



**Embargoed until February 10th am**

## **BioImpact: Biotechnology for patients**

*Presentation of the results of BioImpact<sup>1</sup>, first scientific study on the impact of biotechnology-derived medicines on the quality of life and life expectancy of patients*

*Brussels, Paris, 10th February 2005* - France Biotech ([www.france-biotech.org](http://www.france-biotech.org)), the French Biotechnology Industry Association and its partners, Europabio ([www.europabio.org](http://www.europabio.org)), European Association of Bioindustries, Leem (the French pharmaceutical association [www.leem.org](http://www.leem.org)) and LIR (International Research Laboratories association [www.lir.asso.fr](http://www.lir.asso.fr)), present the results of BioImpact, first scientific study that outlines the major advances achieved thanks to biotechnology-derived medicines (monographs and summary cards for non specialists available on [www.biopact.org](http://www.biopact.org)).

Worldwide 300 million patients are being treated, or could be treated, by the 10 categories of biotechnology medicines described in BioImpact. In France, 2 million patients are affected by the pathologies covered in BioImpact and close to one million individuals<sup>2</sup> are being or could be treated by BioImpact's 10 biotech medicines.

The medicines studied offer efficient therapeutic solutions, especially in fields where unmet medical needs are very high, including cancer, inflammatory diseases, cardiovascular diseases, hepatitis, neurological disorders, and rare diseases. These medicines improve the quality of life and life expectancy of millions of patients while offering them safer, more efficient medicines with reduced side effects, and new therapeutic strategies for very incapacitating illnesses which have gone untreated until the arrival of biotechnology.

With 190 medicines and vaccines already available<sup>3</sup> and more than 400 therapeutic products under development in 2004, the socio-economic impact of biotechnology is highly significant, although this is also very difficult to quantify, in the absence of an unanimously acceptable pharmaco-economic model and taking into account the few cost-efficacy studies available today.

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<sup>1</sup> BioImpact is a study carried out by doctors and pharmacists, under the scientific guidance of Dr Philippe Cramer, Paediatrician, Entrepreneur and Vice-President of France Biotech, and validated by a Steering Committee made up of academic experts and scientific representatives of Europabio, *Les Entreprises du Médicament* (French pharmaceutical industry association) and *Laboratoires Internationaux de Recherche* (International Research Laboratories association). The monographs presented summarise the most accurate scientific data currently available on the causes and characteristics of each disease, its associated complications, numbers of patients and mortality, and compares traditional therapies with biotechnological therapies available. They are also presented in the form of summaries to enable easy understanding by non-specialists.

<sup>2</sup> Target populations according to data from the Commission for Transparency at AFSSAPS (French agency for the sanitary safety of health products), that is, the number of patients in the indication mentioned for Full Market Approval (FMA).

<sup>3</sup> Sources : BIO, PhRMA, 2003

Qualitative advances have however been clearly identified in BioImpact and these are presented in the descriptive sheets and in the monographs available on [www.bioimpact.org](http://www.bioimpact.org) :

***1 - Biotech offers new and more efficient therapeutic weapons for diseases which are either poorly treated or not treated at all***

- Advances in knowledge about the role of TNF alpha in the development of inflammatory lesions associated with rheumatoid polyarthritis and Crohn's disease have enabled the emergence of new medicines, the anti-TNF alphas, have shown very significant results in these pathologies;
- Interferon alpha is today the only medicine which can effectively cure 1/3 of patients suffering from hepatitis C; it is also effective in treating hepatitis B;
- Thrombolytics, if administered sufficiently early, can considerably reduce death by heart attack and stroke;
- Interferon beta is today the only treatment which has a real impact in curbing the degenerative process of multiple sclerosis, the 2<sup>nd</sup> cause of neurological disability in young adults: it reduces disease relapses by 30% and thus slows its progression.

***2 Biotech's-recombinant medicines increase product safety (recombinant Factor VIII for Haemophilia or recombinant human Growth Hormones for growth deficiency)***

***3 - In the treatment of diabetes or cancer (monoclonal antibodies) biotech's better targeted therapies reduce side effects and improve on existing treatments.***

***4- Biotech enables large-scale production techniques for better medical coverage (hepatitis B Vaccine, growth hormones, Factor VIII)***

Finally, pharmacogenomics will help better identify patients, according to their genetic profile, who are likely to respond best to certain types of treatments, and this is a particular advantage in giving more appropriate prescriptions, in reducing side effects and in improving the efficiency of existing treatments.

BioImpact highlights major advances made thanks to years of research. Biomedicines and other biotechnologies represent a large and growing segment of innovative medicines (35 to 40 % of the authorizations for commercialization in 2003). Many of these molecules were developed in the United States. To guarantee continued access to the most innovative care, it is vital to create an optimal environment for the discovery and development of such biotech medicines in Europe.

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**Appendix 1 - General presentation and study methodology**  
(All monographs and summaries are available at [www.bioimpact.org](http://www.bioimpact.org))

**Objective**

The BioImpact project aims to raise awareness of the current value and importance of biotechnologies for public health. It is important to be able to access the latest scientific data available in order to understand the relevance and benefits of these medicines.

BioImpact gives a solid image of the contribution that biotechnologies have made to therapeutic progress and public health, by highlighting the major advances made in these technologies, both in diagnosis and medical treatments. In the long term, BioImpact will draw up an inventory of therapeutic products with high added value and the positive effects that they have on biotechnologies in terms of improvement of public health.

**Medicines developed from biotechnologies** are defined in this study as medicines developed using life sciences techniques, whose production requires living organisms or their cellular components (OCDE definition)

**General methodology**

The monographs presented summarize the best scientific data currently available on the causes and characteristics of each pathology, its associated complications (clinical data), the number of patients affected and the change in the number of patients over time, the death rate (epidemiological data), and compares traditional treatments with biotechnological treatments available, especially in terms of efficiency (pharmacological data, clinical data). Where available, data relating to cost-effectiveness of medicines are also reported.

The study reports on the positive (and negative) effects of major medicines developed through biotechnologies in terms of their effectiveness (impact on quality of life and life expectancy, treatment of diseases that up to now remained without a therapeutic treatment, early or preventive diagnosis...), their safety (impact on the reduction of pathologies associated with previously used treatments) and their impact on health costs.

All data were reviewed by the specialists in pathologies concerned and also by a pluri-disciplinary and independent Steering Committee made up of clinicians, epidemiologists, pharmacologists and pharmo-economists, to provide the most complete and objective information possible.

Furthermore, with the aim of making this sometimes highly technical information available to the greatest number of people, BioImpact offers several levels of readership, from the introductory document to the most comprehensive bibliographical references.

**Acknowledgements**

BioImpact was directed by Dr Philippe Cramer, vice president of France Biotech, with the support of Dr Magali Ballard, Bichat Hospital, Dr Pascal Borderie, Schering-Plough, Pascale Jordan PhD, Dr Arash Jenabian, HEGP, Julien Martinet, PharmD, and Isabelle Nion-Larmurier, Saint-Antoine Hospital, Paris.

The members of the BioImpact Steering committee who validated the methodology were Prof. Leon Fine, of University College London, Dr Bernard Asselain, Curie Institute in Paris, Prof. Michel Aubier, Bichat Hospital in Paris, Prof. Elisabeth Autret-Leca, and Mrs Leguellec, Bretonneau Regional Hospital in Tours, Prof. Roger Salamon, ISPED in Bordeaux and Prof. Gérard Viens, ESSEC France and the scientific representatives of EuropaBio, Leem and LIR.

Appendix 2 -

*Major epidemiological data for the pathologies studied in BioImpact*

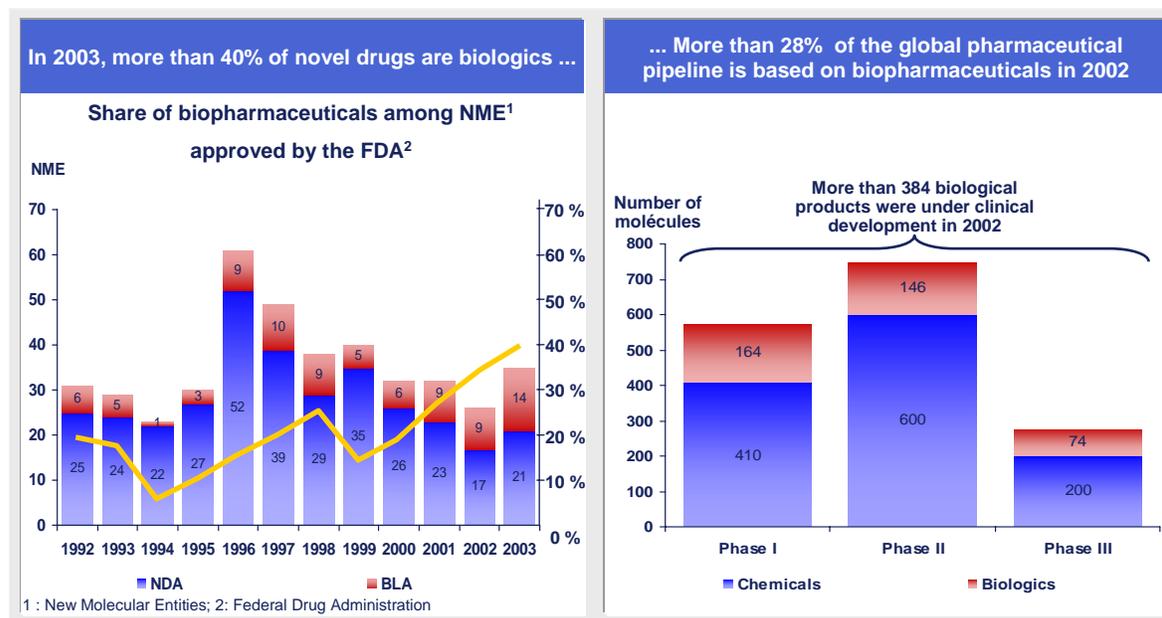
<b>Product</b>	<b>Pathology</b>	<b>Number patients Worldwide (million)</b>	<b>Number of patients France</b>	<b>Target Population France</b>
anti TNF alpha	Arthritis & Crohn Disease	30 / 60	130 000 / 240 000	31 300 / 66 800
Erythropoietin (EPO)	Severe Anaemia (IRC+Cancer+other)		n.a.	183 000 / 232 000
Factor VIII	Haemophilia A	0.05 (US+EU)	4 000	2 000
Human Growth Hormone	Growth Retardation			9 000
Insulin & Analogues	Diabetes	150		315 000
Interferon alpha	Hepatitis C	350	100 000 / 150 000	50 000
	Hepatitis B	400	500 000 / 650 000	
Interferon beta	Multiple Sclerosis	2.5	60 000	12 000 / 15 000
Thrombolytic agents	Cardiovascular Accidents	60	1 000 000	

Sources : Last available data from WHO, AFSSAPS, CNAMTS, NICE

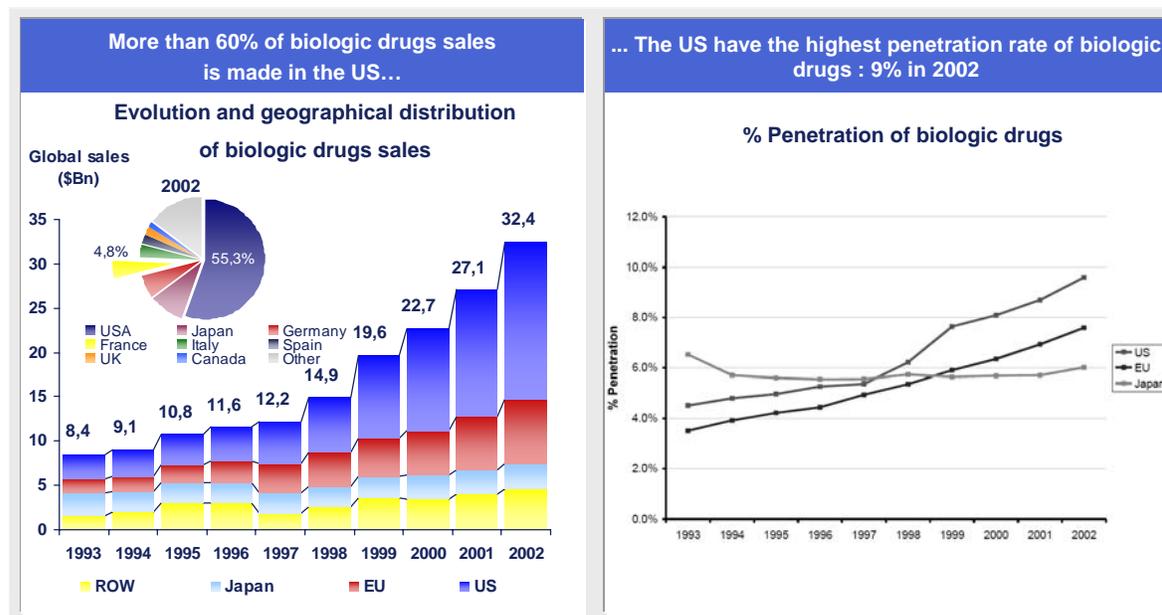
### Appendix 3 -About biotechnology: facts and figures

(graphs below are excerpts of the study Leem-AD Little - Optimisation de l'attractivité de la France pour la production biologique - November 2004)

Biotechnologies are a strategic sector – from both an economic and social point of view – on an international scale: biological products currently represent 40% of the total registered products and if we take into account chemical medicines developed with biotechnologies, we can estimate that over 50% of the new medicines originate from them, notably the most innovative medicines (insulin, growth hormones, recombinant growth factors, vaccinations, monoclonal antibodies for the treatment of cancers, inflammatory and infectious diseases, cell therapy, etc) and almost 250 million patients worldwide are already benefiting from advances made in biotechnologies, both in diagnostics and in treatment. Small and medium-sized biotechnology firms (3500 worldwide, approximately 250 to 300 in France) together with researchers are renewing the pipeline of the therapeutic products available to doctors and patients, undertaking cutting-edge research and using the very latest technologies. The fields of application of biotechnologies are extremely varied, and beyond human or animal health, biotechnology firms are also developing innovative applications in various industrial fields, in environmental protection and in agri-business, in particular.

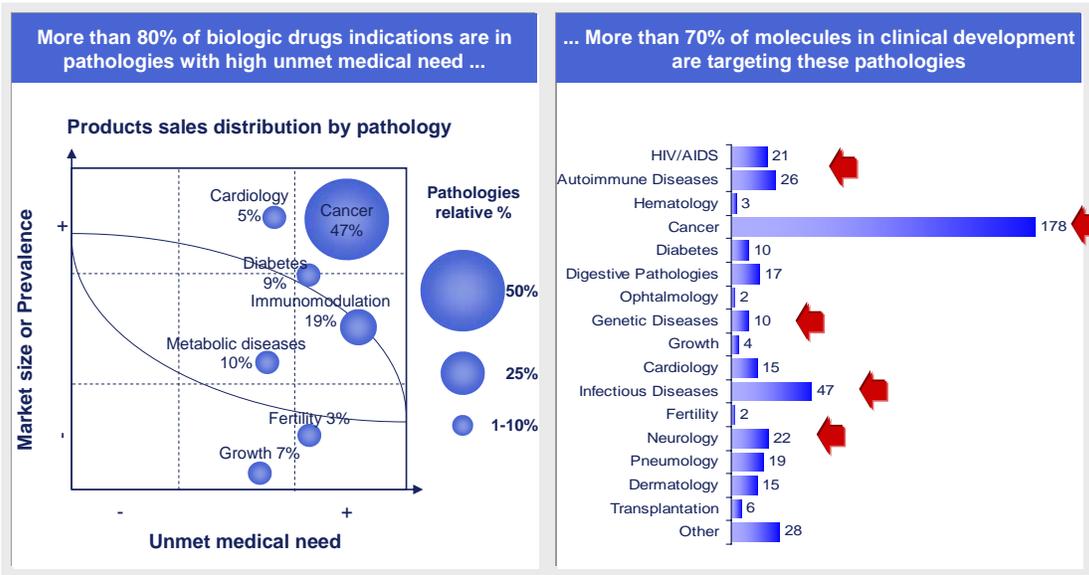


Sources : PhRMA, analyse Arthur D. Little for Leem

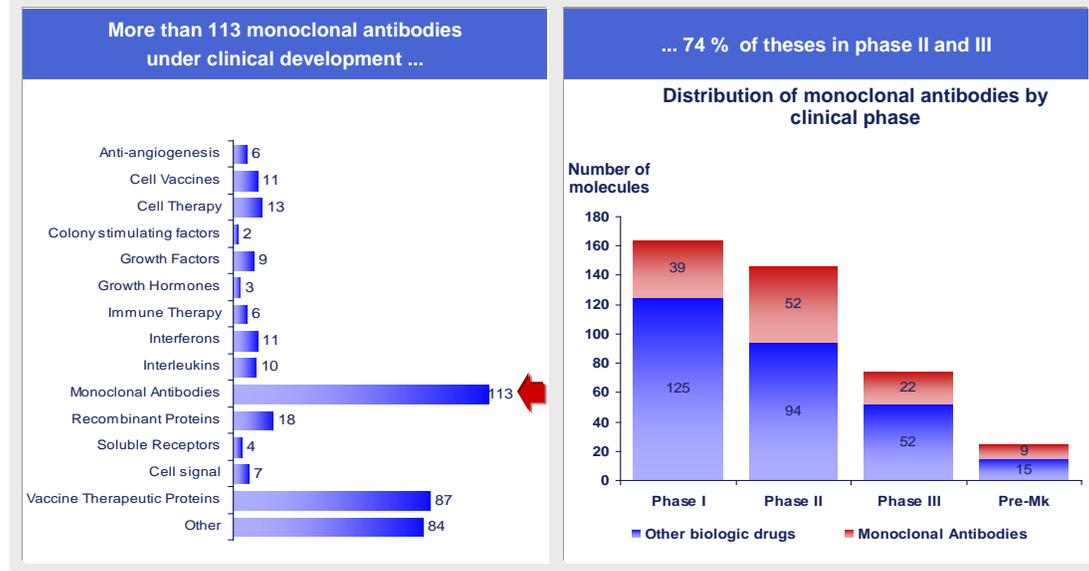


Sources : PhRMA, analyse Arthur D. Little for Leem BioManufacturing Study

Source : IMS 2004



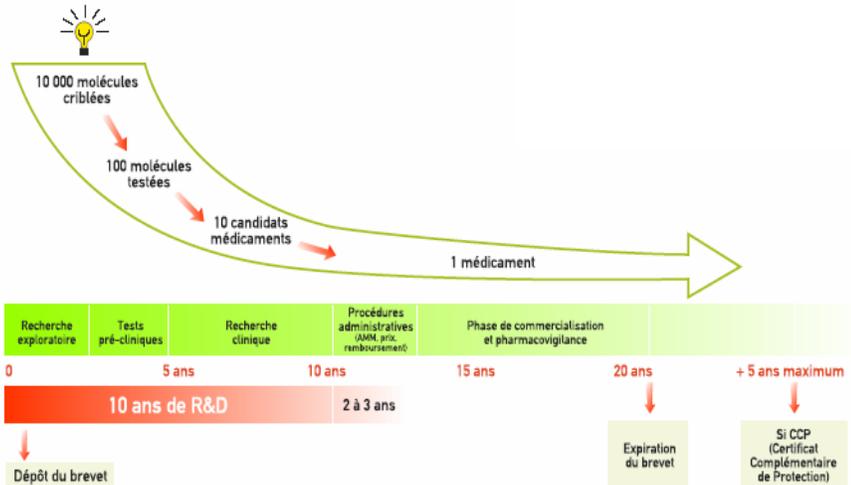
Sources : Analyse Arthur D. Little, données PhRMA et Datamonitor



Sources : Analyse Arthur D. Little, données PhRMA 2003 ajustées pour les anticorps

**The discovery and development of medicines (Sources - Leem)**

**De l'idée au produit : genèse d'un médicament**



## ***Annexe 4 - About France Biotech, Europabio, Leem and LIR***

### ***About France Biotech - [www.france-biotech.org](http://www.france-biotech.org)***

France Biotech is the French biotechnology association and the industry representative. Its mission is to contribute to position France and Europe as leaders in the Life sciences industry.

France Biotech is acting on the four key factors of success for a strong biotechnology industry:

- improving the academic R&D dynamics and funding: France Biotech supported the SCI when it made a series of proposals including the creation of a National Science Agency, project accepted by the French government on June 2004, and the focusing of the Agency's budget on Life Sciences and Nanobiosciences
- ensuring a liquid chain of financing for young biotechnology companies (from seed funding to the stock market): France Biotech has designed and proposed, with the SCI, the status of *Jeune Entreprise Innovante* (Young Innovative Enterprise, JEI). The government implemented this law proposal on January 1st 2004, which now makes France the most attractive country for young research-driven companies and subsidiaries from a tax and social costs standpoint. More recently, France Biotech and a few other organizations of entrepreneurs and investors triggered an initiative that led to the commitment made by the Life insurance companies to invest an additional 6 billion euros in private equity. France Biotech is now proposing the government to provide fiscal incentives for investors that will invest in *Young Listed Enterprises*, in order to prevent the lack of appetite encountered by young technology companies on the European stock markets.
- working on the managerial environment through members networking, benchmarking activities, good practices sharing, etc.
- and lastly improving public perception: the association has organized in 2004 BioPicture Festival, the 1<sup>st</sup> international film and image festival on biotechnology, for conveying a positive image of life sciences among the general public.

France Biotech gathers 150 members, representing most of the French biotechnology investments, pipeline and employees.

### ***About EuropaBio - [www.europabio.org](http://www.europabio.org)***

EuropaBio, the European Association for Bioindustries, has about 40 corporate members operating worldwide and 25 national biotechnology associations representing some 1500 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products.

EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe by stimulating R&D, commercial development, and market access for biotechnology products.

### ***About Leem - Les Entreprises du Médicament - [www.leem.org](http://www.leem.org)***

In France, the pharmaceutical industry is a major sector of activity that includes over 300 companies. They employ 100 000 people, create about 1000 new jobs per year and invest 3.5 billion euros each year in research & development for new medicines.

Leem is the french medicine companies association, and brings together companies operating in France which represent 98.7% of the French medicines market.

Medicines companies worldwide devote about 60 billions euros each year in R&D in order to create and make available innovative and efficient new treatments. The industry mission is to develop new vaccines and new drugs for human use in order to cure severe diseases as well as chronic or everyday pathologies.

Leem is committed to representing the companies which joined the association, facilitating meetings and exchanges between its member, elaborating the ethic code, and ensuring it is respected.

The Leem Biotechnology Committee was founded in March 2004 to gather French biotechnology actors involved in medicine companies.

The committee's main objectives :

- Facilitating the relations between the numerous medicine companies including small and large companies, and emerging biotechnology companies;
- Working together on the specific issues associated to medicine companies;
- Proposing national and European regulatory adaptations in this sector;
- Promoting French biotechnology applications when it comes to medicine companies.

Since July 2004, the young innovative biotechnology companies organization including « le Club Alfa », « le Comité Adebitech », « Organibio », etc.. are involved in the Leem Biotechnology Committee working activities.

**About LIR - Laboratoires Internationaux de Recherche - [www.lir.asso.fr](http://www.lir.asso.fr)**

Le LIR is the international association of research laboratories whose activities are focused on research and development.

Le LIR was founded to raise awareness and promote the role of innovation in the improvement of public health; to highlight the contributions of medicines from both an economical and therapeutic stand point; to generate understanding about the need for pharmaceutical policies to take account of industrial factors, research, exports and jobs as well as patients' interests and the financial balance of Health Insurance.