

## Belgian biotech companies join forces to consolidate the cell therapy sector

- Five cell therapy companies, members of bio.be, group together within the Co-ACT platform: Beta-Cell, Bone Therapeutics, Cardio3 BioSciences, Promethera Biosciences and TiGenix
- The companies plan to create 2,000 jobs by 2017
- The growth potential is threatened by regulatory constraints and difficulties in obtaining capital that limit Belgium competitiveness. The companies are calling for a coherent support policy.

**Brussels, 26 February 2013** – Beta-Cell, Bone Therapeutics, Cardio3 BioSciences, Promethera Biosciences and TiGenix announce that they are joining forces within the Co-ACT platform. Their objective is to consolidate Belgium's position as a preferred investment location for companies working in the field of cell therapy medicinal products. Belgium offers fertile ground for the establishment of such companies. At the bio.be annual meeting, however, Co-ACT warns against an overly restrictive regulatory framework and puts forward proposals to support the future growth of the sector.

### Belgium, "cell therapy valley"?

Belgium is at the cutting edge of life sciences and is highly competitive as a biotech investment location. *"Whereas Belgium accounts for just 2 % of the population of Europe, the overall value of the market of Belgian biotech companies represents 30 % of the European total"*, explains Cathy Plasman, secretary general of bio.be. *"In the field of cell therapies, Belgium clearly has a head start: the very first cell therapy product approved in Europe comes from de TiGenix and proportionally speaking, the products under development in our companies have reached a more advanced stage than in many other countries. But to maintain this advantage, these companies need to have all the conditions required to ensure their growth"*, she states.

The five companies grouped together within Co-ACT agree: at the cutting edge of innovation, they obtained substantial support during their start-up and early development, both from private investors and from the Belgian public authorities. *"The companies receive support mainly from the regions when they are first established and in the initial stages of their development. But this start-up support would be pointless without a purposeful, long-term investment policy and without a favourable regulatory framework: Belgium must be able to support the sector coherently at every level if it wishes to obtain the best possible return on investment"* explains Eric Halioua, CEO of Promethera Biosciences.

### Guaranteeing a competitive framework to support investment and secure employment in Belgium

The five companies joining forces within Co-ACT are planning to create a total of 2,000 jobs by 2017 and see a unique opportunity for Belgium to present itself as a centre of excellence for cell therapies. *"If this opportunity is to become a reality, the support we benefit from must be part of an overall policy"* declares Enrico Bastianelli, CEO of Bone Therapeutics. This is why Co-ACT is today calling upon the public authorities to promote the growth of these companies by providing a competitive regulatory environment and long-term structural financial support.

The first major regulatory constraint for Belgian biotech Small and Medium Enterprises (SMEs) is in establishing manufacturing plants in Belgium. Under current national legislation the companies are reliant on hospital centres for the cells and tissues needed to manufacture their innovative therapies. However, the hospitals have no incentive to develop these services. Co-ACT is requesting that the system be modified to enable them to access the cells and tissues they need for manufacturing as soon as they have been collected by doctors in hospitals and to be made responsible for the upstream quality assurance and control. *"To make Belgium a centre of excellence in cell therapy and attract investment and jobs in new productions sites, the*

*country must have a clear, simple, pragmatic regulatory framework that does not put it at a disadvantage compared with neighbouring countries. The debate with the public authorities has started, and we hope that this will lead to improvements that are essential for the sector”, declared Enrico Bastianelli, CEO of Bone Therapeutics.*

The second regulatory obstacle is the “hospital exemption” rule to the regulations on medicinal products that allows hospital doctors to manufacture their own medicinal products (cells for a specific patient) without having to meet the statutory requirements for quality, proof of efficacy or safety of the product they are administering. Eduardo Bravo, CEO of TiGenix, explains: *This exemption is provided for in a European regulation, but while exceptions are necessary, it is crucial that they be clearly defined. For instance, special cases permitting the use of products manufactured by the hospital when duly approved medicinal products are available for the same purpose must be avoided. We are calling for the clear, precise and specific transposition of the conditions under which this hospital exemption can be invoked. Patient safety and the competitiveness of the sector are at stake here”.*

### **A tax shelter to promote SME development**

Whereas companies can count on financial support when they are first established and during the early stages of their development, it is particularly difficult for these SMEs to grow and mature owing to a structural lack of professional investment funds in Belgium. In order to address this problem, the companies would like to explore the idea of setting up a tax shelter system similar to that already introduced in Belgium for audio-visual producers.

*“The regional aid and the initial capital are essential in the early development stages, but when needs become increasingly important during the later phases, local sources that can be used to finance our activities are no longer available. This forces us to turn to international leading financial players and all too often that results in relocation which means a loss of the benefit from the initial investments” explains Christian Homsy, CEO of Cardio3 BioSciences. “A patient enrolled in a study costs on average € 50,000 while we have to treat several hundred patients to complete these studies with the hope to gain product approval. Typically, professional Venture Capitalist or Private Equity investors have to take over. However, the number and respective resources of these professional players have significantly declined during the economic crisis, and their investments focus mainly on short-term returns. So why not consider a similar tax shelter mechanism to the one, which has been successful in the cinema sector? This would make it possible to secure long-term employment in Belgium and would offer companies or private individuals investment opportunities where the risk would be partly offset by tax breaks. The State would benefit thanks to future tax receipts and the jobs created”, he states.*

Co-ACT member companies are putting forward these proposals at the start of a consultation process with the federal government. Bio.be is representing the cell therapy companies in this process with the regulatory and tax aspects covered in two separate working groups: one chaired by the Minister for Health and Social Affairs, Ms Onkelinx, and the other chaired by the Minister for Finance, Mr Vanackere. The conclusions of this initiative from the Prime Minister, Mr Di Rupo, as part of the growth recovery strategy, are expected in June 2013. The Co-ACT companies hope that their proposals will be looked on favourably: ultimately, the employment potential of an entire sector is at stake.

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**About bio.be:**

Bio.be represents companies and professionals in the sector involved in the research, development, testing, production or marketing of biotechnological applications, as well as service companies in the biotechnology sector. Bio.be is an autonomous division of Essenscia.

Bio.be stimulates, promotes and defends biotechnological innovation and entrepreneurship as essential factors of economic growth and job creation, enabling scientific expansion and the development of new skills.

Bio.be represents the interests of the biotechnology industry at the various levels of authority by anticipating needs, putting forward recommendations and suggesting improvements to the regulations governing the sector.

For further information, please visit: [www.bio.be](http://www.bio.be)

**About Co-ACT:**

Co-ACT is an association bringing together the main biopharmaceutical companies established in Belgium developing advanced therapy medicinal products (ATMP)

The objective of Co-ACT is to protect and stimulate the R&D activities, production and export activities in order to consolidate Belgium's status as an investment location for ATMPs companies.

Its members include the companies Beta-Cell, Bone Therapeutics, Cardio3 Biosciences, Promethera Biosciences, TiGenix.

**About Beta-Cell:**

Beta-Cell is a privately owned company that develops innovative cell therapies and other products related to the treatment of diabetes. The company is a recognized leader in the field, and it has established patented technology to isolate and encapsulate insulin producing beta-cells from young pigs. These micro-sized capsules are implanted in Type-1 Diabetes patients, introducing new 'insulin factories' that produce on demand. Beta Cell is a spin-off from the Vrije Universiteit Brussel – Diabetes Research Center (VUB-DRC), and it is preparing to start clinical trials.

For further information, please visit: [www.beta-cell.com](http://www.beta-cell.com)

**About Bone Therapeutics:**

Bone Therapeutics is a leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases. Utilizing the Company's unique knowledge of the bone/joint physiology and long-standing expertise in cell therapy and cell transplantation, Bone Therapeutics has created a fully integrated business with an advanced product pipeline comprising novel bone cell products, tailored in-house production methods and minimally invasive treatment techniques.

Bone Therapeutics' lead product, PREOB<sup>®</sup>, is an autologous bone cell product, currently in Phase III clinical trials for the treatment of osteonecrosis and non-union fractures. Bone Therapeutics is also developing an allogeneic bone cell therapy product, ALLOB<sup>®</sup>, which is expected to enter the clinic in 2013 and MXB, a combined cell-matrix product for the treatment of large bone defects, currently in preclinical development. All of Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards, comply with all regulations and are protected by a rich IP estate.

The bone disease and reconstruction market is one of the largest healthcare markets in the world, with more than 4 million procedures requiring bone grafts performed annually in Europe and the USA alone. Bone Therapeutics is operating in areas where demand for new products is high and competition is low. Founded in 2006, Bone Therapeutics is privately held and headquartered in Gosselies (south of Brussels), Belgium.

For further information, please visit: [www.bonetherapeutics.com](http://www.bonetherapeutics.com)

#### **About Cardio3 BioSciences:**

Cardio3 BioSciences is a leading biotechnology company focused on the discovery and development of regenerative and protective therapies for the treatment of cardiac diseases.

The Company's lead product candidate, C3BS-CQR-1, is a highly innovative stem cell approach for the treatment of heart failure, one of the world's most pressing unmet medical needs.

Generated through a proprietary technological platform, the C3BS-CQR-1 programme is designed to direct the patient's own stem cells into new heart cells with the potential to rebuild the heart.

Cardio3 BioSciences has also developed C-Cath<sup>ez</sup>, the most technologically injection catheter with superior efficiency of delivery of bio therapeutic agents into the myocardium.

Cardio3 BioSciences was founded in July 2007 and is based in Mont-Saint-Guibert in the Walloon region of Belgium. The company leverages research collaborations in the US and in Europe with Mayo Clinic (Rochester-MN) and the Cardiovascular Centre Aalst, Belgium.

For further information, please visit: [www.c3bs.com](http://www.c3bs.com)

#### **About Promethera Biosciences:**

Promethera Biosciences is a Belgian pharmaceutical company, spin-off of the Université Catholique de Louvain, that develops innovative treatment for liver diseases. The company is a spin-off from the Université Catholique de Louvain (UCL) and has been founded in 2009. The products in development use a stem cell isolated from healthy adult liver, the Heterologous Human Adult Liver Progenitor Cell (HHALPC). The cell is currently in development for the treatment of rare in-born metabolic diseases.

For further information, please visit: [www.promethera.com](http://www.promethera.com)

#### **About TiGenix:**

TiGenix NV (NYSE Euronext: TIG) is a leading European cell therapy company with a commercial product and an advanced clinical stage pipeline of adult stem cell programs.

The company's lead product, ChondroCelect<sup>®</sup>, for cartilage repair in the knee, is the only approved cell-based product in Europe, and is currently being launched in different European countries.

TiGenix's stem cell programs are based on a validated platform of allogeneic expanded adipose-derived stem cells (eASCs) targeting autoimmune and inflammatory diseases. Built on solid pre-clinical and CMC packages, they are being developed in close consultation with the European Medicines Agency. The company has initiated a Phase III clinical trial in complex perianal fistulas in patients with Crohn's disease, is conducting a Phase IIa trial in rheumatoid arthritis, and successfully concluded a Phase I trial to investigate the potential of intra-lymphatic administration of eASCs for autoimmune disorders.

TiGenix is based out of Leuven (Belgium), and has operations in Madrid (Spain), and Sittard-Geleen (the Netherlands).

For further information, please visit: [www.tigenix.com](http://www.tigenix.com)

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