



IDDI Reports Successful Partnership with TiGenix for Approval of ChondroCelect®

IDDI's contributed statistical methodology towards approval of ChondroCelect® TiGenix's lead product for the treatment of full thickness cartilage defects in the knee.

Louvain-la-Neuve, August 27, 2009 – IDDI (International Drug Development Institute), a corporation based in Belgium, reports that its collaboration with TiGenix resulted in the approval by European Medicines Agency for the Evaluation of Medicinal Products (EMA) of ChondroCelect® for the treatment of full thickness cartilage defects in the knee. On June 26, 2009, ChondroCelect® was the first cell therapy product to receive a positive opinion from the Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP) on the European Marketing Authorisation application (MAA) under the new regulation on advanced-therapy medicinal products. IDDI has partnered with TiGenix for their clinical development program, including a phase III clinical trial comparing ChondroCelect® to the present standard-of-care surgical intervention called micro-fracture. The results of this pivotal clinical trial have also been published in the February 2008 issue of the American Journal of Sports Medicine and awarded the Hughston Award, given for the most outstanding paper that appeared in the AJSM the year prior to the award.

TiGenix is currently the only company to have successfully completed a GCP-controlled, prospective, randomized multi-centre clinical trial for a cell based medicinal product intended for cartilage repair, in patients showing symptomatic cartilaginous defects of the femoral condyles of the knee.

IDDI's expertise in trial design and statistics was instrumental in providing robust statistical results, while IDDI's data management capabilities were key in accelerating the preparation and validation of efficacy and safety data for the analyses reviewed by the agency.

For information about ChondroCelect®, please visit <http://www.tigenix.com>

About IDDI

IDDI is a privately owned company with 20 years experience, providing key expertise to optimise the clinical development process in the areas of biostatistics, data management and information systems. IDDI offers advanced technology services to pharmaceutical and biotechnology companies in several disease areas, including ophthalmology and oncology.

For information about IDDI, please visit <http://www.iddi.com/>

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