



**GRAFTYS announces the extension of its CE mark for its calcium phosphate cements to now include GRAFTYS® HBS and GRAFTYS® Quickset for the indication of subchondral bone marrow lesions around the knee joint (BML)**

**Aix-en-Provence, September 14<sup>th</sup>, 2015** – GRAFTYS SA, a company focused on development and commercialization of orthopedic biomaterials, is pleased to announce that it has obtained authorization from its notified body, NSAI (National Standards Authority of Ireland) for European commercialization for two of its cements (GRAFTYS® HBS and GRAFTYS® Quickset) for treatment of bone marrow lesions caused by traumatic injury.

GRAFTYS® HBS and GRAFTYS® Quickset are highly injectable and resorbable calcium phosphate cements, developed by GRAFTYS and currently commercialized in 23 countries.

Subchondral bone marrow lesions, also known as bone marrow edema, results in loss of bone volume and micro fractures and loss of mechanical strength of the subchondral bone above or below the knee joint, which may cause an inflammatory reaction and damage the articular cartilage.

“When these bone marrow lesions occur in the subchondral condyle or under the tibial plateau, they can create pain and lead to total knee replacement once traditional treatments fail” said Jean-Marc Ferrier, Vice President of Clinical and Regulatory Affairs, GRAFTYS SA. “This new surgical treatment, which involves minimally invasive injection of calcium phosphate cement, under radiographic guidance, can provide orthopedic surgeons with a new and less invasive method of treatment for patients who suffer from this type of subchondral pain.

« We are very pleased to have obtained approval for this indication in Europe » said Aurélien Valet, General Manager, GRAFTYS SA. “This strengthens GRAFTYS’ market position, which now includes four CE approvals in Europe and three FDA 510(k) clearances. GRAFTYS will set up a clinical data registry aiming at demonstrating the efficacy of our products in the treatment of post-traumatic bone marrow lesions.

**About GRAFTYS® HBS**

GRAFTYS® HBS is a calcium phosphate apatitic cement, highly injectable, particularly adapted to minimally invasive approaches. Its proprietary composition includes a resorbable polymer which allows a better injectability and resorbability of the device.

**About GRAFTYS® Quickset**

GRAFTYS® Quickset, with a similar composition as the GRAFTYS® HBS, has a quicker setting time, is very cohesive, and features an improved mechanical resistance in compression.

**About GRAFTYS SA**

Founded in 2005, GRAFTYS is based in Aix en Provence and Nantes (France), with a US office in Chicago. The company develops, manufactures and markets synthetic bioactive orthopedic biomaterials. GRAFTYS technologies provide innovative therapeutic products in bone tissue engineering. The company has partnered with leading research institutions in France and co-owns several patents with these organizations. GRAFTYS has received FDA clearance for three 510(k) applications, with its calcium phosphate materials, which are also CE marked. GRAFTYS products address various indications in orthopedics, traumatology, podiatry, spine and dental. GRAFTYS markets its range of products in over 20 additional countries, including the United States, through distribution partnerships.

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

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