

Press release - 14 October 2015

Advanced Therapies: forthcoming improvements to Belgium's regulatory framework

- The Belgian advanced therapies sector welcomes the forthcoming publication of a royal decree implementing the requirements for the hospital exemption.
- The Minister of Health and Social Affairs confirms her commitment to pursue the necessary reform to stimulate the development of advanced therapies.

Mont-Saint-Guibert, Belgium - On the occasion of *European Biotech Week*, bio.be, the federation of Belgian companies active in biosciences, and Co-ACT, the platform for Belgian cell therapy companies, take the opportunity of a company visit to Celyad to highlight the needs of the sector. The two organisations welcome the forthcoming publication of a royal decree implementing requirements for hospital exemption and encourage the federal Minister of Health and Social Affairs to carry on the required regulatory adaptations to stimulate the development and production of advanced therapies in Belgium.

Maintaining the excellence and the competitiveness of the Belgian cell therapy companies

Three Belgian small- and medium-size enterprises (Bone Therapeutics, Celyad and TiGenix) have reached the final stages of clinical development for their lead products and are planning to submit an application for marketing authorisation in Europe within the next two years. An outstanding achievement, this would make Belgium, together with the U.S., one of the leading countries in the advanced therapies world.

« In less than a year, about 200 million euros have been raised by the five leading companies in Belgium: Bone Therapeutics, Celyad, Novadip Biosciences, Promethera Biosciences and TiGenix. The public authorities have actively contributed to this investment momentum and we now expect that they adapt the regulatory framework to boost the industrial deployment and sustain the competitiveness of these and other companies. », explains Cathy Plasman, Secretary General of bio.be.

Towards an imperative clarification and simplification of the Belgian national law

As part of her 'Pact for the Future' agreement signed with the pharmaceutical industry in August 2015, the federal Minister of Public Health and Social Affairs, Maggie De Block has committed to clarify the regulatory framework for advanced therapy products defining requirements for hospitals to produce and use advanced therapies in the context of the hospital exemption scheme. The Minister has recently confirmed the forthcoming publication of a royal decree that will determine the modalities thereof. In addition, the Minister has reiterated her commitment to examine and improve, in consultation with other stakeholders, the conditions in which pharmaceutical establishments can access human cells and tissues required for the production of their therapies.

« *The national implementation of the European legislation has been carried out in a more restrictive way in Belgium than in surrounding countries, making the companies in the country completely dependent on hospitals. The revision of these requirements is critically important to ensure the competitiveness of Belgian companies. We are very pleased that this topic is one of the Minister's political priorities during 2016.* », declares Annie Hubert, representative of Co-ACT.

European Biotech Week

The 2015 European Biotech Week (12 to 19 October) highlights the added value of biotech innovations (biotechweek.org). «*Today the focus is on advanced therapies, such as the product developed by Celyad which aims to repair cardiac tissue that is damaged in heart failure. This product is unique of its kind and could potentially dramatically change a patient's life* », says Cathy Plasman, Secretary General of bio.be, the federation of Belgian companies active in the biosciences and part of essenscia.

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About bio.be :

bio.be is the federation of Belgian companies active in the biosciences and is part of essenscia (chemicals and life sciences). bio.be represents the interests of its members as regards legislation and standards at various policy levels (Belgium, EU, OECD). Its mission is to create a stable legal framework in line with the trend for innovation, an essential factor for the economic sustainability and growth of employment in this sector. For further information, please visit: 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 R&D activities, production and export activities in order to consolidate Belgium's status as an investment location for ATMP companies. Its members include Bone Therapeutics, Celyad Biosciences, Novadip Biosciences, Promethera Biosciences and TiGenix.

For further information, please visit www.co-act.be.
