Biom’up receives CE Mark Approval for HEMOBLAST™ Bellows, the first active hemostatic powder for management of mild to moderate intra-operative bleedings

Lyon (France), December 7th, 2016

Biom’up announces today that it has received CE Marking for HEMOBLAST™ Bellows active hemostatic powder and delivery system. HEMOBLAST™ Bellows is indicated in open surgical procedures as an adjunct to hemostasis when control of bleeding by conventional techniques is ineffective or impractical. HEMOBLAST™ Bellows is indicated in the following surgical specialties: cardiac, vascular, abdominal, urology, gynecology, orthopedic, spine, ear nose and throat (ENT), and head and neck.

Valerie Centis, Chief Scientific Officer, comments "The development of HEMOBLAST™ Bellows was a true team effort that has now reached its CE marking milestone on time after several years of focused development". William D. Spotnitz, Chief Medical Officer, believes that “the product combines efficacy, ease of use, and rapid availability as well as local or more diffuse application”.

"This is a major Milestone for Biom’up, bringing this innovative solution to the market. As the first active hemostatic powder, it will support surgeons in their care for their patients with a simple, effective, and holistic solution for the management of bleeding” said Etienne Binant, Chief Executive Officer of Biom’up.

As a new innovative solution, HEMOBLAST™ Bellows launches into a market worth USD 2 billion. While indicated for open and laparoscopic procedures, a laparoscopic applicator for HEMOBLAST™ Bellows is currently under development. Over the coming months, the company will start to market HEMOBLAST™ Bellows in target surgical procedures in Europe, specifically cardiac, hepatic and spine surgery.

HEMOBLAST™ Bellows IDE pivotal clinical trial – USFDA PMA
The company is currently enrolling patients into a prospective, randomized, controlled, multicenter, pivotal, clinical investigation evaluating the safety and efficacy of HEMOBLAST™ Bellows in cardiothoracic, abdominal, and orthopedic lower extremity surgeries with the aim to reach post market approval by the FDA in 2018.

About Biom’up
Founded in 2005, Biom’up, a specialist in collagen-based absorbable medical devices for biosurgery, is developing a new generation hemostatic product composed of patent-protected biopolymers. With broad expertise in biomaterials, Biom’up is creating innovative and clinically proven products that are used in many surgical specialties such as orthopedics, spine, cardiothoracic, general, maxillofacial and dental surgery. Biom’up is committed to the design, development, and delivery of novel, high-performing solutions that make life easier for surgeons and better for patients.

Biom’up:
CEO: Etienne BINANT
CSO Valérie CENTIS, Ph.D.
CMO: William D. SPOTNITZ M.D
Contact : Guillaume Laurent, Marketing Manager : g.laurent@biomup.com
www.biomup.com