +886 2 8729 2122
jack.lee@clarivate.com

The Clarivate Analytics logo, consisting of the stylized 'C' icon followed by the text 'Clarivate Analytics' in a bold, black, sans-serif font.