



Graftys Announces Creation of an International Implant Registry to Follow up Graftys® HBS and Graftys® QuickSet

Aix-en-Provence, November 16th, 2015 – GRAFTYS SA, a company which develops and commercializes biomaterials used in orthopedic surgery, announces that it has recently established an ambitious Post Marketing Surveillance program, in the form of an internationally based registry of patients who have received implants of GRAFTYS® HBS and GRAFTYS® QuickSet. Both of these advanced phosphocalcic cements are highly injectable and resorbable.

This registry will put into practice «evidence-based medicine », which is highly applicable in the medical device industry and is being prioritized by government health authorities throughout the world. The goal is to systematically validate short term and long term clinical results for implantable devices after product launch.

In addition, the registry will document clinical results for recently approved innovative applications of GRAFTYS® HBS and GRAFTYS® QuickSet. Thanks to their high injectability, GRAFTYS cements can be used in numerous applications, such as bone marrow lesions (BML) in the knee, which was recently approved in Europe.

« It is important to be able to follow our patients over the middle and long term » states Pr. Sébastien Paratte, from the Institute of Movement and Locomotion (IML), at Hôpital de La Timone, Marseille, France, and coordinator of the GRAFTYS registry. « Three centers are currently participating in the program, and data from the first patients have already been included in France. »

« Discussions with additional international centers are underway to join the program » reports Jean-Marc Ferrier, Graftys' Director of Regulatory and Clinical Affairs. « This registry will allow us to follow the long term outcomes for patients treated in about 20 centers and will thus become one of the most important registries in the field of injectable bone substitutes. Our plan is to use this data for publication in clinical journals. »

About GRAFTYS® HBS

GRAFTYS® HBS is a phosphocalcic apatitic cement, highly injectible and well adapted to the needs of minimally invasive implant procedures. The patented formula includes a resorbable polymer which permits the cement to offer superior injectability and high resorbability.

About GRAFTYS® QuickSet

GRAFTYS® Quickset, which has a composition similar to that of GRAFTYS® HBS, provides a faster setting time, high cohesiveness, and a higher resistance to compressive force.

About GRAFTYS SA

Established in 2005 in France (Aix-en-Provence and Nantes), GRAFTYS has an office in the United States (Chicago). The company develops, manufactures and commercializes bioactive, synthetic biomaterials for orthopedics. GRAFTYS' technologies provide innovative therapeutic solutions in the field of bone tissue engineering. The company has partnerships with the key public academic research institutions in France and is co-owner of several patents filed jointly with these partners. GRAFTYS has obtained clearance of three 510(k) applications from the FDA for its biomaterials using calcium phosphate, products which also have CE approval. GRAFTYS' technologies provide treatment options for numerous indications in surgical applications in spine, orthopedics, trauma, and dental. GRAFTYS products are sold in more than 20 countries, including the United States, by specialized distributors.

For further information: <http://www.graftys.com>

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