



Biom'Up provides regulatory update regarding HEMOBLAST™ Bellows

Saint-Priest, France, October 27, 2017 – Biom'Up, specialist of surgical hemostasis, today provides a regulatory update regarding the United States Food and Drug Administration's (FDA) review of the company's Premarket Approval (PMA) application for its HEMOBLAST™ Bellows.

The FDA conducted a PMA pre-approval inspection at the Biom'up Saint Priest, France, manufacturing facility. The four-day Premarket Approval inspection focused on the firm's HEMOBLAST™ Bellows product line and did not result in any FDA-483, Inspectional Observations.

This inspection was part of the medical device approval process to market HEMOBLAST™ Bellows within the United States of America. Following the inspection, the FDA will provide the company with an inspection report and continue its review of the PMA.

HEMOBLAST™ Bellows is currently CE Marked. HEMOBLAST™ Bellows is an investigational device in the United States and is under review pending PMA approval by the FDA.

Lori A. Carr, RAC (US), CQA (ASQ), RABQSA, FDA Medical Device Regulatory Consultant, stated that: *"A PMA premarket inspection is a final phase in the FDA review and approval process for Class III medical devices for legal commercial distribution of product within the United States."*

Biom'Up also enhanced the firm's sales and marketing team for the US, under Steven Ford, US VP Marketing and Dave Clark, US VP Sales, in order to prepare the future launch of HEMOBLAST™ Bellows.

"I warmly thank our operational and scientific teams, notably Hélène Plas, Head of Quality, Laetitia Trony, Head of Manufacturing, Pierre Poulain, Head of Engineering and Dr. Valerie Centis, Executive Vice President and Chief Scientific Officer, who participated in the FDA inspection for HEMOBLAST™ Bellows approval in the United States." stated Etienne Binant, CEO of Biom'Up.



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About Biom'Up

Founded in 2005 and based in the Lyon suburb of Saint-Priest (France), Biom'Up designs hemostatic products based on patented biopolymers that aim to simplify surgical procedures in numerous specialties (spine, cardiothoracic, general, orthopedic, plastic) and give patients a better quality of life. Its flagship product, HEMOBLAST™ Bellows, is a unique hemostatic solution, ready to use (no preparation time needed, no need to mix, no heat required), usable once or several times during the surgery. Developed by a world-renowned scientific team, HEMOBLAST™ Bellows has obtained positive results for all the primary and secondary endpoints of Phase III of its pivotal study involving 412 patients in the United States. HEMOBLAST™ Bellows obtained its CE Mark in December 2016, and its PMA (Pre-Market Approval) application was submitted to the FDA (Food & Drug Administration) in July 2017 with a view to obtaining marketing approval in the United States in mid-2018. Since its creation, Biom'Up has benefited from the support of prominent European investors such as Bpifrance, Innobio, GIMV, Lundbeckfond, Mérieux Participation, SHAM and ACG, as well as all the Company's managers, who have invested €2 million in equity. Biom'Up successfully completed its IPO on Euronext Paris, raising 38.1 million euros in October 2017.