Cancer Drugs in the FDA Fast Lane Drug Pipeline Update

Description: The US Food and Drug Administration (FDA) has throughout the last decades added four major ways it can speed up the market approval of new drugs, ranging from Fast track (1988), Accelerated approval (1992), Priority review (1992) to the most recent Breakthrough therapy (2012).

This pipeline update, Cancer Drugs in the FDA Fast Lane, gives a thorough account on which cancer drugs the FDA has chosen to favor for one or more of the above mentioned fast lane programs. Each drug carries in-depth information detailing overall developmental progression for each drug, targets, pathways, indications etc. helping you to analyze trends and facts on what could tip the FDA in your favor. Now be warned this is not really an exact science as Percy Ivy, associate chief of the Investigational Drug Branch at the US National Cancer Institute's Cancer Therapy Evaluation Program in Rockville, Maryland, expressed it by likens the definition of a breakthrough drug to US Supreme Court Justice Potter Stewart's notorious 1964 definition of pornography: “You’re just going to know it when you see it,” Ivy says.

There are today 136 companies plus partners developing 162 cancer drugs in the FDA fast lane drugs in 1450 developmental projects in cancer. In addition, there are 5 suspended drugs and the accumulated number of ceased drugs over the last years amount to another 61 drugs. Cancer Drugs In The Fda Fast Lane Drug Pipeline Update lists all drugs and gives you a progress analysis on each one of them. Identified drugs are linked to 168 different targets. All included targets have been cross-referenced for the presence of mutations associated with human cancer. To date 160 out of the 160 studied drug targets so far have been recorded with somatic mutations. The software application lets you narrow in on these mutations and links out to the mutational analysis for each of the drug targets for detailed information. All drugs targets are further categorized on in the software application by 50 classifications of molecular function and with pathway referrals to BioCarta, KEGG, NCI-Nature and NetPath.

How May Drug Pipeline Update Be of Use?
- Show investors/board/management that you are right on top of drug development progress in your therapeutic area. * Find competitors, collaborations partners, M&A candidates etc. * Jump start competitive drug intelligence operations * Excellent starting point for world wide benchmarking * Compare portfolio and therapy focus with your peers * Speed up pro-active in-/out licensing strategy work * Fast and easy way of tracking drugs using search engines; just one click from inside the application and you may search the World Wide Web and PubMed for any drug.

Drug Pipeline Update at a Glance

Investigators
Includes more than 136 principal companies plus their collaborators. There is direct access from inside the application to web pages of all principal companies.

Note: You are able to sort and find drugs according to companies and partners from drop-down menus in the application. You may also sort and find drugs according to country of companies.

Drug name & Synonyms
Lists commercial, generic and code names for drugs.

Developmental stage
This Drug Pipeline Update contains 162 cancer drugs in the FDA fast lane drugs in development, which have a total of 1450 developmental projects in cancer. In addition there are suspended and ceased drugs.

Pipeline Breakdown According to Number of Drugs
Marketed# 68
Pre-registration# 14
Phase III# 80
Phase II# 125
Phase # 84
Preclinical# 15
No Data# 13
Suspended# 5
Note: You are able to sort and find drugs according to developmental stage from drop-down menu in the application.

Indications
Included cancer drugs in the FDA fast lane drugs are also in development for 280 other indications, where of 186 are different cancer indications.

Note: You are able to find and sort drugs according to type of indication from drop-down menu in the application.

Targets
Mutations
All targets are cross-referenced with the Catalogue of Somatic Mutations in Cancer (COSMIC). It is designed to store and display somatic mutation information and related details and contains information relating to human cancers. To date 160 out of the 160 studied drug targets so far have been recorded with somatic mutations and the software application lets you narrow in on these mutations and links out to the mutational analysis for each of the drug targets for detailed information.

Biological Structures
The identity of available biological structures on 132 drug targets was retrieved from the RCSB Protein Databank for you to easily review the 3356 structures available today among drug targets.

Identified drugs are linked to more than 168 different targets, divided into 50 classifications of molecular function:
- Acid phosphatase activity
- Auxiliary transport protein activity
- Carboxypeptidase activity
- Catalytic activity
- Cell adhesion molecule activity
- Chaperone activity
- Chemokine activity
- Cofactor binding
- Complement activity
- Cysteine-type peptidase activity
- Cytokine activity
- DNA topoisomerase activity
- DNA-directed DNA polymerase activity
- G-protein coupled receptor activity
- Glutathione transferase activity
- Growth factor activity
- Heat shock protein activity
- Hydrolase activity
- Isomerase activity
- Kinase activity
- Kinase regulator activity
- Ligand-dependent nuclear receptor activity
- Ligase activity
- Lipid kinase activity
- Lipid phosphatase activity
- Metalloproteinase activity
- MHC class I receptor activity
- Molecular function unknown
- Oxidoreductase activity
- Peptidase activity
- Peptide hormone
- Phosphorylase activity
- Protein binding
- Protein serine/threonine kinase activity
- Protein threonine/tyrosine kinase activity
- Protein-tyrosine kinase activity
- Receptor activity
- Receptor binding
- Receptor signaling complex scaffold activity
- Serine-type peptidase activity
- Structural constituent of cytoskeleton
- T cell receptor activity
- T cell receptor binding
- Transcription factor activity
- Transcription regulator activity
- Transferase activity
- Translation regulator activity
- Transmembrane receptor activity
- Transmembrane receptor protein tyrosine kinase activity
- Transporter activity

Sub-Cellular Localization
Identified targets are categorized into 18 different primary and alternate sub-cellular localizations:
- Cell surface
- Clathrin-coated vesicle
- Cytoplasm
- Cytoskeleton
- Cytosol
- Endoplasmic reticulum
- Endosome
- Extracellular
- Golgi apparatus
- Kinetochore
- Lysosome
- Microtubule
- Mitochondrion
- Nucleolus
- Nucleus
- Plasma membrane
- Sarcoplasmic reticulum
- Secretory granule

Note: You are able to find and sort drugs according to target gene name, protein name, molecular function of target, target localization, presence of mutations and availability of biological structures of target from drop-down menus in the application.

Target Expression Profile
Direct links are provided from inside the application to 239 protein expression profiles of 151 drug targets in various human tissues and cancer types, cell lines and primary cells, including up to:
- 48 different normal tissue types
- 20 different types of cancer
- 47 cell lines
- 12 samples of primary blood cells

Pathway Referals
Identified targets have been cross referenced against their involvement in different cellular pathways, according to BioCarta, KEGG, NCI-Nature and NetPath.
- BioCarta# 210 Pathways
- KEGG# 172 Pathways
- NCI-Nature# 230 Pathways
- NetPath# 32 Pathways

Note: You are able to find and sort drugs according to targeted pathways from drop-down menus in the application.

Mechanism
In total there are different drug mechanism of action represented in this Drug Pipeline Update.

Note: You are able to find and sort drugs according to mechanism of action from drop-down menu in the
Compound
Identified drug compounds are described by:

Compound type, Chemical name, CAS Number and molecular weight

Note: You are able to sort and find drugs according to compound type from drop-down menu in the application.

Drug Profile
Progress analysis and review of drug development. A typical drug profile reports on, depending on stage of development and available information:

Drug Name & Synonyms
Presentation of drug name and synonyms

Principal Company & Partners
Presentation of principal company and partners

Target and Molecular Function of Target
Described target(s) is/are presented with:
Official Gene Symbol – Chromosome Location – Gene & Protein Name – Molecular Function

Target Localization
Described target(s) is/are presented with primary and alternate localizations.

Target Expression Profiles
Links to protein expression profile(s) of target(s) in various human tissues, cell lines and primary cells, including up to:
48 different normal tissue types
20 different types of cancer
47 cell lines
12 samples of primary blood cells

Mutation
All targets are cross-referenced with the Catalogue of Somatic Mutations in Cancer (COSMIC). It is designed to store and display somatic mutation information and related details and contains information relating to human cancers.

Biological Structures
The identity of available biological structures on drug targets was retrieved from the RCSB Protein Databank for you to easily review what available structures of drug targets exist.

Targeted Pathways
Described target(s) is/are matched for the involvement in cellular pathways according to BioCarta, KEGG, NCI-Nature and NetPath.

Mechanism
Drug mechanism of action

Developmental Projects
Summary field of developmental projects for the drug, including indication, developmental stage and status.
Example:
Cancer, myeloma – Phase II Clinical Trial – Active
Cancer, prostate – Phase III Clinical Trial – Ceased

Drug BioSeeker Group's software
Short introduction to drug

Compound Data
Compound type, Chemical name, CAS Number and molecular weight

Patent Data
Available patent information related to the drug is presented here.

Fillings and Approvals
Approvals and submissions
Analyst comments

Deals & Licensing
Collaborations and deals
Availability for licensing

Phase IV Data
Available Phase IV development data, developmental history and scientific data.

Phase III Data
Available Phase III development data, developmental history and scientific data.

Phase II Data
Available Phase II development data, developmental history and scientific data.

Phase I Data
Available Phase I development data, developmental history and scientific data.

Phase 0 Data
Available Phase 0 development data, developmental history and scientific data.

Preclinical Data
Available preclinical development data, developmental history and scientific data.

Discovery Data
Available discovery development data, developmental history and scientific data.

Application Features
Search, Find and Filter Panel with Initial Result Presentation
With this panel you can define your selectivity in each drug search with up to 24 different drug specific parameters. Each parameter has multi-select options to them and can be used as either an inclusion parameter or exclusion parameter.

The initial result table is a dynamic sortable table which gives you a fast overview of found results and can be narrowed down further by your own additional keywords.

Direct linkage from inside the application to related internet resources
- Drug data is linked to search engines like Google and PubMed
- Drug target data is linked directly to BioCarta, Human Protein Atlas, KEGG, NCI-Nature, NetPath etc.
- Direct links to company web pages of companies

Dynamic Report Generator
Our dynamic report generator lets you with ease and speed generate html reports directly in your web browser (Internet Explorer and FireFox), whether it is a single drug profile or an entire search you want have a report of.

System Requirements
- Operating system: Windows (2000/XP/Vista/7/8) for Mac Users the service is only available online
- Browser Application (Internet Explorer, Firefox, Chrome, Safari)
- Internet access (to access related internet resources)

Ordering:
Order Online - http://www.researchandmarkets.com/reports/2633255/

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit
http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

Product Name: Cancer Drugs in the FDA Fast Lane Drug Pipeline Update
Web Address: http://www.researchandmarkets.com/reports/2633255/
Office Code: SCD23GG4

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Format</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (Online Access) -</td>
<td></td>
<td>USD 1495</td>
</tr>
<tr>
<td>Single User:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic (Online Access) -</td>
<td></td>
<td>USD 2990</td>
</tr>
<tr>
<td>Site License:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic (Online Access) -</td>
<td></td>
<td>USD 4485</td>
</tr>
<tr>
<td>Enterprisewide:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Contact Information
Please enter all the information below in **BLOCK CAPITALS**

Title: Mr [ ] Mrs [ ] Dr [ ] Miss [ ] Ms [ ] Prof [ ]
First Name: ____________________________________________ Last Name: ____________________________________________
Email Address: * _______________________________________
Job Title: _____________________________________________
Organisation: __________________________________________
Address: ______________________________________________
City: __________________________________________________
Postal / Zip Code: _____________________________________
Country: ______________________________________________
Phone Number: _________________________________________
Fax Number: ___________________________________________

*Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: ________________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World