



Biom'Up receives FDA marketing approval for HEMOBLAST™ Bellows, its flagship product

- Approval granted several months ahead of the initial schedule
- Launch of HEMOBLAST™ Bellows in the United States expected over the summer in 2018

Saint-Priest, France, December 18, 2017, 7:00 am (CET) – Biom'Up, specialist in surgical hemostasis, announces today that it has received FDA marketing approval for HEMOBLAST™ Bellows, its flagship product, 7 months ahead of schedule.

This pre-marketing approval (PMA), which allows a Class III medical device to be marketed in the United States, is the most stringent pathway to approval by FDA for devices. The PMA application is based on scientific and clinical data demonstrating that the device is safe and effective for patients and users under usage prerequisites.

HEMOBLAST™ Bellows, a best in class hemostatic product that aims to control bleeding during surgical procedures (heart surgery, general surgery, orthopedic surgery, etc.) is thus now accessible to American surgeons.

This FDA approval is notably based on the results of a prospective, controlled, randomized clinical trial carried out among 412 patients undergoing either cardiothoracic, abdominal or orthopedic (lower limb) surgery. All primary and secondary endpoints of this study were met with very high statistical significance. In view of the exceptional nature of these interim results (93% efficacy at 6 minutes, versus 74% for the control arm), the members of an Independent Data Monitoring Committee (IDMC) unanimously recommended that the study be stopped prior to the initially-scheduled end of this trial and that the application be submitted faster.

This approval follows an FDA inspection of the Biom'Up facility where HEMOBLAST™ Bellows is manufactured, which was concluded with no findings. This highly-positive outcome led the Company's management to anticipate the recruitment of the sales & marketing teams for the US market to prepare the launch of HEMOBLAST™ Bellows.

Biom'Up's company-wide unparalleled dedication to the approval process, and its continued striving towards a landmark PMA process, allowed a record time access to the American market for HEMOBLAST™ Bellows, in only ca. 2 and ½ years. The United States accounts for 46% of a global market estimated to be worth a minimum of \$2 billion¹, i.e. approximately \$920 million.

Etienne Binant, Chief Executive Officer of Biom'Up, comments: *"This FDA approval to market HEMOBLAST™ Bellows represents the most significant milestone in Biom'Up's development since its creation. We have done everything we could to obtain this approval, and we are delighted to have achieved it over half a year ahead of our initial schedule. This performance, which has set a new record in the surgical hemostasis sector for a first PMA, is the result of the extraordinary mobilization of all our teams. I would particularly like to congratulate and thank*

¹ sources: Company, IMS Health and DNA Ink

Professor William D. Spotnitz, our Chief Medical Officer, and Doctor Valérie Centis, our Chief Scientific Officer, without whom this success would not have been possible. I would also like to thank Mr. Thomas Maguire, our VP Clinical and Regulatory Affairs, and the entire NAMSA team, our CRO, headed by Mrs. Rachel W. Hoffman, the entire Hogan Lovells team headed by Ms. Janice M. Hogan, Professor Daniel L. Gillen, and all the surgeons who have helped us undertake the clinical study.

Lastly, I would like to thank the FDA for its interactive contribution to the PMA process, as well as its input within the framework of the development of the SPOT GRADE™ surface bleeding severity scale.

We will now be able to market our product over the summer in 2018. This approval, obtained in record time, allows us to calmly analyze access to other potential markets of very high strategic and commercial interest.”



Contacts

Biom'Up

Chief Financial Officer
Jean-Paul Alvès
investisseurs@biomup.com
+33 (0)4 86 57 36 10

NewCap

Investor Relations
Tristan Roquet Montégon
biomup@newcap.eu
+33 (0)1 44 71 00 16

NewCap

Media Relations
Nicolas Merigeau
biomup@newcap.eu
+33 (0)1 44 71 94 98

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 granted by the FDA (Food & Drug Administration) in December 2017 with a view to commercializing in the United States over the summer in 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 42.5 million euros in October 2017.

Biom'Up is listed on Euronext, Compartment C

ISIN: FR0013284080 – Ticker: BUP

