REGULATED INFORMATION
SEPTEMBER 25, 2012

TiGenix's new European production facility obtains EMA approval for commercial production of ChondroCelect

Leuven (BELGIUM) – September 25, 2012 – TiGenix (Euronext Brussels: TIG) announced today that after the successful cGMP inspection by the Dutch authorities earlier this year, it has now obtained the crucial approval from the European Medicines Agency (EMA) for the production of ChondroCelect, the company's commercial cell therapy product for cartilage repair in the knee, in its new state-of-the-art manufacturing facility in Sittard Geleen (NL).

"The EMA approval of our facility in the Netherlands for the production of ChondroCelect is another amazing feat from our manufacturing and regulatory affairs teams," said Eduardo Bravo, CEO of TiGenix. "The complexities of manufacturing an advanced therapy medicinal product (ATMP) like ChondroCelect are hard to overstate, and the seamless transfer of these capabilities to a new production facility, while keeping all facets of the process on a par with the original and meeting all requirements of the European regulator are immensely demanding. Our production site is unique in Europe as it is 100% geared towards the production of innovative cell therapy products. It provides us with crucial manufacturing capabilities to support the anticipated growth in demand for ChondroCelect for cartilage repair, with sufficient capacity for the production of other advanced stem cell therapy products."

The EMA's approval concerns a so-called Type II variation, which is required when a pharmaceutical manufacturer expands its production capabilities to a new location. At the time of approval of a medicinal product, its manufacturing procedures are an essential part of the Marketing Authorisation Application submitted to the agency, and are meticulously reviewed. When manufacturing is moved to a new plant, the EMA needs to approve the comparability of the manufacturing procedures to ensure there are no discrepancies with the original process. This Type II variation is particularly challenging for ATMPs that are characterized by more complex variables than traditional pharmaceutical products. ChondroCelect is the first ATMP ever approved by the agency.

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About TiGenix

TiGenix NV (Euronext Brussels: TIG) is a leading European cell therapy company with a marketed product for cartilage repair, ChondroCelect®, and a strong pipeline with clinical stage allogeneic adult stem cell programs for the treatment of autoimmune and inflammatory diseases. TiGenix is based out of Leuven (Belgium) and has operations in Madrid (Spain), and Sittard-Geleen (the Netherlands). For more information please visit www.tigenix.com.

Forward-looking information

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