

中国药科大学

Informa医药数据库培训

Pharmaprojects – 全球临床药物信息
Scrip – 制药行业综合资讯
Pink Sheet – 监管及法规资讯

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Informa
生命科学智库公众号

内容

□ Informa医药智库

▪ Citeline

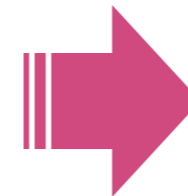
- **Pharmaprojects**
- *Trialtrove*
- *Sitetrove*
- *Trialpredict*

▪ Insights Solution

- **Scrip**
- **Pink Sheet**
- *Medtech Insights*
- *In Vivo*
- *HBW Insights*
- *Generics Bulletin*

- *Datamonitor Healthcare*
- *Biomedtracker*
- *Meddevicetracker*
- *Pharmapremia*
- *Medtrack*
- *Strategic Transactions*

全球临床药物
信息
&
制药行业综合
资讯
&
监管及法规
资讯



□ Informa集团介绍

- ❖ 2019 Informa医药智库一览
- ❖ 如何自主注册或登录使用?

□ 各数据库概要

- ❖ Pharmaprojects – 研发药物信息
 - ❖ Citeline一览
 - ❖ 涵盖范围
 - ❖ 主要功能
- ❖ Scrip/Pink Sheet – 行业资讯 (市场、监管等)
 - ❖ Scrip涵盖范围及关键信息
 - ❖ Pink Sheet涵盖范围及关键信息

□ 分析师咨询服务 (Ask-the-Analyst)

□ 调研案例

- ❖ 银屑病综合分析 (Psoriasis)

□ 客服支持

- ❖ 关键辅助连接

Informa 集团介绍



Discovery.
Insight.
Advantage.



Analysis.
Insight.
Advantage.



Exchange.
Insight.
Advantage.



Network.
Insight.
Advantage.

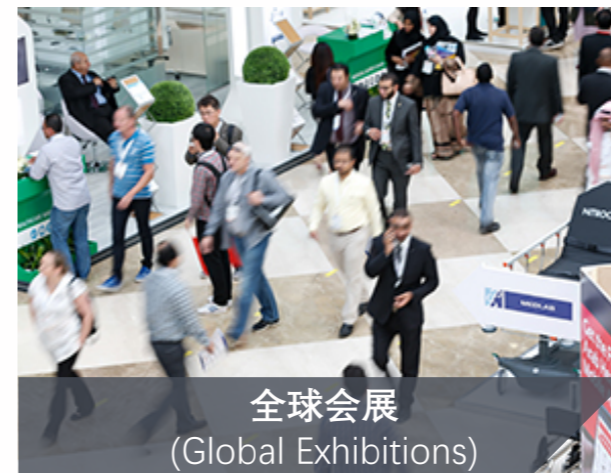
- ❑ Informa集团系知识及专业咨询领域领航者。
- ❑ 提供行业情报分析及全球会展的业界顶尖企业，拥有超过**11000名雇员**，并全球各地设有超**100个办事处**。
- ❑ 以高质量行业信息为本，通过优秀的专业人才，为学术、商业或专业团体提供针对性行业分析情报。
- ❑ Informa旗下**四大部门**：



学术出版
(Academic Publishing)



行业智库
(Business Intelligence)



全球会展
(Global Exhibitions)



知识与交流
(Knowledge & Networking)




2019 Informa医药智库全产品一览

Insights系列 – News and Insights

| | |
|---|--|
|  | 全球制药行业之关键商业及企业资讯与见解，助业内人士作出更明智商业决策。 |
|  | 全球医药行业监管及法规之最新资讯与见解，掌握全球行业发展及相关影响。 |
|  | 全球医疗器械技术市场之资讯、见解及分析，其中包含最新行业趋势、交易、法规及权威意见。 |
|  | 涵盖生物制药、医疗器械及诊断市场，为生命科学领域决策者提供关键市场战略分析。 |
|  | 业界领先之非处方药、医美及保健市场统一资讯平台，提供商业、监管、法规及立法之最新动向与分析。 |
|  | 关注全球仿制药、生物类似药及高附加值药物市场，提供业界领先之资讯涵盖及专家分析。 |

Consulting – 订制咨询

| | |
|---|---|
|  | 通过订制咨询服务，获取综合市场各领域（如：生物药企管产品组合管理、商业开发或药物研发战略制定）之顶级分析。 |
|---|---|

Intelligence系列 – Data Analysis

| | |
|---|---------------------------------------|
|  | |
|  | 为业内专家订制之全球临床试验数据平台，一切信息皆由行业专家亲自制定。 |
|  | 无限扩大潜在临床研究人选、国家或地点选址。 |
|  | 最值得信赖之研发药物数据库，全面追踪全球范围内从临床前至上市的R&D管线。 |
|  | 医药行业之深度市场综合分析及未来竞争市场预测。 |
|  | 通过研发概率，分析在研药物于临床与监管之成功因素。 |
|  | 实时追踪及分析医药及生物技术市场之关键事件。 |
|  | 全面追踪及涵盖全球制药、医疗器械及诊断行业之药品及公司信息与周期管理过程。 |
|  | 获取医疗器械市场最新动态与关键事件分析。 |
|  | 市场交易事件千变万化，通过顶级交易分析获取最佳资讯。 |

如何注册或登录使用？



- 个人账号
- 须自主注册
- 登录网址：

<https://citeline.informa.com/>

- 公用账号
- 详情见图书馆网站
- 登录网址：

<https://scrip.pharmaintelligence.informa.com>

<https://pink.pharmaintelligence.informa.com>

Pharmaprojects自主注册: <https://citeline.informa.com/>

注册: 进入网站后点击界面下方的“**Register here**”进入注册界面

登录: 输入账号及密码点击“**Login**”

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Citeline
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Email Address/Username *

Password *

Remember me

Forgot Password > Login >

Click 'Forgot Password' to receive an email with a reset link. If your username is not a valid email or you need assistance please [click here](#)

Don't have an account? [Register here](#)

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Pharma intelligence

Pharmaprojects自主注册: <https://citeline.informa.com/>

informa

Citeline
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Please complete the form below to register your Citeline account.

Email (Username) *

First Name *

Last Name *

Company *

Country *

Password *

Confirm Password *

Your password must be at least 8 characters long. Your password must have a mix of letters and numbers

By ticking this box, you agree to receive emails such as promotional offers from other members of the Informa group and selected 3rd party companies

I'm not a robot

REGISTER

Already registered? [Login here](#)

请按以下步骤完成注册:

1. 输入个人信息
2. 设置个人密码
3. 点击验证
4. 点击“Register”完成注册

- ❖ 所有信息必须以英文字母填写
- ❖ “Username”一栏请输入您的邮箱地址
- ❖ 请使用以下邮箱域名进行注册:
 - ✓ @cpu.edu.cn
 - ✓ @stu.cpu.edu.cn
- ❖ 密码必须是8字节或以上
(同时含有英文字母与数字)

注: 若有任何问题, 请联系 Robert.wu@informa.com。

各数据库概要

Pharmaprojects

研发药物数据

R&D领域的全方位统一服务咨询平台

Pharmaprojects 临床药物信息

| Drug ID | Search Drug Name | Target | Target Disease | Therapeutic Class |
|---------|------------------|-------------------------------|----------------|-------------------|
| 1 | 100000000 | retroviral protease inhibitor | AIDS | Antiretroviral |
| 2 | 100000000 | anti-CD4 receptor | AIDS | Antiretroviral |
| 3 | 100000000 | anti-CD4 receptor | AIDS | Antiretroviral |
| 4 | 100000000 | anti-CD4 receptor | AIDS | Antiretroviral |
| 5 | 100000000 | anti-CD4 receptor | AIDS | Antiretroviral |

Citeline
Pharma intelligence | informa

全球领先的研发资讯
相结合
(药物、临床试验、
研究人员、地点)

Sitetrove 临床研究人员及地点信息

| Investigator ID | Full Name | Last Name | Investigator City |
|-----------------|-----------------|-----------|-------------------|
| 1 | John Doe | Doe | New York |
| 2 | Jane Smith | Smith | Los Angeles |
| 3 | Michael Johnson | Johnson | Chicago |
| 4 | Emily White | White | San Francisco |
| 5 | David Brown | Brown | London |

Trialtrove 临床试验信息

| Trial ID | Trial Title | Product/Drug ID | Trial Status |
|----------|--|-----------------|--------------|
| 1 | Phase I Study of Drug X in Cancer Patients | 100000000 | Completed |
| 2 | Phase II Study of Drug Y in Heart Disease | 200000000 | In Progress |
| 3 | Phase III Study of Drug Z in Diabetes | 300000000 | Planned |
| 4 | Phase IV Study of Drug W in Alzheimer's | 400000000 | Completed |

Trialpredict (内置于Trialtrove) 受试者募集分析及预测

| Enrollment Date | Enrollment Count | Enrollment Rate |
|-----------------|------------------|-----------------|
| 2024-01-15 | 120 | 0.85 |
| 2024-02-15 | 150 | 0.90 |
| 2024-03-15 | 180 | 0.95 |
| 2024-04-15 | 210 | 1.00 |
| 2024-05-15 | 240 | 1.05 |

更快速、简易的
统一数据平台

Citeline分析师团队



拥有超250名常驻全球主要市场的各疾病领域专家团队
了解您的独特需求



精通各研发领域

跨产品的分析师团队通力合作，
统一收集、评估及分析从临床前
至上市的一切研发信息



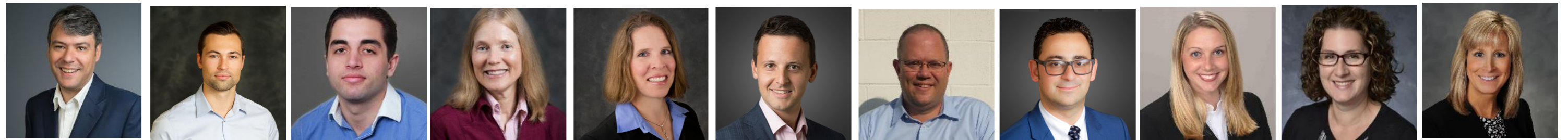
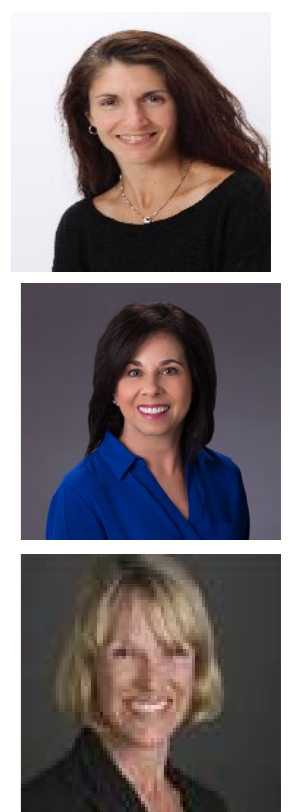
多年经验值得信赖

累积数千年的从业及专业经验，
分析师团队可提供值得信赖的
专业见解



业内顶级分析

以全面、透明及独立的
视角作出专业分析



数据均由业内专家验证，并配有无限限制分析支持

无可比拟的数据“质”与“量”

涵盖临床试验、研究人员及地点，以及药物研发管线

原始数据均由业内专家亲自确认、分析及增强

配有无限限制分析师咨询服务

引用

超43,000条网上资源

- 基于事件的更新
- 反复验证关键信息来源
- 排除重叠数据

分析

分析师专业见解是关键所在

增强

通过业界及各疾病领域专家分析与运用所有相关额外补充数据，最大程度优化信息范围及质量

编辑

信息均可在线上统一平台查询，各种信息（如：药物、临床试验、受试者募集及临床用时、研究人员及地点等）均以相互连接的方式编辑及排列

内容范围涵盖整个公共领域

主要信息来源 – 目前引用超过43,000个信息来源并持续增长

- 超过70个来自各国或地区的临床试验注册机构（如：ClinicalTrials.gov, EUCTR, JAPIC, ChiCTR等）
- 超过90个其他临床试验资讯来源（如：申办方注册信息、合作机构、主要医疗中心）
- 超过5000个企业信息（全面涵盖管线、新闻报道、投资者，以及其他网页）
- 所有主要医疗会议（超过250个会议）
- 新闻资源、投资者演讲、美国证监会文件，以及公司年度报告等
- 各国医疗及卫生机构的官方网页
- 医学杂志及论坛
- USAN与INN lists, eMolecules, ChemSpider, & ChemIDplus
- 其他线上资源，如：Gene（前身为EntrezGene）、PubMed，以及Espacenet等

Pharmaprojects如何能帮到您？

商业发展 (Business Development)

- 识别潜在合作机遇 (In/out-licensing)
- 分析药物研发历程
- 发掘全新疾病领域研发战略

竞争分析 (Competitive Intelligence)




- 通过各种筛选条件 (如: 公司、适应症、作用机制或靶点等), 评估竞争市场格局
- 分析重大市场事件 (如: 研发终止、上市、获批或孤儿药状态等)





研究与开发 (Research & Development)

- 哪些药物拥有相似的化学结构或作用机制?
- 哪些应用创新靶点的药物进入了研发阶段?

Pharmaprojects

“完整覆盖**1980**年后全球创新药及研发历程”

-  产品销售数据
-  完整药物专利数据（仅含主要国家专利号码或申请日期）
-  完整公司管线（未涵盖仿制药、非处方药等）

-  药物信息（如：作用机制、关联公司、化学结构、各国上市时间、各期关键临床数据等）
-  关联临床试验
-  研发事件历程（临床前至上市）
-  公司基本信息（如：附属及并购公司、营收及研发投入等）

内容涵盖范围说明：<https://citeline.zendesk.com/hc/en-us/articles/360007579834-Pharmaprojects-Scope-Statement>

常见问答：<https://citeline.zendesk.com/hc/en-us/articles/360008530913-Pharmaprojects-Frequently-Asked-Questions>

完整涵盖临床前至上市信息...

全面覆盖1980年至今所有商用或处方用的全球各疾病领域药物研发信息 – 其中包括：创新药、生物制剂、疫苗、新型或重新配方药物及技术，以及伴随诊断（非处方药、仿制药、医疗器械等除外）



超过78,000个完整药物报告

- 研发方及合作方信息
- 所有应用适应症及最高临床阶段信息
- 重大事件综述 – 全面追踪关键事件（如：研发状态变动、孤儿药申请批准或首次上市等）
- 作用机制及靶点
- 全球各国上市或获批状态
- 是否有合作空间？
- 药物化学信息（如：药物来源、化学名、药代动力学或化学结构等）
- 研发信息
- 临床前信息

Pharmaprojects 药物报告涵盖范围

Drug

obeticholic acid

6-ECDCA; 6-ECDCA (capsule); 6-ECDCA (tablet); 6alpha-ethylchenodeoxycholic acid; DSP-1747; DSP-1747 (capsule); DSP-1747 (tablet); INT-747; INT-747 (capsule); INT-747 (tablet); obeticholic acid; obeticholic acid (capsule); obeticholic acid (tablet); Ocaliva

Drug Summary

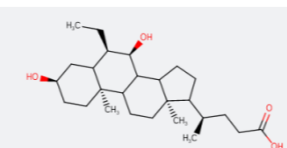
| | | | |
|--------------------|----------|--------------------|--|
| Global Status | Launched | Latest Change | Approval in Australia and Israel as Ocaliva for primary biliary cirrhosis (PBC) reported |
| Development Status | Active | Latest Change Date | 2018/12/10 |

Summary
Obeticholic acid (INT-747) is an orally-active analogue of the natural human bile acid CDCA (chenodeoxycholic acid), developed by Intercept Pharmaceuticals (Genextra) as a first-in-class farnesoid X receptor (FXR) agonist for the treatment of primary biliary cirrhosis (PBC). It is also under development for the treatment of non-alcoholic steatohepatitis (NASH) and primary sclerosing cholangitis (PSC) (Scrip Daily Online, 6 Sep 2004, S00856390; Company Web Page, Intercept, 21 Jun 2007; USAN Web Page, 5 Nov 2008; Press release, Intercept Pharmaceuticals, 8 Oct 2014, <http://ir.interceptpharma.com/releasedetail.cfm?ReleaseID=875121>; Company pipeline, Sumitomo Dainippon Pharma, 29 Jan 2015, <http://www.ds-pharma.com/rd/clinical/pipeline.html>).

- Drug Summary
- Company Data
- Diseases
- Activity
- Event History
- Chemical data
- Country data
- Trialtrove Trials
- Marketing
- Licensing
- Phase III
- Phase II
- Phase I
- Preclinical
- Supporting URLs

| Company Data | | |
|--|--------------------------|----------|
| Originator | | |
| Name | Country | Status |
| Intercept Pharmaceuticals (part of Genextra) | USA | Launched |
| Licensee | | |
| Name | Country | |
| Sumitomo Dainippon Pharma | Japan | |
| Diseases | | |
| Name | Status | |
| Cirrhosis, primary biliary | Launched | |
| Non-alcoholic steatohepatitis | Phase III Clinical Trial | |
| Hypertension, portal | Phase II Clinical Trial | |
| Primary sclerosing cholangitis | Phase II Clinical Trial | |
| Biliary atresia | Phase II Clinical Trial | |
| Diarrhoea, unspecified | Preclinical | |

| Chemical data | |
|---------------------|---------------------|
| Origin | Chemical, synthetic |
| NCE | Yes |
| CAS registry number | 459789-99-2 |
| Molecular Formula | C28H44O4 |
| Molecular Weight | 420.63 |
| logP | 4.52 |
| Chemical Structure | |



| | |
|------------------------------------|---|
| H Bond Donors | 3 |
| H Bond Acceptors | 4 |
| Rotatable Bonds | 5 |
| Chemical Name | (4R)-4-[(3R,6R,7R,10S,13R)-6-ethyl-10-hydroxy-3,6,7,10-tetrahydro-2H-benzofuran-2-yl]pentanoic acid |
| Chemical Structure (SMILES format) | CC[C@@H]1[C@@H](O)C[C@@H](C)C[C@@H]1C(=O)O |

| Trialtrove Trials | | | | | |
|---------------------------|-------------------------|--|--|---|-----------|
| Trialtrove Trial Count 27 | | | | | |
| Phase | Disease | Sponsor | Drugs tested | Protocol/Trial ID | Status |
| (N/A) | ClinicalTrials.gov | University of Aarhus | obeticholic acid, Placebos | NCT02532776; OCAPBC | Open |
| I | Hepatic Fibrosis, NAFLD | Sumitomo Dainippon Pharma (Dainippon Sumitomo) | obeticholic acid | Trial/TroveID-167308 | Completed |
| I | Hepatic Fibrosis | Genextra/Intercept Pharmaceuticals | obeticholic acid | Trial/TroveID-336296 | Completed |
| I | Hepatic Fibrosis, NAFLD | Genextra/Intercept Pharmaceuticals | obeticholic acid (tablet) | Trial/TroveID-245334; 747-104; NCT01914562 | Completed |
| I | Hepatic Fibrosis, NAFLD | Genextra/Intercept Pharmaceuticals | obeticholic acid | Trial/TroveID-249887 | Planned |
| I | Hepatic Fibrosis, NAFLD | Genextra/Intercept Pharmaceuticals | obeticholic acid | Trial/TroveID-186863 | Completed |
| I | ClinicalTrials.gov | Schngrenska University Hospital, Sweden | obeticholic acid, Obeticholic acid placebo | NCT02532335; OCAPUSH | Open |
| I | Hepatic Fibrosis, NAFLD | Genextra/Intercept Pharmaceuticals | obeticholic acid | Trial/TroveID-186889; 747-105; NCT01933503 | Completed |
| II | NAFLD | Genextra/Intercept Pharmaceuticals | atorvastatin calcium, obeticholic acid | Trial/TroveID-169972; 747-209; CONTROL; NCT02613956 | Completed |
| II | Hepatic Fibrosis | Genextra/Intercept | obeticholic acid | Trial/TroveID-162443; 747-201; | Completed |

Pharmaprojects 药物报告涵盖范围 (续)

Drug

- Drug Summary
- Company Data
- Diseases
- Activity
- Event History**
- Chemical data
- Country data
- Trialtrove Trials
- Marketing
- Licensing
- Phase III
- Phase II
- Phase I
- Preclinical
- Supporting URLs

Event History

| Date | Status | Description |
|------------|--------------------------------------|---|
| 2018/10/31 | New Approval | Australia & Israel; Cirrhosis, primary biliary |
| 2017/05/25 | New Approval | Canada; Primary biliary cholangitis when used in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA |
| 2017/01/15 | New Launch | The EU; Primary biliary cholangitis |
| 2016/12/14 | New Approval | The EU; Primary biliary cholangitis |
| 2016/09/19 | Expedited Review Designation Granted | Canada; Primary biliary cirrhosis; Priority review |
| 2016/09/19 | New Filing | Canada; for the treatment of primary biliary cholangitis, also referred to as primary biliary cirrhosis (PBC), when used in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. |
| 2016/06/15 | First Launch | NAS; USA; PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA |
| 2016/05/27 | First Approval | The US; Primary biliary cholangitis in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA |
| 2015/10/15 | Disease Phase Change | Biliary atresia; Phase II Clinical Trial |
| 2015/09/28 | Disease Phase Change | Non-alcoholic steatohepatitis; Phase III Clinical Trial |
| 2015/08/31 | Expedited Review Designation Granted | The US; Primary biliary cirrhosis; Priority review |
| 2015/08/05 | New Disease | Biliary atresia |

[点击查看详细信息](#)

Marketing

- 上市批准
- 各类申请
- 孤儿药状态
- 各类优先审查申请
- 监管部门警告信

Pharmaprojects

主要功能

视觉逻辑搜索 (Visual Boolean Search)

进行动态交互式搜索

- 凭直觉建立复杂的搜索
- 调整搜索并同步查看筛选经过

快速获取所需的信息

提高搜索结果的准确性，
即便是不常用的用户也可
轻易做到

随意尝试各种搭配和开发
新的见解

The screenshot illustrates the Visual Boolean Search interface. At the top, a search bar shows '272,706 trials' (circled in red) with options to 'View related: Trials | Investigators | Organizations' and buttons for 'Table' and 'Map'. Below this, a series of stacked panels show the search being refined with filters:

- Panel 1: Trial Phase is II or III
- Panel 2: Therapeutic Area is Infectious Disease
- Panel 3: Trial Region is North America
- Panel 4: Trial Status is Open

Each filter is connected to the previous one by an 'and' operator. At the bottom, the refined search results are shown as '229 trials' (circled in red), with the same 'View related' and 'Table/Map' options.

视觉逻辑搜索 (Visual Boolean Search)

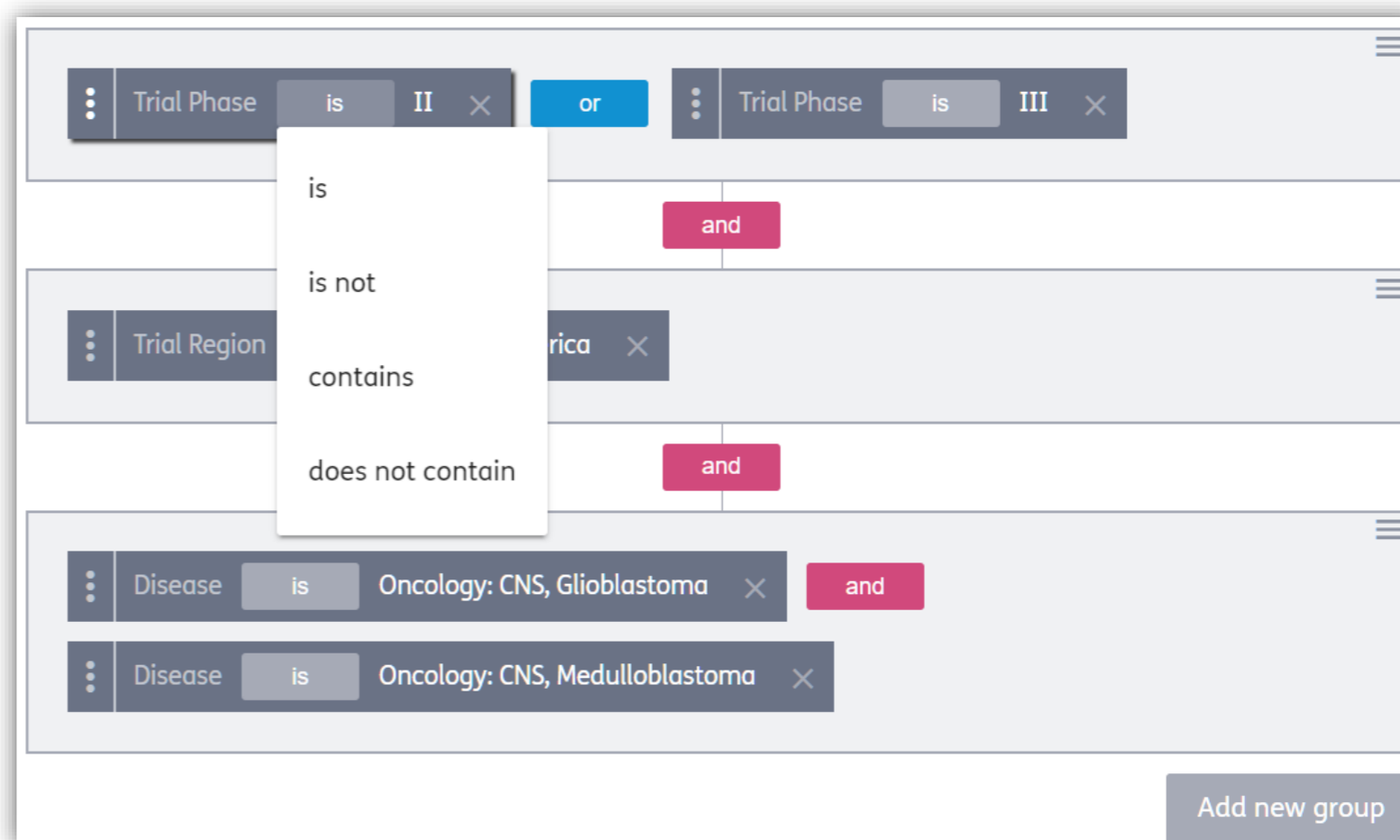
方便修改、注重逻辑思维

- 指定每个连接词语该如何使用 (is, is not, contains, does not contain)
- 组合词语用于处理复杂逻辑思维
- 使用参数连接词 (and/or) 建立复杂搜索

无须再记住复杂的搜索配搭及结构

实时同步查看与验证检索结果

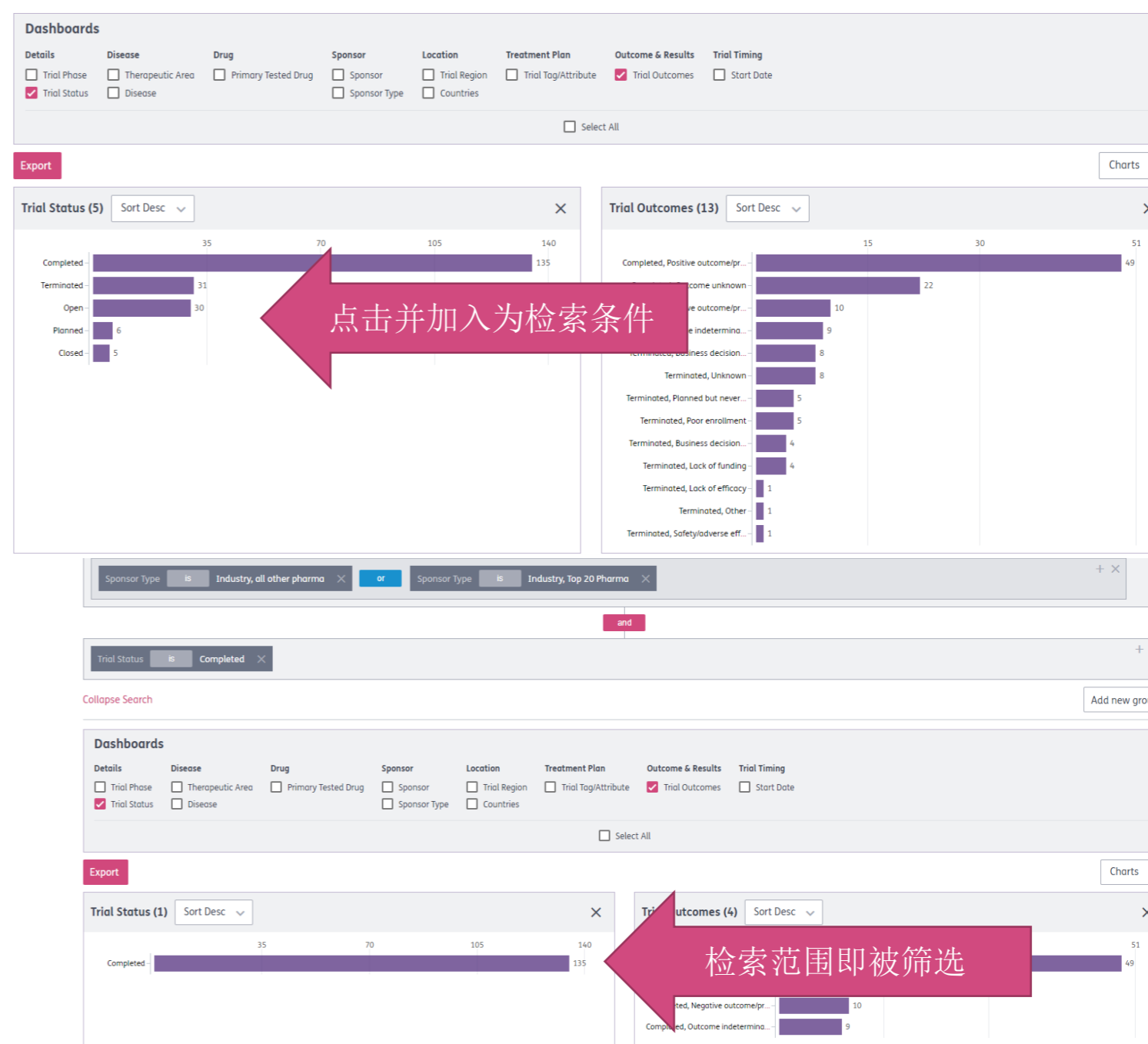
快速与准确地确认搜索条件，即便是
储存或共享的检索



可下载的交互式图表 (Interactive Dashboards)

分析 > 修正 > 导出

- 随意选择显示部分或全部图表内容
- 随意切换图表或列表模式、以及选择显示前20或所有结果
- 一键导出至Excel格式以便修改或直接复制图表至演示资料
- 每当修改检索条件，图表即刻自动同步更新
- 点击图表内容即可加入至检索条件并同步更新



分析数据并快速优化检索及结果

立即更新您的演示资料

药物化学结构检索 (Chemical Structure Searching)

[点击](#) 查阅更多信息

快速绘出化学结构搜索下部或相似的结构 – 无需安装额外插件

- 可简单画出结构，也可导入/导出化学结构
- 可通过下部结构 (sub-structure) 或相似度百分比进行检索
- 无需下载任何额外插件，适用于所有主流浏览器

Chemical Structure

直观的绘画工具
直接导入或导出资料

Powered by ChemAxon Marvin JS

Sub Structure Similarity 80%

34 drugs
View related: Trials | Investigators | Organizations

Chemical Structure is substructure of M182000 24 26 0 0 0 0 0 0 0 9999 V2000 4.3326 0.4125 0...

| Clinical Drug ID | Generic Drug Name | Drug Names | Development Status | Trials/Trial Count | Target | Summary | Marketing | Select |
|------------------|---|---|--------------------|--------------------|---|---|--|--------------------------|
| 75921 | esomeprazole magnesium DR + levosulpride ER | Nexpro L; esomeprazole magnesium DR + levosulpride ER; levosulpride ER + esomeprazole magnesium DR | Widely Launched | 2 | ATPase, H+K+ exchanging, alp... 5-hydroxytryptamine (seroton)... dopamine receptor D2 | Nexpro L is a fixed-dose combination of esomeprazole magnesium and levosulpride, developed by Torrent Pharmaceuticals for the treatment of gastroesophageal reflux disease (GERD) (ClinicalTrials.gov Identifier: NCT01234567) | Approvals... oesophageal reflux (Indic... as Nexpro L (Company We... rent, 3 Sep 2015, http://www.pharma.com/the_gastroin-gl). | <input type="checkbox"/> |
| 36948 | esomeprazole + low-dose ASA | ASA + Nexium; ASA + esomeprazole; ASA+ esomeprazole magnesium; Axanum; D-9613; D9613; Nexium + ASA; esomeprazole + ASA; esomeprazole + acetylsalicylic; esomeprazole + low-dose ASA; esomeprazole magnesium + ASA; esomeprazole/ASA; esomeprazole/acetylsalicylic | Widely Launched | 6 | ATPase, H+K+ exchanging, alp... prostaglandin-endoperoxide s... prostaglandin-endoperoxide s... | Axanum is a fixed-dose combination (FDC) of esomeprazole and low-dose ASA, developed for the prevention of peptic ulcers associated with low-dose ASA, and for the prevention of cardio- and cerebrovascular events in patients requiring continuous... | Approvals... on, myocardial; Ischaemic Thrombosis, cerebral; Ulcer Ulcer, duodenal (EU approx... um via the decentralized with Germany acting as re... member state for the prever | <input type="checkbox"/> |
| 65130 | omeprazole + cinitapride ER, Zydus | cinitapride ER + omeprazole, Zydus; cinitapride ER/omeprazole, Zydus; omeprazole + cinitapride ER, Zydus; omeprazole/cinitapride ER, Zydus | Ceased | 1 | 5-hydroxytryptamine (seroton)... ATPase, H+K+ exchanging, alp... | Zydus Cadila was developing a fixed-dose combination capsule of omeprazole + cinitapride ER for the treatment of non-ulcer dyspepsia or gastroesophageal reflux disease (GORD) (ClinicalTrials.gov Identifier: NCT01234567) | | <input type="checkbox"/> |

利用Pharmaprojects巨大数据资源
识别及分析拥有相似化学结构的药物

查询所有已被中止研发的药物化学
结构

评估处于研发的新药物组合物

历史研发趋势 (Historical Trends)

[点击](#) 查阅更多信息

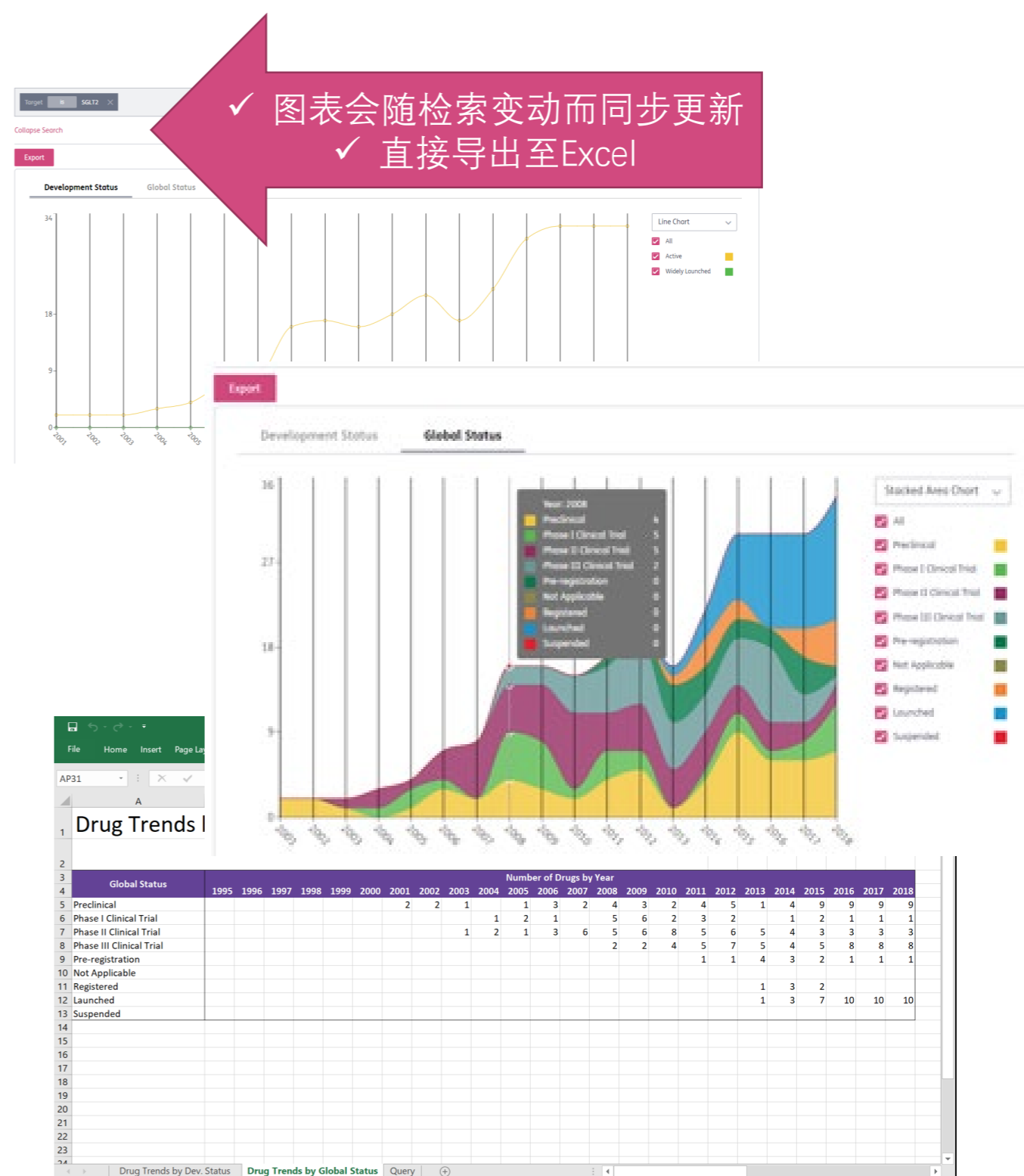
查阅及分析药物的历史研发趋势，更好进行预测及战略规划

- 通过药物、类型、作用机制、药用物质、靶点、国家及地区、公司等检索条件分析研发趋势
- 选择通过数据、图表或列表进行显示
- 通过研发阶段或管线、已获批上市或研发中止等条件快速筛选
- 导出至Excel作进一步分析或用于演示

准确分析历年药物研发变化

追踪研发趋势变化

查阅及比较各种药物或类型



自动邮件提醒功能 (Alerts)

[点击](#) 查阅更多信息

线上追踪及邮件提醒功能 (Watches and Alerts) - 掌握最新发展及变化

- 实时追踪药物及市场最新动态及监管事件更新
- 可对个别药物或整个检索范围进行设置
- 自动获取提醒邮件，掌握所有重要事件更新

| Date Saved | Name | Query | Total When Saved | Product | Action |
|------------------|---|---|------------------|--------------------------|---------------------------------|
| 2018/10/24 14:35 | Oncology Triple Negative Breast | (Disease is Oncology: Breast) AND (Patient Segment is Breast: Triple receptor negative) AND (Specialty is Oncology) | 6,977 | Sitetrove - Organization | Watch Open Share Remove |
| 2018/10/22 13:30 | The Ohio State University Comprehensive Cancer Center (OSUCCC) - The James (Arthur G. James Cancer... | (Organization ID is 34419) | 1 | Sitetrove - Organization | Watch Open Share Remove |
| 2018/10/22 13:28 | Callaghan, John T | (Investigator ID is 13295) | 1 | Sitetrove - Investigator | Unwatch Open Share Remove |

Filter categories: Triple Receptor Negative Add

Organization: Breast: Triple receptor negative

Displaying 1 of 1,631 keywords

Disease is Oncology: Breast

Create your alert

Name your alert (optional)

Oncology Specialty Breast Triple Receptor Negative

Receive email alerts for this search

Cancel Create Alert

Organization Name: The University of Texas - MD Anderson

Organization Type: Academic Hospital / Clinic

Organization Country: United States

feedback

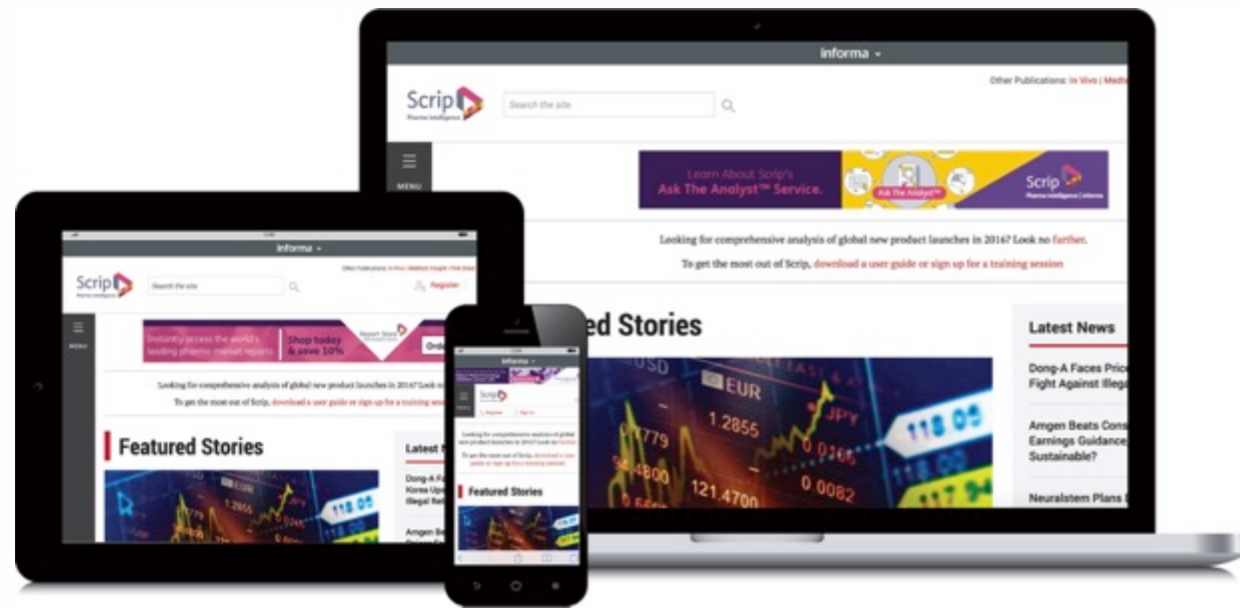
- ✓ 追踪药物、监管及市场格局信息
- ✓ 掌握竞争市场最新进展
- ✓ 快速查阅竞争对手动向

Scrip/Pink Sheet

- 制药行业综合资讯
- 监管及法规资讯

所有资讯尽在统一线上平台

支持多媒体使用及 多功能检索与操作



Video, audio, and proprietary data sets bring our articles and analyses to life.

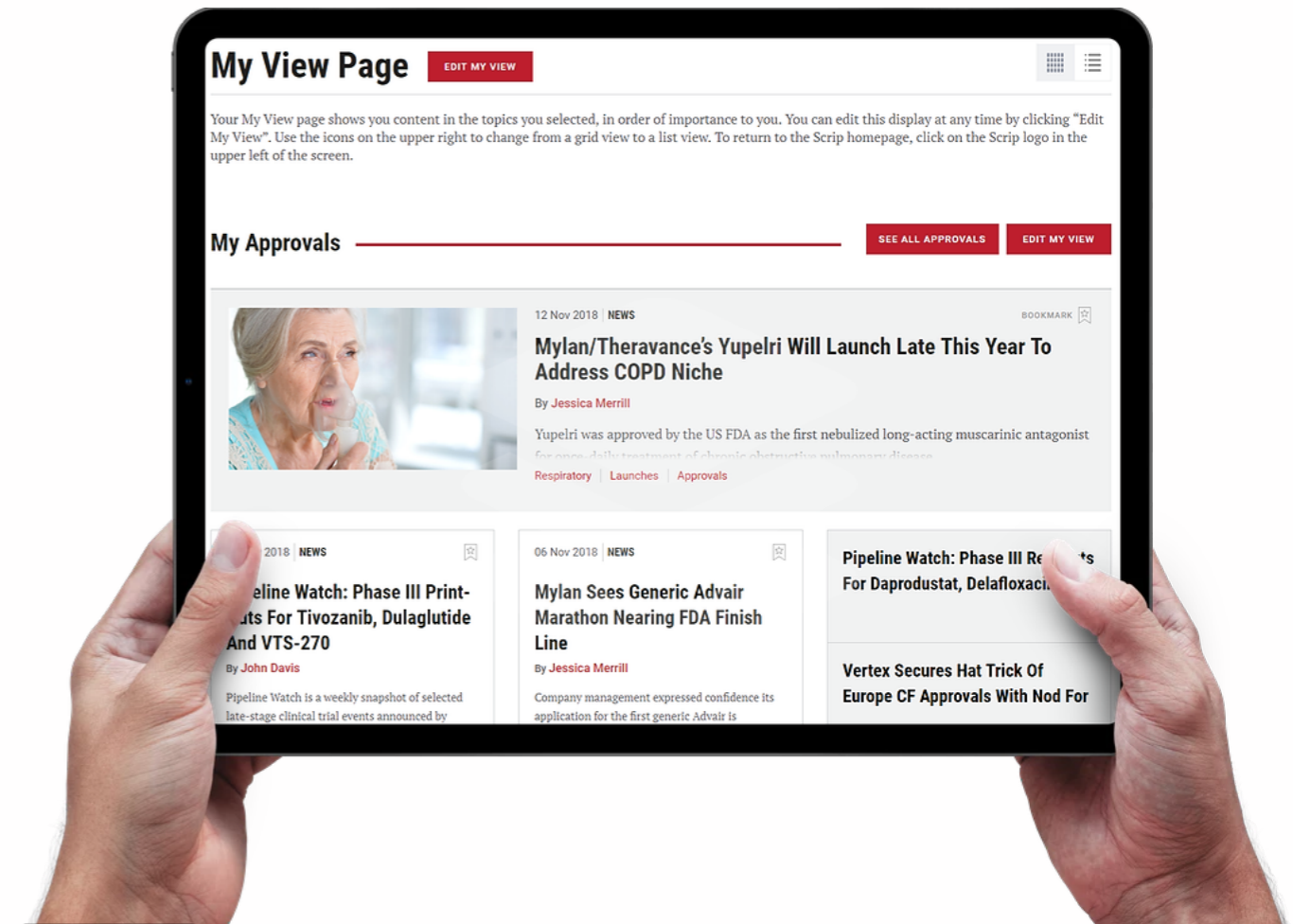


Numerous search filters allow for precise content targeting, and articles and searches can be saved and shared with one-click



Set custom email alerts on any topic or search criteria so you never miss what you need to know most.

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Scrip



Pharma intelligence | informa

The insight advantage
commercial biopharma
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globe rely on

实时行业资讯及深度专家见解 – Scrip是医药领域商业决策者的必要资讯来源



从Licensing、临床试验、竞争对手动向，再到生物技术初创企业或跨国巨头，Scrip将助您掌握业内最新动态与关键事件。



掌握关键事件背后含意及影响 – Scrip关注于全球医药领域商业资讯之战略意义，助您了解所有潜在或实际影响。



完整覆盖业内各领域之商业资讯，全球各地驻有共40+名专题记者与分析师并不间断地发表文章。

Scrip: 追踪市场动向与掌握事件背后含意

Scrip提供:

- ✓ 业界关键人士独家专访
- ✓ 研发管线追踪
- ✓ 新兴企业简介
- ✓ 医药企业专题报道
- ✓ 业内高管任命动向
- ✓ 分析师见解
- ✓ 企业并购与交易事件
- ✓ 识别及追踪行业趋势
- ✓ 临床试验专家见解
- ✓ 独家市场预测
- ✓ 全面融资分析

Plus...

- ❖ **Scrip 100:** 全球医药产业综合表现与前景年度分析
- ❖ **Asia 100:** 亚太区市场综合年度报告

如何帮助您:

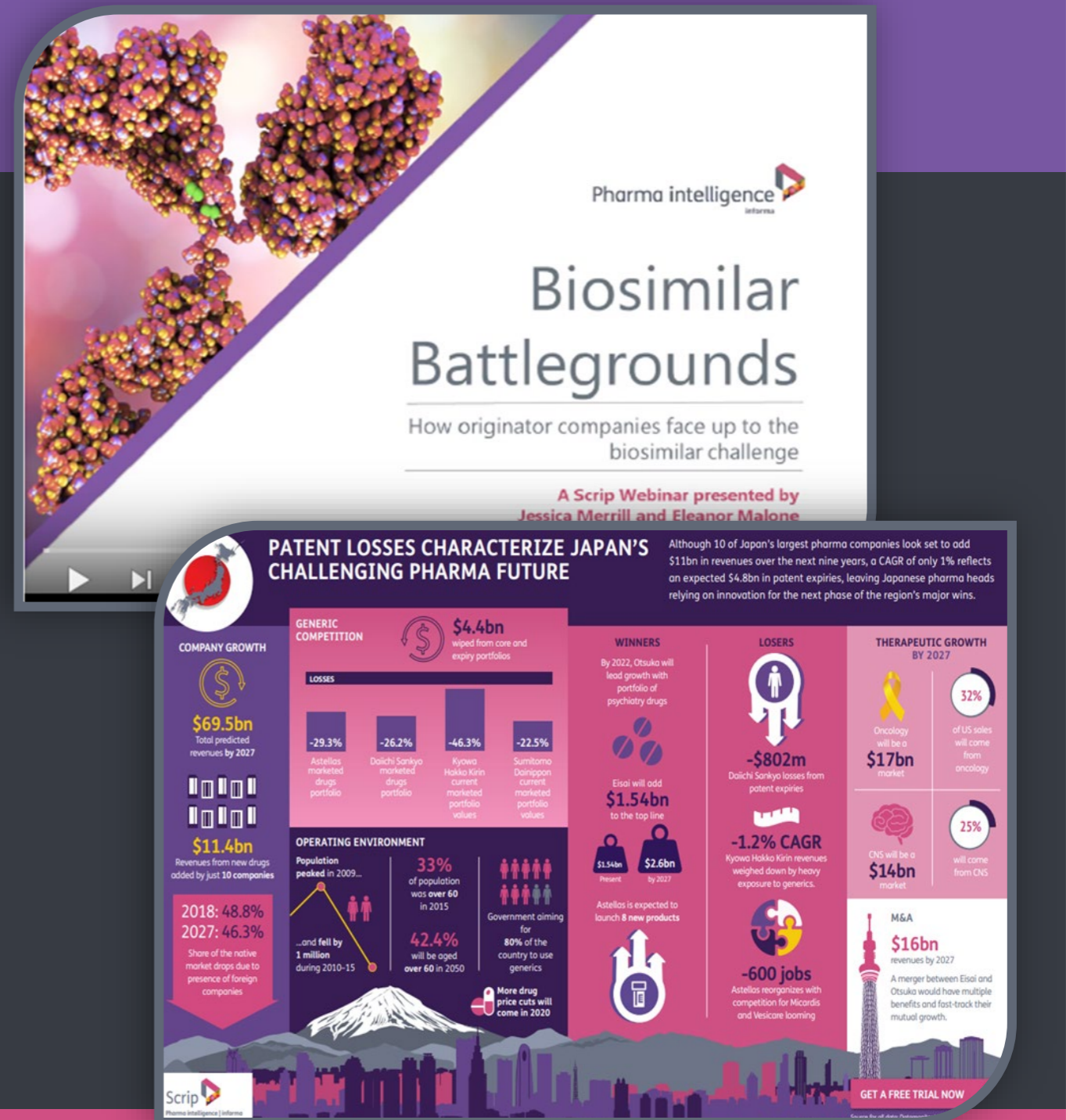
- 掌握当前与未来市场竞争格局
- 识别市场趋势及潜在风险
- 了解所在领域之权威意见



Scrip: 关注业界事件背后含意及潜在机遇

为何选择Scrip?

- 通过涵盖药物发现、开发及生命周期管理等完整过程，Scrip提供横跨各疾病领域与产品种类的市场分析、资讯及专业见解。
- Scrip助您获悉市场最新潜在授权机遇、合作事件、药物研发动向、市场准入资讯，以及公司发展动态。
- Scrip不仅完整覆盖市场商业资讯及事件追踪，同时注重于事件发生之原因与影响，助您以纵观全局之势了解全球医药市场各类事件背后的战略含义。



Pink Sheet

Pharma intelligence | informa



The policy and regulatory insights advantage for biopharma decision-makers around the globe

时刻掌握监管资讯及扩展潜在商机 – 推向市场、确保合规，扩展消费者覆盖范围



通过业界顶尖监管资讯，掌握及预测至关重要的最新政策或监管发展。



Pink Sheet提供极具前瞻性的政策分析、监管内部人士及业界权威见解，以及关键数据追踪。



以全球各大市场完整覆盖及业界权威独家专访为本，系业内最佳监管资讯及商业竞争见解提供者。

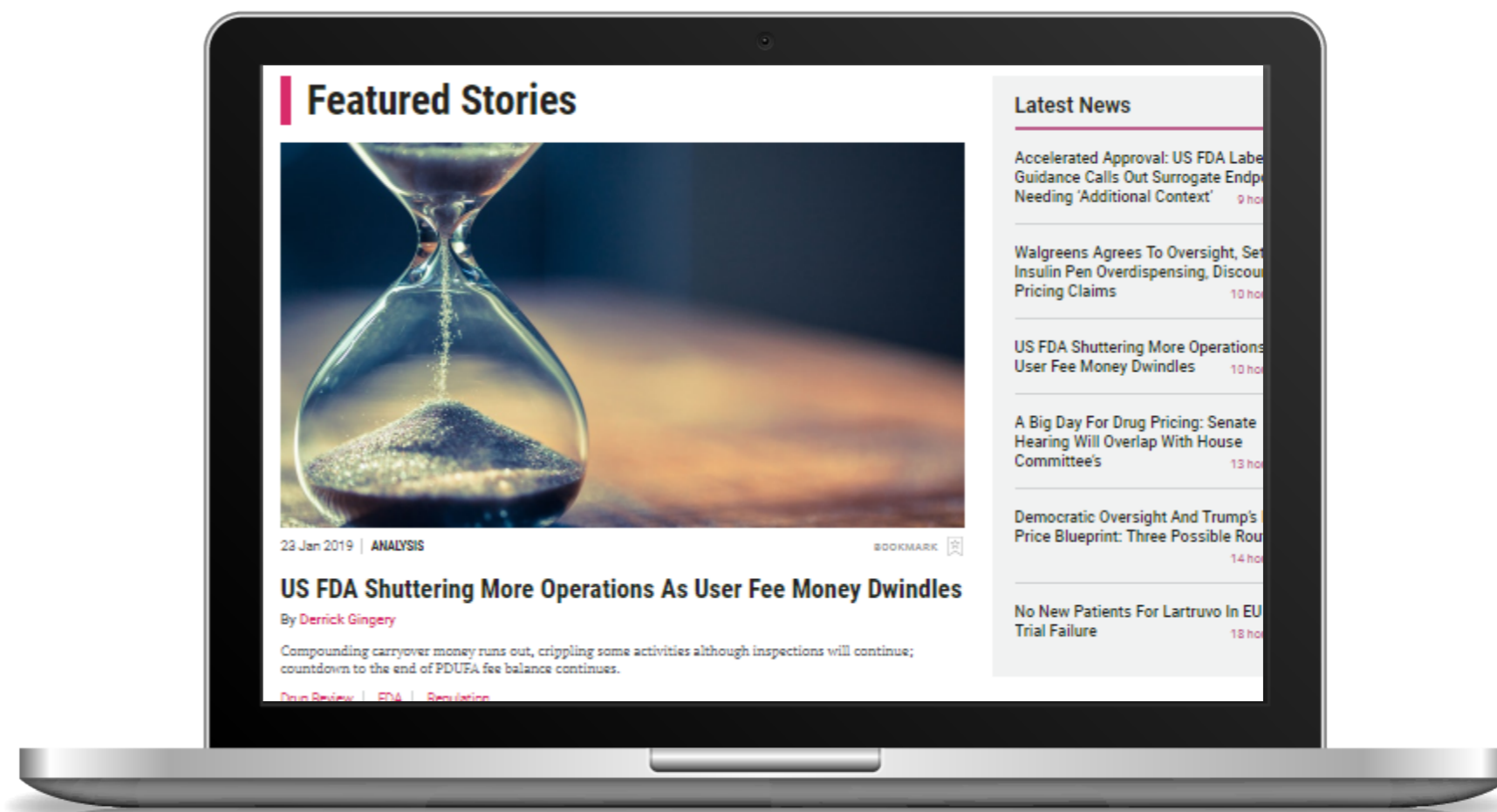
Pink Sheet: 关乎您业务的监管资讯

Pink Sheet提供:

- ✓ 最新审批途径及潜在机遇
- ✓ 最新监管资讯
- ✓ 最新消费者需求
- ✓ 监管部门及职位任命资讯
- ✓ 影响监管机构政策及预算的最新行业立法
- ✓ 获批上市后问题
- ✓ 专利问题
- ✓ 产品上市批准要求
- ✓ 欧洲监管市场追踪

独家内容:

- ❖ **FDA Performance Tracker:** 掌握产品递交申请或批准事件, 以及自订追踪特定领域
- ❖ **Drug Review Profiles:** 通过专家反馈及见解深入了解FDA批准事件
- ❖ **Global Guidance Tracker:** 提供每月最新法规及指南资讯, 其中含有官方文件链接
- ❖ **Special focus areas:** 产品定价争议、英国脱欧、或质量保证/管理 (QA/QC) 等话题



Pink Sheet: 掌握最新监管走向及影响

为何选择Pink Sheet?

- 我们的全球网络将助您掌握与预测潜在挑战、降低风险及扩大机遇。
- Pink Sheet提供监管及法规领域的深度分析，助您了解与个人业务相互连接的全球市场最新动态及发展。
- 业界顶级专题作者及分析师遍布全球，完整追踪产品从提交申请至获批上市审查过程，同时也引用Informa医药智库旗下深度市场分析的专业数据。

Companion Diagnostics Webinar Recording

Pharma intelligence

Companion Diagnostics: Oncology Technologies and Pathways

Host: Derrick Gingery
Speakers: Bridget Silverman

CHECKPOINT INHIBITOR CHECKLIST

| KEY | Merck's KEYTRUDA (pembrolizumab) | Roche (Genentech)'s TECENTRIQ (atezolizumab) | Pfizer and Merck KGAA (EMD Serono)'s BAVENCIO (durvalumab) |
|---|------------------------------------|--|--|
| Bristol-Myers Squibb's OPDIVO (nivolumab) | AstraZeneca's IMFINZI (durvalumab) | | |

SKIN CANCERS

| | |
|---|--|
| Melanoma, Adjuvant | OPDIVO ✓ 12/20/2017 ★ |
| Melanoma, First Line | KEYTRUDA ✓ 12/18/2015 |
| Melanoma, Second Line | KEYTRUDA ✓ 9/4/2014 |
| Cutaneous Squamous Cell Carcinoma, First Line | LIBTAYO ✓ 9/28/2018 ★ |
| Merkel Cell Carcinoma, First Line | KEYTRUDA Under review with 12/28/2018 user fee goal ⌚ |
| Merkel Cell Carcinoma, Second Line | BAVENCIO ✓ 3/23/2017 ★ |

BLADDER CANCER OR METASTATIC UROTHELIAL CARCINOMA (MUC)

Vanda Warning Letter From US FDA Leaves Firm "Puzzled"

05 Nov 2018 | NEWS

by M. Nielsen Hobbs
@PinkSheetHobbs | nielsen.hobbs@informa.com

Executive Summary

CEO Polymeropoulos tells the Pink Sheet that both subject and severity of letter regarding description of products on corporate website seem like an overreaction by the agency.

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专家解答 – 为订阅者独家提供可行的个性化咨询服务，其中包括定制的数据收集及调研支持



高效答复 – 通过透明及可查证的信息来源，提供完整解答以便作出正确决策



跨产品调研支持 – 引用我司其他医药产品，提供完整资讯辅助



Got a question?
Ask the Analyst™

业界及各疾病领域专家团队鼎力相助

难题待解?

直接点击“Ask the Analyst”按钮向分析师团队进行提问!

您将获得针对您具体需求的一对一分析师咨询支持 – 分析师团队每天负责对所有信息进行整编、验证及分析,并向您提供所需帮助。

分析师咨询服务
(Ask the Analyst)

Pharmaprojects

例: “我想了解作用机制“AB-024”的最新状况。”

Trialtrove

例: “我想了解所有在欧盟或日本市场目前处于计划中或正在进行中并有应用Avastin的临床试验列表, 其中包括开始日期、结束日期, 以及目标及实际受试者募集状况。”

Sitetrove

例: “哪些常驻伦敦的临床研究人员及地点曾在过去两年有HER2阳性乳腺癌临床三期的研究经历?”

Trialpredict

例: “我想通过查阅名为【HES 130/0.4 in balanced electrolyte solution (Volulyte®) vs. balanced crystalloid solution in patients undergoing elective abdominal surgery】的临床试验作比对调研, 不知如何检索?”

Ask the Analyst
Your questions answered by our experts

Ask the Analyst is a complimentary service that is included in your Pharmaprojects subscription.

Citeline's therapy and product experts will assist you with questions about specific clinical trials within the scope of coverage, building effective search strategies and other creative solutions to meet your information needs. Up to three hours of analyst support is available per request.

Please take advantage of this valuable service and fill in the details of your request below. You will receive an automated acknowledgement, and a Citeline analyst will respond to you directly by the next business day.

Describe the information you need

Send

调研案例

调研案例

银屑病（Psoriasis） – Search, Analyze, Benchmark

Pharmaprojects – 全球临床药物信息

- a) 如何查询当前市场格局（如：在研及上市管线、靶点、公司等）？ [Search Available](#)
- b) 比照药物在何地及何时获批，并找出所有相应临床试验？ [Drug Profile Available](#)
- c) 如何查询拥有孤儿药或快速审评状态的抗银屑病药物，并了解其进展？ [Search Available](#)
- d) 如何查询全球tyrosine kinase 2靶点的历史研发趋势，并如何导出各年份药物列表？ [Search Available](#)
- e) 如何查询正寻找合作伙伴（中国）的抗银屑病研发药物？ [Search Available](#)

Scrip/Pink Sheet – 市场综合资讯（交易、临床、创新、监管等）

- a) **【商业】** 如何查询当前市场动态（如：交易、市场格局分析、高层专访等）？ [Search Available](#)
- b) **【研发】** 如何查询最新研发进展（如：创新及临床数据分析等）？ [Search Available](#)
- c) **【监管】** 如何查询最新监管更新（如：上市申请、FDA警告、获批途径更新或立法等）？ [Search Available](#)

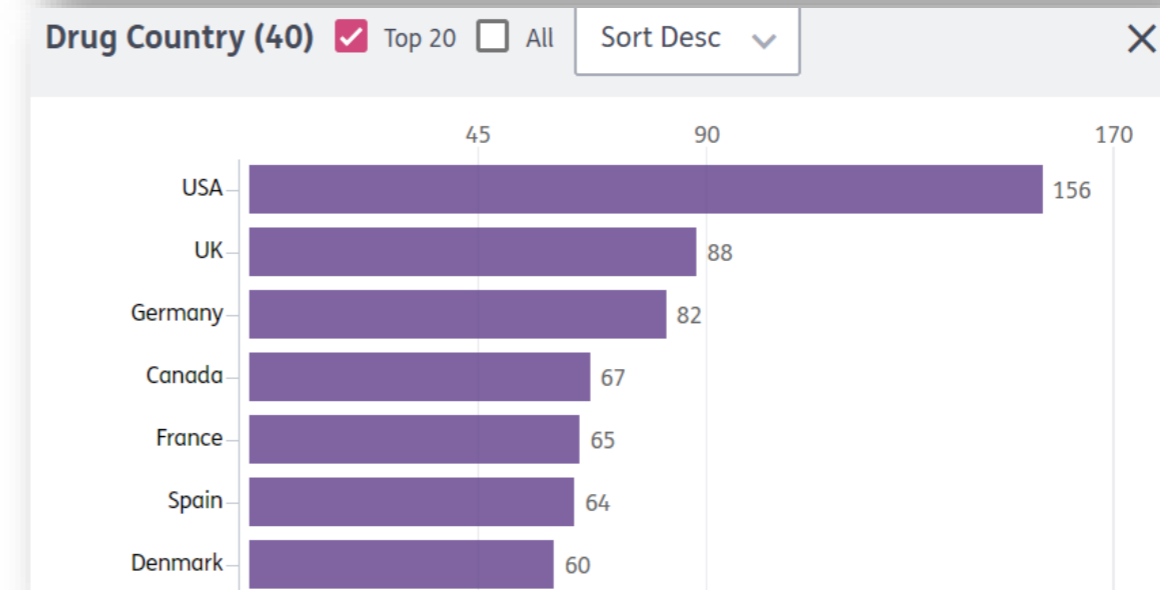
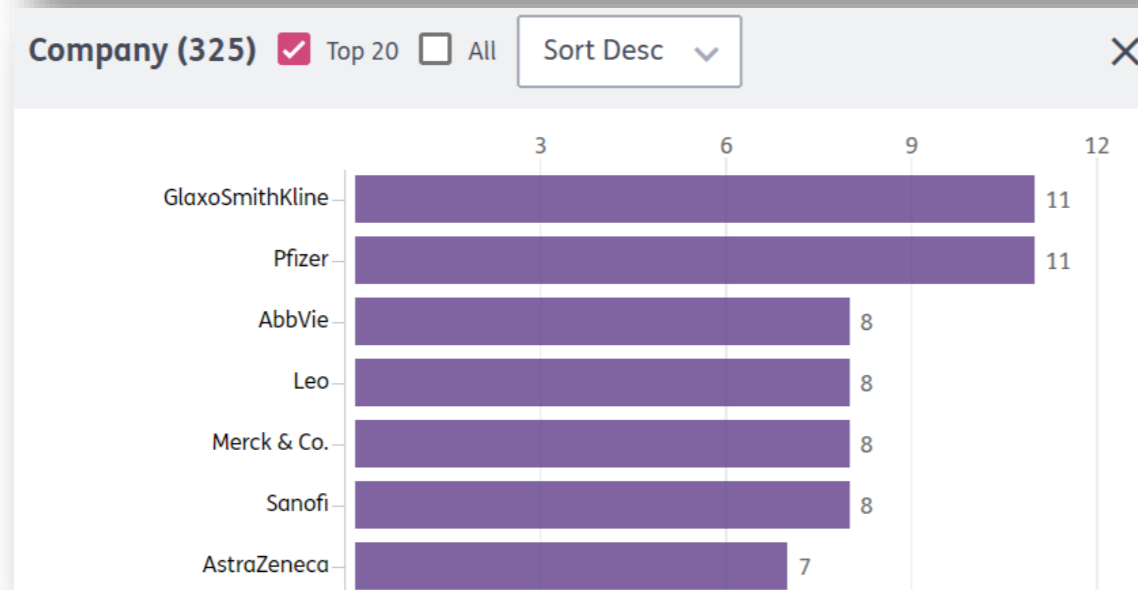
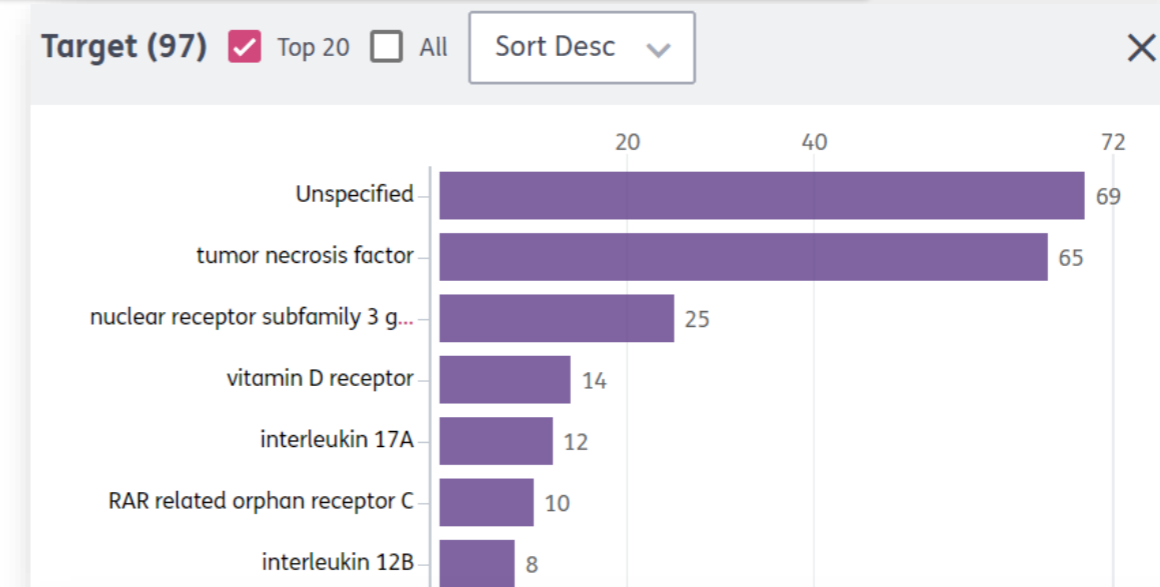
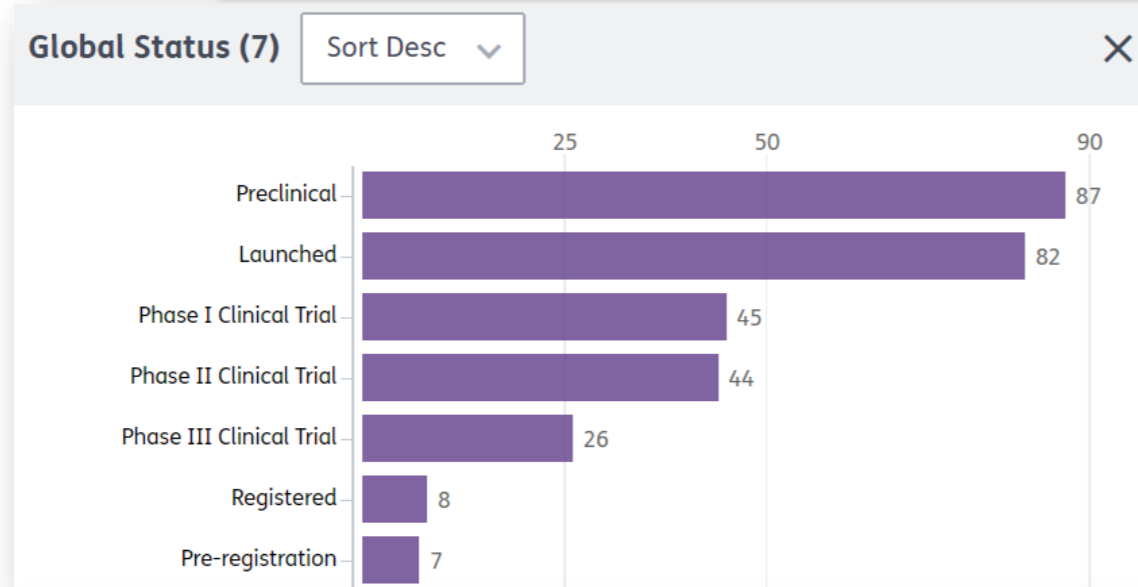
Case Study – Pharmaprojects

1、如何查询当前研发市场格局（如：在研及上市管线、靶点、公司等）？ [Search Available](#)

Drug Disease is Psoriasis ×

and

Drug Disease Status is Pipeline × or Drug Disease Status is Approved ×



Case Study – Pharmaprojects

2、比照药物在何地及何时获批，并找出所有相应临床试验？ [Drug Profile Available](#)

Drug

risankizumab

ABBV 066; ABBV-066; ABBV066; BI 655066; BI 655066 (IV); BI 655066 (SC); BI-655066; BI-655066 (IV); BI-655066 (SC); BI655066; risankizumab; risankizumab (IV); risankizumab (SC); SKYRIZI

Drug Summary

| | | | |
|--------------------|----------|--------------------|---|
| Global Status | Launched | Latest Change | Approval in Brazil for psoriasis reported |
| Development Status | Active | Latest Change Date | 2019/07/17 |

Summary
 Risankizumab is a humanized IgG1 monoclonal antibody that binds and neutralizes the p19 subunit of IL-23, developed by AbbVie for the treatment of psoriasis, Crohn's disease and ankylosing spondylitis (ClinicalTrials.gov, 17 Apr 2012, <http://www.clinicaltrials.gov/ct2/show/NCT01577550>; Dermatol Ther (Heidelb), 25 Oct 2012, PMID: PMC3510410, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3510410/>; <http://www.clinicaltrials.gov/ct2/show/NCT02031276>; ClinicalTrials.gov, 29 Jan 2013, <http://www.clinicaltrials.gov/ct2/show/NCT02031276>).

Approvals

Psoriasis; Arthritis psoriatic
 Japan (2019); as Skyrizi for the treatment of plaque **psoriasis**, generalized pustular **psoriasis**, erythrodermic **psoriasis** and psoriatic arthritis response to conventional therapies (Press release, AbbVie, 26 Mar 2019, <https://news.abbvie.com/news/press-releases/abbvie-announces-f> 2019, <https://www.abbvie.co.jp/content/dam/abbvie-dotcom/jp/documents/press-relea...>).

Psoriasis
 Brazil; as Skyrizi for the treatment of **psoriasis** in adults (Scrip Intelligence, 3 Jun 2019, <https://scrip.pharmaintelligence.informa.com/SC125>);
 Canada; as Skyrizi for the treatment of moderate to severe plaque **psoriasis** in adult patients who are candidates for systemic therapy or phototherapy (Scrip Intelligence, 28 Oct 2017, <https://scrip.pharmaintelligence.informa.com/SC099770/New-AbbVie-Guidance-S...>; Pink Sheet Intelligence, 28 Oct 2017, <https://pink.pharmaintelligence.informa.com/PS124822/Risankizumab-Andexanet...>; Press release, AbbVie, 23 Apr 2019, <https://news.abbvie.com/news/press-releases/european-commission-approves-sk...>);
 EU including Iceland, Liechtenstein and Norway; as Skyrizi for the treatment of moderate to severe plaque **psoriasis** in adult patients who are candidates for systemic therapy or phototherapy (Scrip Intelligence, 28 Oct 2017, <https://scrip.pharmaintelligence.informa.com/SC099770/New-AbbVie-Guidance-S...>; Pink Sheet Intelligence, 28 Oct 2017, <https://pink.pharmaintelligence.informa.com/PS124822/Risankizumab-Andexanet...>; Press release, AbbVie, 23 Apr 2019, <https://news.abbvie.com/news/press-releases/european-commission-approves-sk...>);
 USA; as Skyrizi for the treatment of moderate to severe plaque **psoriasis** in adult patients who are candidates for systemic therapy or phototherapy (Scrip Intelligence, 28 Oct 2017, <https://scrip.pharmaintelligence.informa.com/SC099770/New-AbbVie-Guidance-S...>; Pink Sheet Intelligence, 28 Oct 2017, <https://pink.pharmaintelligence.informa.com/PS124822/Risankizumab-Andexanet...>; Press release, AbbVie, 23 Apr 2019, <https://news.abbvie.com/news/press-releases/european-commission-approves-sk...>);
 immunology-portf...).

| Name | Status |
|-----------|--------------------------|
| Argentina | Phase III Clinical Trial |
| Australia | Phase III Clinical Trial |
| Austria | Registered |
| Belgium | Registered |
| Brazil | Registered |
| Canada | Registered |
| Chile | Phase III Clinical Trial |
| China | Undisclosed |
| Colombia | Phase III Clinical Trial |
| Denmark | Registered |
| Finland | Registered |
| France | Registered |
| Germany | Registered |
| Greece | Registered |
| Hong Kong | Phase II Clinical Trial |
| India | Undisclosed |
| Ireland | Registered |
| Israel | Phase III Clinical Trial |
| Italy | Registered |
| Japan | Launched 2019 |

- Drug Summary
- Company Data
- Diseases
- Activity
- Event History
- Chemical data
- Country data**
- Trialrove Trials
- Marketing**
- Licensing
- Phase III
- Phase II
- Phase I
- Preclinical
- Supporting URLs

Case Study – Pharmaprojects

2、比照药物在何地及何时获批，并找出所有相应临床试验？ [Drug Profile Available](#)

Drug

Drug Summary

Company Data

Diseases

Activity

Event History

Chemical data

Country data

Trialtrove Trials

Marketing

Licensing

Phase III

Phase II

Phase I

Preclinical

Supporting URLs

Trialtrove Trials

Trialtrove Trial Count

37

| Phase | Disease | Sponsor | Drugs tested | Protocol/Trial ID | Status |
|-------|---|------------------------------|--------------------------------------|--|--------|
| IV | Psoriasis | AbbVie | risankizumab; undisclosed - biologic | TrialTroveID-351313; NCT03982394; P19-377; VALUE | Open |
| III | Other Inflammatory Arthritis, Psoriasis | Boehringer Ingelheim, AbbVie | risankizumab | TrialTroveID-262918; EudraCT Number: 2017-002464-40; IMMpect2; M15-998; NCT03671148; NL67817.078.18 | Open |
| III | Crohn's Disease | AbbVie | risankizumab (IV); risankizumab (SC) | TrialTroveID-298925; 18-ABV-02; EudraCT Number: 2016-003190-17; M15-991; NCT03104413; NMRR-17-1305-36321 | Open |

37 trials

View related: [Investigators \(151\)](#) | [Organizations \(1,687\)](#) | [Drugs \(1\)](#)

Results

Timeline

Dashboards

Map

Benchmark

Clear Search

Share Search

Save Search

Create Alert

Drug Names

is

risankizumab

Collapse Search

Add new group

Export

Templates

Show/Hide columns

50 results

| Trial Title | Sponsor | Study Keywords | Target Accrual | Countries | Trial |
|---|--------------------------------|--|----------------|--|---|
| A Multicenter, Open Label Study To Assess The Safety And Efficacy Of Risankizumab For Maintenance In Moderate To Severe Plaque Type Psoriasis (LIMITLESS) | Boehringer Ingelheim AbbVie | efficacy; open label; pharmacokinetics; safety; single arm | 2200 | Australia; Austria; Belgium; Canada; Czech Republic; Finland; France; Germany; Italy; Japan; Mexico; Poland; Portugal; South Korea; Spain; Sweden; Taiwan; United Kingdom; United States | <p>Trial Summary</p> <p>Trial Outcomes</p> <p>Trial Objectives</p> <p>Trial Timing</p> <p>Patient Population</p> <p>Trial Locations</p> <p>Study Keywords</p> <p>Treatment Plan</p> <p>Trial Notes</p> <p>Primary Research</p> <p>Results</p> |

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Assess the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Crohn's Disease Who Failed Prior Biologic Treatment

Trial Summary

| | | | |
|-----------------|---|-------------------|--|
| TrialTrove ID | TrialTroveID-298925 | Phase | III |
| Source | Trialtrove | Sponsor | AbbVie |
| Disease | Crohn's Disease | Primary Drugs | risankizumab (IV); risankizumab (SC) |
| Patient Segment | Moderate; Remission; Severe; Treatment naive; Treatment resistant | Other Drugs | — |
| MeSH Term | Crohn Disease | Protocol/Trial ID | 18-ABV-02; EudraCT Number: 2016-003190-17; M15-991; NCT03104413; NMRR-17-1305-36321; 18-ABV-02; EudraCT Number: 2016-003190-17 |

Case Study – Pharmaprojects

3、如何查询拥有孤儿药或快速审评状态的抗银屑病药物，并了解其进展？
[Search Available](#)

Drug Disease Status is Pipeline ×

and

Drug Disease is Psoriasis ×

and

Event Type is Orphan Drug Status Granted × or Event Type is Expedited Review Designation Granted ×

| Generic Drug Name | Originator | Target | Phase III | Phase II | Phase I | Preclinical |
|--------------------------------|-----------------------|------------------------------|---|---|--|--|
| mirikizumab | Eli Lilly | interleukin 23 subunit alpha | Psoriasis It is in a non-randomized, open-label, single group, long-term extension of OASIS-1& 2 trials, Phase III trial (OASIS-3; I6T-MC-AMAH; 16491) in 1816 patients with moderate-to-severe plaque psoriasis in Argentina, Australia, Canada, Czech ... | Crohn's disease A randomized, double-blind, parallel Phase II trial (SERENITY; 16492; I6T-MC-AMAG; 2016-002204-84) in 180 patients with active Crohn's disease in Austria, Australia, Canada, France, India, Japan, Poland, Romania, Russia, Switzerland, ... | An open-label, randomized, parallel assignment Phase I (16861; I90-MC-AA BA) trial in the UK in 72 healthy subjects, to assess the absolute and relative bioavailability subcutaneous doses of LY3074828 + LY9999QS (LY900021), is complete ... | |
| adalimumab, Innovent Biologics | Innovent Biologics | tumor necrosis factor | Ankylosing spondylitis It is in a pivotal, randomized, double-blind, active controlled, parallel, head-to-head, pharmacokinetics and bioequivalence comparability Phase III trial (CIBI303A301) in 400 patients with ankylosing spondylitis in China, to ... | | In an exploratory healthy volunteers study, it was demonstrated to be safe (Press release, Innovent Biologics, 13 Sep 2016, http://www.innoventbio.com/en/News.aspx?key=news&Id=1361&type=%E6%96%B0%E9%...). | In analytical and pre-clinical comparability studies it is highly similar to adalimumab (Press release, Innovent Biologics, 13 Sep 2016, http://www.innoventbio.com/en/News.aspx?key=news&Id=1361&type=%E6%96%B0%E9%...). In vivo In ... |
| belapectin | Galectin Therapeutics | galectin 1 galectin 3 | Fibrosis, liver; Non-alcoholic steatohepatitis A Phase III trial (NASH-RX) in the US in patients with NASH cirrhosis, is expected in later 2019 (Press release, Galectin, 6 Mar 2019, ... | Fibrosis, liver A randomized, double-blind, placebo-controlled, parallel-group -assignment Phase IIb trial (NASH-CX) in the US, to assess the safety and efficacy of GR-MD-02 2mg/kg, 8mg/kg infusion in 162 patients for the treatment of liver fibrosis ... | In an open-label Phase I pharmacokinetic trial in 17 normal healthy volunteers in the US, single iv dose of GR-MD-02 followed by x3wk iv doses of GR-MD-02 had met the primary endpoint of midazolam clearance when administered alone, compared with when ... | In rat models, GR-MD-02, its development-stage galectin-3 inhibitor, has shown a positive effect on vascular remodeling and demonstrates that rat models of pulmonary arterial hypertension have significantly increased right ventricular systolic ... |
| bermekimab | XBiotech | interleukin 1 alpha | Cancer, colorectal A randomized, parallel-assignment, double-blind, placebo-controlled, registration Phase III trial (2014-PT026) in Argentina, Bulgaria, the Czech Republic, France, Georgia, Germany, Georgia, Hungary, Poland Russia and the UK in 333 ... | Hidradenitis Suppurativa XBiotech A randomized, double-blind, placebo controlled, parallel assignment, Phase II trial (2019-PT047) in 150 patients with moderate to severe hidradenitis suppurativa (HS), to evaluate the safety, tolerability and ... | An open label, single group assignment, Phase I trial (2017-PT041) in the US, in 6 healthy volunteers, to evaluate the safety and tolerability of pharmacokinetic study of MABp1 iv, was completed. All the subjects have been dosed. This Phase I study ... | In vivo Toxicology studies were conducted (Company Web Page, XBiotech, 7 Dec 2009). Patents An US '489 patent related to antibodies and methods of using these antibodies to treat, prevent, and detect disease progression associated with a key ... |

Case Study – Pharmaprojects

3、如何查询拥有孤儿药或快速审评状态的抗银屑病药物，并了解其进展？

[Drug Profile Available](#)

Drug

[< Previous](#)
6 / 8
[Next >](#)

[Back to search](#)
[Print Page](#)
[Download PDF](#)
[Share Drug](#)
[Create Alert](#)

Drug Summary

Company Data

Activity

Chemical data

Diseases

Country data

Event History

Trialrove Trials

Marketing

Licensing

Phase III

Phase II

Phase I

Preclinical

Supporting URLs

SLx-2119

KD 025; KD-025; KD025; ROCK2 inhibitors, Nano Terra-1; ROCK2 inhibitors, Surface Logix-1; SLx-2119

Drug Summary

| | | | |
|--------------------|-------------------------|--------------------|---|
| Global Status | Phase II Clinical Trial | Latest Change | Completion of Phase II trial (KD025-211) for psoriasis reported |
| Development Status | Active | Latest Change Date | 2019/06/24 |

Summary

SLx-2119 is an orally-available ROCK-2 inhibitor in a series of small-molecule inhibitors of the Rho-associated kinase ROCK, under development by Nano Terra (Surface Logix before the acquisition) for the treatment of multiple diseases. It has potential in metabolic syndrome, diabetes, cancer, autoimmune diseases and spinal cord injury (Press release, Kadmon & Nano Terra, 25 Apr 2011, <http://www.kadmon.com/pdfs/kadmon-nano-terra.pdf>). It also has potential in liver fibrosis and liver steatosis, and glaucoma (Corporate Fact Sheet, Surface Logix, Jun 2008 & Jan 2009; Company Web Page, Surface Logix, 22 Feb 2010). It is also under development for the treatment of infectious diseases (JP Morgan 20th Ann Healthcare Conf (San Francisco), 2012, Slide 13). It is also indicated for the treatment of psoriatic arthritis (<http://kadmon.com/research-development/pipeline/>). It is also indicated for the treatment of

Marketing

Orphan drug status

Graft-versus-host disease
Kadmon Holdings
USA; for the treatment of chronic graft-versus-host disease (Press release, Kadmon, 6 Oct 2017, <http://investors.kadmon.com/recent-press-releases/2017/10-06-2017-131051686>; FDA Orphan Drugs List, 5 Oct 2017, <https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cf...>).

Expedited Review Designation

USA; it has granted breakthrough therapy designation for the treatment of patients with more lines of systemic therapy (Press release, Kadmon, 17 Oct 2018, <http://investors.kadmon.com/recent-press-releases/2018/10-17-2018-131051686>).

Psoriasis
Kadmon Pharmaceuticals

A double-blind, placebo-controlled, dose-finding, Phase II trial (KD025-211) in the US in 150 patients with moderate to severe chronic plaque psoriasis, to examine KD-025 200mg qd, 200mg bid, 400 and 600mg qd compared to placebo bid x16wk, is complete (Press release, Kadmon, 21 Sep 2016, [http://investors.kadmon.com/tools/viewpdf.aspx?page={316A68D0-C349-4331-AA0...}](http://investors.kadmon.com/tools/viewpdf.aspx?page={316A68D0-C349-4331-AA0...); ClinicalTrials.gov, 10 Jun 2019, <https://clinicaltrials.gov/ct2/show/NCT02852967>).

An open-label, non-randomized, parallel-assignment, dose-finding Phase II trial (KD025-206) in 38 subjects with psoriasis vulgaris who failed 1st-line therapy in the US, to evaluate the safety, tolerability, activity, pharmacokinetics (PK) and daily dose regimen of SLx-2119 200 and 400mg po bid x12wk, is complete. Preliminary results were expected in 1st half of 2015 (ClinicalTrials.gov, 17 Dec 2014 & 16 Mar & 5 May 2016, <https://www.clinicaltrials.gov/show/NCT02317627>; Press release, Kadmon, 6 Jan 2015, <http://kadmon.com/posts/view/124>).

Case Study – Pharmaprojects

4、如何查询全球tyrosine kinase 2靶点的历史研发趋势，并如何导出各年份药物列表？

[Search Available](#)



25 drugs
View related: [Trials \(65\)](#) | [Investigators \(408\)](#) | [Organizations \(919\)](#)

Target is tyrosine kinase 2

Development Status **Global Status**

Export options

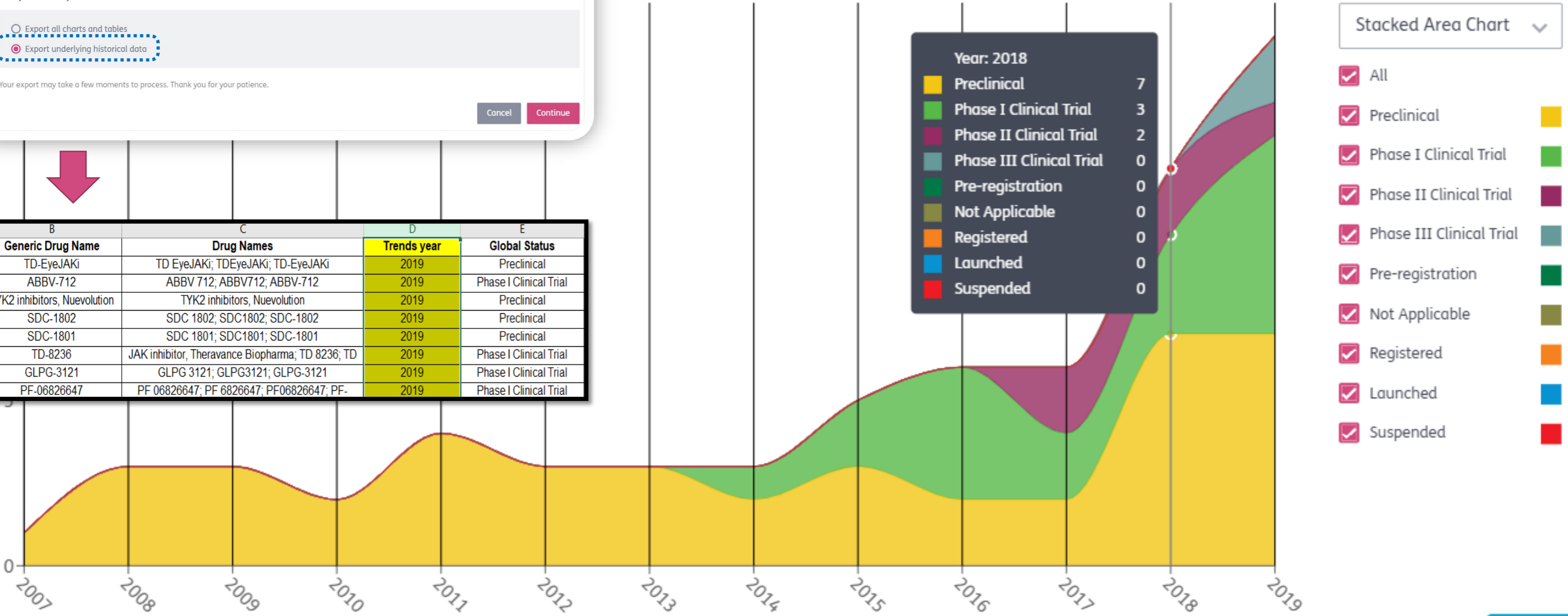
Export all charts and tables

Export underlying historical data

Your export may take a few moments to process. Thank you for your patience.

Cancel Continue

| B | C | D | E |
|------------------------------|--|-------------|------------------------|
| Generic Drug Name | Drug Names | Trends year | Global Status |
| TD-EyeJAKi | TD EyeJAKi; TDEyeJAKi; TD-EyeJAKi | 2019 | Preclinical |
| ABBV-712 | ABBV 712; ABBV712; ABBV-712 | 2019 | Phase I Clinical Trial |
| TYK2 inhibitors, Nuevolution | TYK2 inhibitors, Nuevolution | 2019 | Preclinical |
| SDC-1802 | SDC 1802; SDC1802; SDC-1802 | 2019 | Preclinical |
| SDC-1801 | SDC 1801; SDC1801; SDC-1801 | 2019 | Preclinical |
| TD-8236 | JAK inhibitor, Theravance Biopharma; TD 8236; TD | 2019 | Phase I Clinical Trial |
| GLPG-3121 | GLPG 3121; GLPG3121; GLPG-3121 | 2019 | Phase I Clinical Trial |
| PF-06826647 | PF 06826647; PF 6826647; PF06826647; PF- | 2019 | Phase I Clinical Trial |



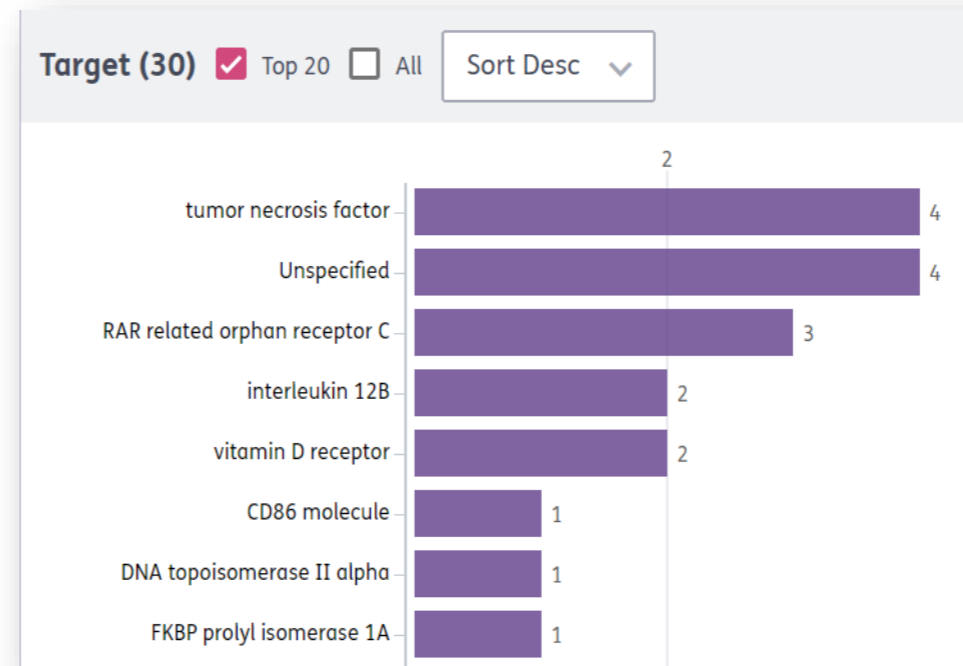
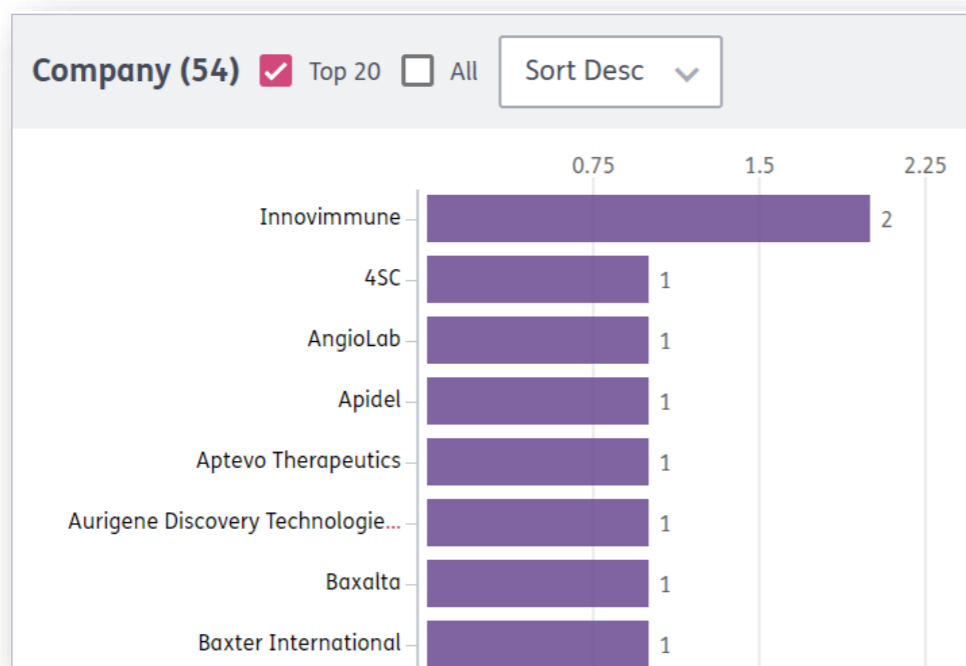
Case Study – Pharmaprojects

5、如何查询正寻找合作伙伴（中国）的抗银屑病研发药物？

[Search Available](#)

The screenshot shows a search query builder with the following filters:

- Drug Disease is Psoriasis
- and
- Drug Disease Status is Pipeline
- and
- Partnering Availability is Yes
- and
- Partnering Availability: Country is China



Note:

1. “Partnership Availability” tool mines through all publicly disclosed information with credible sources available via URL links.
2. Please also feel free to add in the filter of “Partnership Availability: Country is Undisclosed”, as some potential candidates may be open for partnership agreement upon contact.

Case Study – Pharmaprojects

5、如何查询正寻找合作伙伴（中国）的抗银屑病研发药物？

[Drug Profile Available](#)

- Drug Summary
- Company Data
- Activity
- Chemical data
- Diseases
- Country data**
- Event History
- Trialrove Trials
- Marketing
- Licensing**
- Phase III
- Phase II
- Phase I
- Preclinical
- Supporting URLs

Country data

| Name | Status | Licensing Opportunity |
|-----------|-------------|-----------------------|
| Argentina | Undisclosed | Yes |
| Australia | Undisclosed | Yes |
| Austria | Undisclosed | Yes |
| Belgium | Undisclosed | Yes |
| Brazil | Undisclosed | Yes |
| Canada | Undisclosed | Yes |
| Chile | Undisclosed | Yes |
| China | Undisclosed | Yes |
| Colombia | Undisclosed | Yes |

Licensing

Agreements

Changchun Changsheng Life Sciences Ltd
China; Gene Techno Science has a commercialization agreement with Changchun Changsheng, for the development of adalimumab biosimilar (GBS-005) (2nd Qtr Financial Results, Gene Techno Science, 31 Mar 2018, Page 4, <http://ir.g-gts.com/en/topics/topics-5993042486956472119/main/0/link/Tanshi...>; Company pipeline, Gene Techno Science, 25 Apr 2018, http://ir.g-gts.com/rd_en/Top.html). On 27 Jul 2018, GTS has decided to negotiate with Changsheng Biotechnology to terminate collaboration agreement for commercializing Adalimumab biosimilars in Chinese market as it found, Changsheng Biotechnology's corporate culture, problematic from a series of scandals and judged they are not appropriate partner because they committed unethical act (1st qtr Financial Res, GTS, 6 Aug 2018, Slide 7, <http://ir.g-gts.com/en/topics/topics7886883687562388415/main/0/link/pdfFile...>).

Availability

Gene Techno Science
Worldwide; Gene Techno Science is seeking partners for the development of GBS-005 (Company Analysis and Research Report, 8 Sep 2016, Page 9, <http://ir.g-gts.com/en/topics/topics-3320682343421915332/main/0/link/gts201...>). After termination with Changsheng Biotechnology, GTS is seeking for partnership in China (1st qtr Financial Res, GTS, 6 Aug 2018, Slide 7, <http://ir.g-gts.com/en/topics/topics7886883687562388415/main/0/link/pdfFile...>).

Case Study – Scrip/Pink Sheet

6、【商业】如何查询当前市场动态（如：交易、市场格局分析、高层专访等）？
[Search Available](#)

The screenshot shows a search results page for 'psoriasis'. On the left, there is a 'Filter By' sidebar with categories like Publication, Industry, Subject, and Therapy Areas. The main search area shows 'Showing 1 - 10 of 34 results for "psoriasis"'. Three articles are highlighted with arrows pointing to their full content pages on the right:

- Taltz Tops Tremfya In Head-To-Head Psoriasis Study On Complete Skin Clearance** (14 Aug 2019 | NEWS) by Jessica Merrill
- Psoriasis Drugs Poised For The Q2 Spotlight** (11 Jul 2019 | ANALYSIS) by Jessica Merrill
- Novartis Settles Short-Lived Suit Over Janssen's Psoriasis Drug Promo** (28 Apr 2019 | NEWS) by Brenda Sandburg

Note:

- 可通过文章标题筛选
- 可通过左侧筛选目录进一步搜索（如：国家、公司名称、日期、文章类别等）
- 可根据需求随意检索关键词（如：Gene Therapy、CAR-T、Roche等）
- 可输入“+”号搭配检索（如：PD-L1 + China等）
- 可输入双引号锁定关键词（如：“Immuno Oncology”）

Case Study – Scrip/Pink Sheet

7、【研发】如何查询最新研发进展（如：创新及临床数据分析等）？ Search Available

The screenshot shows a search results page for the keyword 'psoriasis'. On the left, there is a 'Filter By' sidebar with categories: Publication (Scrip, Pink Sheet, In Vivo, Generics Bulletin, Medtech Insight), Industry (BioPharmaceutical, Medical Device, Consumer), and Subject (Clinical Trials, Research & Development, Research and Development Strategies, Business Strategies). The main content area shows search results for 'psoriasis', with the top result being 'UCB Spotlights Bimekizumab And Other Later-Stage R&D Projects' dated 31 Jul 2019. A red arrow points from this result to the article preview on the right.

TAGS: Immune Disorders | Clinical Trials | Research & Development | ASK THE ANALYST | EMAIL

UCB Spotlights Bimekizumab And Other Later-Stage R&D Projects

31 Jul 2019 | ANALYSIS



by John Davis
john.davis@informa.com

Executive Summary

Belgium-headquartered UCB has a group of antibody studies which will be competing in the dermatology years.

Belgium's mid-sized pharmaceutical company, UCB Group, has highlighted new understanding of the importance of axial spondyloarthritis and psoriatic arthritis, both of which are now believed to be more common than rheumatoid arthritis, as a factor in the development of its late-stage investigational selective IL-17A and IL-17F inhibitor, bimekizumab.

CEO Jean-Christophe Tellier reported that Phase III results involving bimekizumab are expected in the fourth quarter of this year, and a Phase III study of padsevonil, potentially the first anti-epileptic to target two receptors, has started in refractory patients.



Further, a proof-of-concept study has started with rozanolixizumab in chronic inflammatory demyelinating polyneuropathy (CIDP). Rozanolixizumab is already in Phase III in myasthenia gravis, with results expected in the first half of 2021, and a Phase III study in immune thrombocytopenia patients is expected to start in the fourth quarter of 2019, Tellier said in a 25 July call with analysts.

An anti-tau antibody, UCB-0107, is in a Phase I study in patients with progressive supranuclear palsy, Tellier added.

Bimekizumab currently features in eight late-stage studies by UCB, including three pivotal Phase III studies and a Phase IIIb study in psoriasis, two studies in psoriatic arthritis, one study in ankylosing spondylitis and one in non-radiographic axial spondyloarthritis, UCB executive vice-president and head of immunology patient value unit, Emmanuel Caeymaex said in the same call. "Four out of the eight studies have an active comparator arm, that includes the market leaders," he noted.

UCB Buoyed By More P Bimekizumab Data

By Kevin Grogan
20 Jun 2019

The Belgian group has a lot of do with Cosentyx and Taltz already established but is confident bir mechanism of action, which ne IL-17A and IL-17F cytokines, o

The market for psoriasis, psoriatic arthritis and axial spondylarthritis treatments is expected to grow to \$37bn by 2027, Caeymaex noted, driven by IL-17 and IL-23 inhibitors. "In psoriasis, the IL-17s and IL-23s will gain the majority of dollar share as more patients gain access to systemic treatments, and as the treatment goals evolve towards sustained, totally clear skin and resolution of inflammation as a means to prevent co-morbidities," Caeymaex added.

Recently Launched Products

The product developed in partnership with Amgen Inc., Eeventy (romosozumab), has been approved now in the US, Japan, South Korea, Canada and Australia, although in the EU it has received a negative opinion by the CHMP, and UCB has requested a re-examination, which should take four to six months. (Also see 'Amgen Launches Eventy For High-Risk Osteoporosis At \$21,900 List Price' - Scrip, 15 Apr, 2019.)

"There is no reason for us to believe that a numeric imbalance in cardiovascular events, seen in one of our studies, is linked to Eventy, which has shown a strong benefit in patients with fragility fractures," Tellier remarked.

"UCB is the lead company for Eventy in Europe, and that for us is a clear priority and we are doing everything we can in order to have a positive outcome of the reexamination," he added. (Also see 'Disappointed' UCB And Amgen Will Appeal CHMP's Negative Eventy Decision' - Scrip, 28 Jun, 2019.)

UCB has also gained approvals for Nayzilam (midazolam nasal spray) for acute repetitive seizures in the US this May. The product "completes our portfolio in epilepsy," Tellier added. (Also see 'Keeping Track: Novartis Scores Big Ahead Of US Memorial Day With Approvals For Gene Therapy Zolgensma, Oncologic Piqray' - Pink Sheet, 26 May, 2019.)

Note:

- 可通过文章标题筛选
- 可通过左侧筛选目录进一步搜索（如：国家、公司名称、日期、文章类别等）
- 可根据需求随意检索关键词（如：Gene Therapy、CAR-T、Roche等）
- 可输入“+”号搭配检索（如：PD-L1 + China等）
- 可输入双引号锁定关键词（如：“Immuno Oncology”）

Case Study – Scrip/Pink Sheet

8、【监管】如何查询最新监管更新（如：上市申请、FDA警告、获批途径更新或立法等）？ Search Available

TAGS: [Biosimilars](#) | [Legislation](#) | [Pricing Debate](#) ASK THE ANALYST EMAIL

Biosimilars In US Drug Pricing Debate: Second Chance – Or Maybe Last Chance

02 Sep 2019 | ANALYSIS

by [Michael McCaughan](#)
@RPMReportMike | michael.mccaughan@previsionpolicy.com

Executive Summary

Current drug pricing legislative effort offers the prospect of a substantial law – substantial at least in the list of statutory changes, if not in the marketplace.

Whatever else emerges from the legislative push to address drug pricing in the US, the final bill appears likely to serve as the first substantial update to the biosimilar law enacted in 2010. For now, the center of activity on the legislative front appears to be the Senate, where a bipartisan Finance Committee drug pricing bill is the most likely vehicle to move forward sometime between September and the end of the year. (Also see ["Point-Of-Sale Rebates May Be Added To US Senate Finance Drug Pricing Bill"](#) - Pink Sheet, 25 Jul, 2019.)

The Senate Health and Judiciary Committees have also reported out bills to address drug pricing, and those are likely to be combined into an effort to push through something that addresses the bipartisan concern about high drug costs.

While not the primary focus by any means, all three bills have provisions that directly focus on the biosimilars. In fact, there are legislative changes that touch on all aspects of the pathway: regulation, reimbursement, patent challenges and non-patent barriers. It may not be described as such, but the collective impact would amount to the first comprehensive update of the BPCIA provisions that were included in the 2010 Affordable Care Act.

The timing is crucial, as there is a nascent push to give up on biosimilars as viable strategy for assuring affordable treatments in US in favor of more direct post-patent price regulation. A package of reforms could thus give the competitive model for follow-on biologics a second chance – or maybe a last chance – to start to deliver significant savings.

Note:

- 可通过文章标题筛选
- 可通过左侧筛选目录进一步搜索（如：国家、公司名称、日期、文章类别等）
- 可根据需求随意检索关键词（如：Gene Therapy、CAR-T、Roche等）
- 可输入“+”号搭配检索（如：PD-L1 + China等）
- 可输入双引号锁定关键词（如：“Immuno Oncology”）

客服支持

顶级客服团队鼎力相助

产品培训

- 订制或多人培训
- 特定部门实际应用培训
- 基础培训
- 订制培训
- 高级培训（含实际各类信息进阶操作）
- 线下视频、短片及常见答疑
- 现场培训（需10名或以上）

使用辅助

- 一般咨询
- 产品使用问题
- 个性化技术支持
- 数据导出或使用辅助支持或培训
- 用户反馈

联络方式：

client.services@citeline.com

亚太区客服：

Robert.wu@informa.com

关键辅助链接 – Citeline Help Center ([点击查阅](#))

■ 各产品涵盖范围

- Trialtrove & Sitetrove 疾病涵盖说明 – <https://citeline.zendesk.com/hc/en-us/categories/360000327534-Trialtrove-and-Sitetrove-Disease-Scope-Statements>
- Pharmaprojects 内容涵盖说明 – <https://citeline.zendesk.com/hc/en-us/articles/360007579834-Pharmaprojects-Scope-Statement>

■ 用词释义

- Trialtrove & Sitetrove Study Keyword 释义 – <https://citeline.zendesk.com/hc/en-us/articles/360017923593-Trialtrove-Sitetrove-Study-Keyword-Definitions>
- Trialtrove & Trialpredict Category 释义 – <https://citeline.zendesk.com/hc/en-us/articles/360006300933-Trialtrove-Trialpredict-Sitetrove-Glossary-Category-Definitions->
- Pharmaprojects 用词释义 (一般) – <https://citeline.zendesk.com/hc/en-us/articles/360008401514-Pharmaprojects-Glossary-General>
- Pharmaprojects 事件一览及释义 – <https://citeline.zendesk.com/hc/en-us/articles/360008402554-Pharmaprojects-Glossary-Drug-Events>

■ 关键功能教程

- 基础使用 – <https://citeline.zendesk.com/hc/en-us/sections/360000990334-General-Citeline-Functionality>
- Sitetrove – <https://citeline.zendesk.com/hc/en-us/sections/360000819674-Sitetrove>
- Pharmaprojects – <https://citeline.zendesk.com/hc/en-us/sections/360000990354-Pharmaprojects>
- Trialpredict – <https://citeline.zendesk.com/hc/en-us/sections/360000819854-Trialpredict-Trial-Timing-Data>
- BizInt Smart Charts – <https://citeline.zendesk.com/hc/en-us/sections/360001764533-BizInt-Pharmaprojects-Trialtrove>

■ 分析师提示

- Trialtrove – <https://citeline.zendesk.com/hc/en-us/sections/360002365814-Trialtrove-Analyst-Tips>
- Sitetrove – <https://citeline.zendesk.com/hc/en-us/sections/360002387573-Sitetrove-Analyst-Tips>
- Pharmaprojects – <https://citeline.zendesk.com/hc/en-us/sections/360002365854-Pharmaprojects-Analyst-Tips>

■ 线上教程视频

- Trialtrove 基础教程 – <https://citeline.zendesk.com/hc/en-us/articles/360007613553-Welcome-to-Trialtrove-recorded-training-link-July-2018-10-minutes>
- Sitetrove 基础教程 – <https://citeline.zendesk.com/hc/en-us/articles/360007513034-Welcome-to-Sitetrove-recorded-training-link-July-2018-9-minutes>
- Pharmaprojects 基础教程 – <https://citeline.zendesk.com/hc/en-us/articles/360005354894-Welcome-to-Pharmaprojects-demo-5-minutes>
- 自动邮件提醒设置 – <https://citeline.zendesk.com/hc/en-us/articles/360006039174-Watches-and-Alerts-recorded-link>
- Citeline 临床调研及可行性分析 – <https://citeline.zendesk.com/hc/en-us/articles/360015534754-Using-Citeline-for-Clinical-Operations-and-Feasibility-recorded-training-link-29-Min>