BioPharmAnalyses

MANUAL

CONTENT

Databases

BioPharmAnalyses' databases contain more than 10,000 fact sheets on agreements, clinical trials, fundraising, biopharmaceutical mergers and acquisitions and the regulatory life of biopharmaceuticals under development in Europe since January 2011.

BioPharmAnalyses is accessible from the address: http://biopharmanalyses.fr.

Then click on Databases / Login (http://biopharmanalyses.fr/login) and enter your username and password to access all five databases.

If you forget your password, you can click on the link "Lost your password" and follow the inductions.

The products and Companies database

Once you have clicked on Products and Companies, the homepage gives you access to a search engine allowing a simultaneous query of the five databases based on simple criteria:

- Product
- Country
- Action mechanism
- Company [biotech company, pharmaceutical laboratory, academic laboratory, technological and scientific service providers]
- Disease

You get a synthetic and dynamic vision of the activity of a company (last agreements concluded, progress of its clinical trials, fundraising carried out …) or the number and progression of clinical studies for a pathology given.

Each of the databases can also be individually interrogated about its own criteria. Access to the specific engine of each database is done by clicking directly on the link in the menu.

You then reach a search engine that allows you to perform your query. After clicking Launch Search, the result is displayed as a summary table. Then click on the loupes displayed in the left column of the table to access the detailed information sheets. Once your search results are displayed, you can export them as a PDF by clicking on PDF print"

Number of results: 908

Date	Database type	Country	Company	Product name	Disease	Action mechanism	Type of Information
2018-10-19	Clinical Trials		apceth (Germany)	apceth-201	acute graft-versus-host disease (aGvHD)	cell therapy, apceth-201 are allogeneic human mesenchymal stromal cells (MSCs) that have been genet...	Presentation of results at a congress
2018-10-16	Clinical Trials		BioInvent (Sweden)	BI-1607 (anti FcgammaRIIB antibody/anti-PD1 antibody)	solid tumors	monoclonal antibody/immune checkpoint inhibitor	Initiation of development program
2018-10-16	Clinical Trials		BioInvent (Sweden)	anti FcgammaRIIB antibody/anti-PD1 antibody program	solid tumors	monoclonal antibody/immune checkpoint inhibitor	Initiation of development program
2018-10-16	Clinical Trials		BioInvent (Sweden)	BI-1808	solid tumors	monoclonal antibody - immune checkpoint inhibitor	Initiation of development program

The Clinical Trials database

The Clinical Trials database currently has more than 3,000 fact sheets detailing the available data on the drug candidate, its mechanism of action, the developing society, the targeted pathology, the characteristics of the trial, the countries in which the clinical study takes place as well as the latest information provided.

Six research criteria: History, Product, Disease, Phase, Company and Therapeutic Area

Each sheet corresponds to the announcement of a new news item for a clinical trial (application for authorization, authorization of the study, initiation of patient recruitment, finalization of patient recruitment, intermediate results, evaluation by the DSMB …).

Number of results: 339

Date	Product	Disease	Phase	Company	Therapeutic area
2012-12-27	nepicastat (SYN117)	post-traumatic stress disorder (PTSD)	2	Biotie Therapies (Finland)	Mental diseases
2012-12-21	cadazolid	Clostridium difficile associated diarrhea (CDAD)	2	Actelion (Switzerland)	Infectious diseases
2012-12-21	DPK-060	external otitis (swimmers ear)	2	Pergamum (Sweden)	Infectious diseases
2012-12-19	anti-NKG2D (NN8555)	Crohn's disease	2a	Novo Nordisk (Denmark)	Autoimmune diseases - Inflammatory diseases - Digestive diseases
2012-12-18	VB-111 (ofranergene obadenovec)	ovarian cancer	1-2	VBL Therapeutics (Israel)	Cancer - Oncology
2012-12-18	ponesimod	psoriasis	2	Actelion (Switzerland)	Autoimmune diseases - Dermatological diseases
2012-12-15	fostamatinib	rheumatoid arthritis	2b	AstraZeneca (UK)	Autoimmune diseases - Inflammatory diseases - Rheumatic diseases

The Aggrements database

The Agreements database is currently developing more than 3,000 agreements involving at least one stakeholder in the European biopharmaceutical sector. Each sheet presents the characteristics of the agreement concerned and its financial terms when they are known.

Six research criteria: Date, Type of agreement, Disease, Company, Compound and Therapeutic area

In the Type of agreement criterion, the search can be carried out using one of the following keywords: R & D agreement, Develpment agreement, Collaboration agreement, Licensing agreement, Clinical research agreement, Marketing agreement, Production agreement, Promotion agreement, Distribution agreement, Joint-venture agreement, Exercise of an option agreement, Termination of an agreement, Refusal of an option, Milestone, Termination of an agreement.

This database also contains all the data relating to the life of companies. The other key words that can be used in the Type of Agreement criterion are the following:a Restructuring, Establishment of a new subsidiary in the EU, Establishment of a new subsidiary in the US, Opening of new premises, Opening of a new center/lab/plant, Construction of new premises, Construction of a production plant, Product acquisition, Pipeline acquisition, Plant acquisition, Company acquisition,Validation of a production plant, Services contract, Nomination, Resignation.

Date	Company	Compound	Disease	Type of agreement	Therapeutic area	Type of Information
2018-11-26	Intrasense (France) 12 Sigma Technologies (USA - CA)	?Discover Lung Nodule, Artificial Intelligence-based Computer Aided Diagnostics (CAD) solutions	lung cancer	collaboration	Technology - Services	Collaboration agreement
2018-11-26	RegenXBio (USA - MD) Rocket Pharmaceuticals (USA - NY)	NAV AAV9 vector and two additional NAV AAV vectors	Danon disease	licensing	Rare diseases - Genetic diseases - Cardiovascular diseases - Neuromuscular diseases	Licensing agreement
2018-11-20	Santhera	VBP15	Duchenne muscular	licensing	Rare diseases -	Licensing

The fundraisings and IPOs database

The fundraising and IPOs database presents more than 1,000 fundraising events (fundraising, grants) obtained by players in the European biopharmaceutical sector since January 2011. Each sheet develops the investors involved, the financing modalities and the use planned by the company concerned.

The mergers and acquisistions database

The Buyouts database shows the characteristics of over 400 transactions in the biopharmaceutical sphere (transaction terms, amount, impact on the portfolio of medicines, etc.) since January 2011.

Four research criteria: Date, Acquiring company, Acquired company, Amount
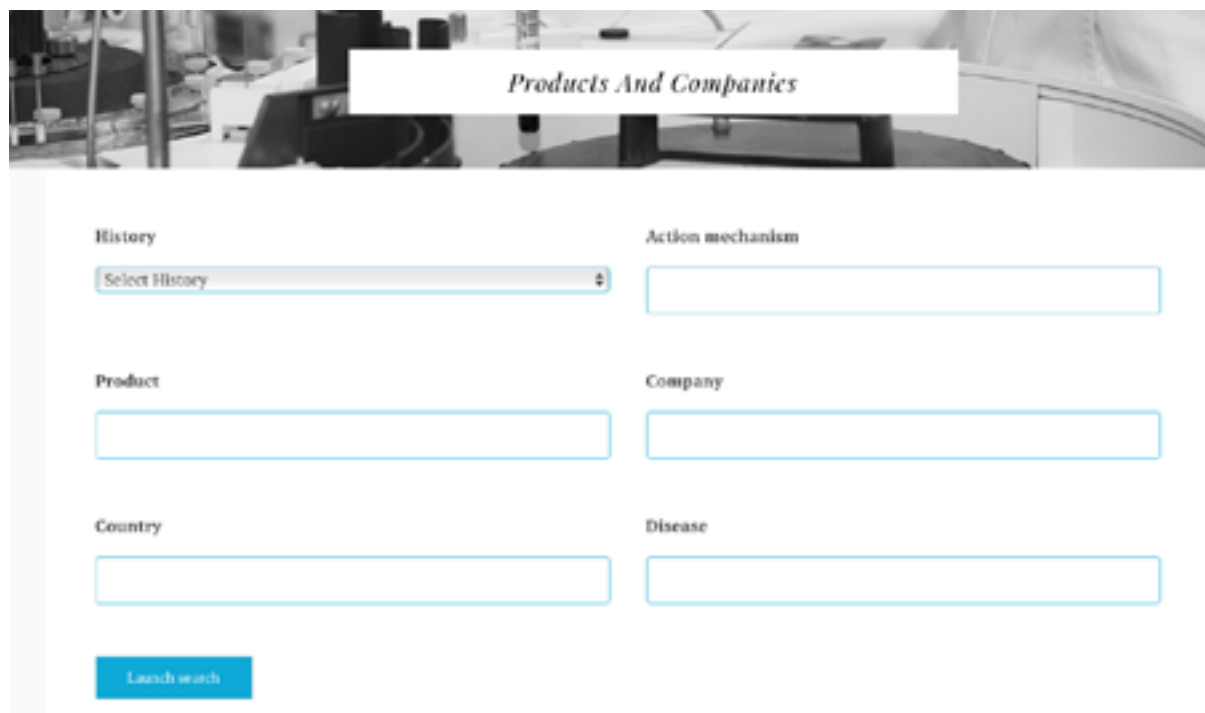
The products database

The product database provides data on the latest regulatory information registered on a biopharmaceutical product (submission of the marketing authorization application in the United States and Europe, issuance of a favorable opinion, date of authorization, obtaining orphan status in the United States, Europe …). It now lists more than 2,000 biopharmaceutical products.

Six research criteria: Date, Action mechanism, Company, Product name, Compound and Disease

History tab

In addition to the five bases Agreements, Clinical Trials, Fundraisings and IPOs, Mergers and Acquisitions, Products, BioPharmAnalyses offers a search mode "History", which allows you to find over two weeks, one month, six months, one year or two years, the main events occurring in a society, in a therapeutic area or for a pathology or a given product.

Therapeutic areas

The therapeutic areas on which you can search the BioPharmAnalyses databases are:

Allergic diseases, Autoimmune diseases, Bone diseases, Cancer – Oncology, Cardiovascular diseases, Cerebrovascular diseases, CNS diseases, Dermatological diseases, Diagnostic, Digestive diseases, Endocrinological diseases, Fertility – Women health, Fibrotic diseases, Gastroenterology, Genetic diseases, Gynecology, Hematological diseases, Hormonal diseases, Immunological diseases, Infectious diseases, Inflammatory diseases, Kidney diseases, Liver diseases, Lung diseases, Metabolic diseases, Mental diseases, Neurodegenerative diseases, Neurodevelopmental diseases, Neuromuscular diseases, Ophtalmological diseases, Otorhinolaryngology, Rare diseases, Regenerative medicine, Renal diseases, Respiratory diseases, Rheumatic diseases, Transplantation, Veterinary medicine.

Summary of the types of events listed in the BioPharmAnalyses databases

Clinical trials

- Initiation of preclinical development
- Initiation of development program
- Submission of a clinical trial application
- Filing of an IND
- Clinical trial authorisation
- Preclinical data
- Initiation of the trial
- Initiation of patient enrollment
- Recruitment of the first patient
- Treatment of the first patient

- Resumption of patient enrollment
- Completion of patient enrollment
- Completion of the trial
- DSMB assessment
- Amendment to the study protocol
- Halting of the trial
- Interim results
- Results
- Presentation of results at a congress
- Publication of results in a medical journal

Corporate data

- R&D agreement
- Development agreement
- Collaboration agreement
- Licensing agreement
- Clinical research agreement
- Commercialisation agreement
- Production agreement
- Promotion agreement
- Co-promotion agreement
- Distribution agreement
- Joint-venture agreement
- Exercise of an option agreement
- Refusal of an option
- Milestone
- Termination of an agreement

- Restructuring
- Establishment of a new subsidiary in the EU
- Establishment of a new subsidiary in the US
- Opening of new premises
- Opening of a new center/lab/plant
- Construction of new premises
- Construction of a production plant
- Product acquisition
- Pipeline acquisition
- Plant acquisition
- Company acquisition
- Validation of a production plant
- Services contract
- Nomination
- Resignation

Fundraising

- Grant
- Subvention
- Capital increase
- IPO
- Private placement
- Financing round

- Series A financing round
- Series B financing round
- Series C financing round
- Series D financing round
- Credit line
- Loan

Products

- Granting of a patent
- Positive opinion for the granting of the orphan status in the EU
- Negative opinion for the granting of the orphan status in the EU
- Granting of the orphan status in the EU
- Granting of the orphan status in the US
- Submission of a MA in the EU
- Submission of a MA in the US
- Submission of an NDA
- Acceptation for review of a NDA
- Acceptation for review of a sNDA
- Refiling of a MA in the EU
- Refiling of a MA in the US
- Granting of a Fast Track status
- Granting of the Breakthrough Therapy status
- Positive opinion for the granting of a MA in the EU
- Negative opinion for the granting of a MA in the EU

- Positive opinion for the granting of a MA in the US
- Negative opinion for the granting of a MA in the US
- Granting of a MA in the EU
- Granting of a MA in the US
- Granting of a MA in Canada
- Granting of a MA in Japan
- Granting of a MA in China
- Refusal of a MA in the EU
- Refusal of a MA in the US
- Withdrawal of a MA in the EU
- Withdrawal of a MA in the US
- Submission of an extension indication
- Granting of a pediatric exclusivity
- Reimbursement
- Product launch
- Withdrawal of the product