

Biom'up granted FDA approval for its HEMOBLAST™ Bellows Laparoscopic Applicator

- HEMOBLAST Bellows can be used with a specially designed 35 cm cannula in the United States in minimally-invasive surgeries
- FDA approval creates options for patients and surgeons across a broad spectrum of multiple surgical specialties
- The market opportunity for HEMOBLAST will increase by more than 400,000 surgical procedures annually in the U.S. alone

Saint-Priest, France, January 22, 2019, 8:00 am (CET) – Biom'up (the "**Company**"), specializing in surgical hemostasis, has announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for its HEMOBLAST Bellows Laparoscopic Applicator for all minimally-invasive procedures. Biom'up submitted the premarket approval (PMA) supplement to the FDA in July, 2018. The FDA completed its response within the standard 180 days, for this type of supplement, applicable when no challenge is raised, demonstrating the quality of the Company's regulatory work.

FDA approval expands the indications of the HEMOBLAST Bellows device and enables U.S. surgeons to use the hemostatic powder for both traditional and laparoscopic surgeries with the same patient and surgeon benefits of efficacy, simplicity and rapid availability.

The HEMOBLAST Bellows Laparoscopic Applicator offers a quick and simple delivery of the HEMOBLAST powder to bleeding sites in minimally invasive surgeries. The 35cm long polycarbonate applicator fits easily into the existing applicator and delivers HEMOBLAST powder to minimally invasive bleeding sites in under one minute. HEMOBLAST Bellows is the only surgical hemostatic agent approved by the FDA based on the validated Spot Grade™ Surface Bleeding Severity Scale (SBSS), which demonstrates its ability to control a range of bleeding from minimal (oozing), mild (pooling) and moderate (flowing) bleeding. HEMOBLAST Bellows is proven to control bleeding with flow rates up to 117 mL per minute.

Uncontrolled bleeding is a major surgical complication associated with increased mortality, longer hospitalization, higher rates of transfusions, and reoperations. Controlling bleeding in minimally invasive surgery is especially challenging because surgeons have to utilize instruments and cameras through small port sites of 5mm to 10mm instead of a much larger field of operation in traditional surgery.

PRESS RELEASE

The FDA approval allows Biom'up to expand its use of HEMOBLAST Bellows in a growing laparoscopy market that is estimated at nearly 443,000 surgeries per year¹. Biom'up obtained a CE Mark for its HEMOBLAST Bellows Laparoscopic Applicator in July 2018 for use in the European market, valued at 500,000 laparoscopic procedures annually¹.

«Today we have reached a new, significant regulatory milestone with the approval of HEMOBLAST Bellows for laparoscopic surgery in the U.S. Minimally invasive surgeries are challenging procedures for traditional hemostats. HEMOBLAST Bellows stands out amongst the competition because it combines strength, ease of use, and a swift time to hemostasis while preserving a surgeon's field of vision.» **said Etienne Binant, Chief Executive Officer of Biom'up**, *«This approval provides a significant expansion of the addressable market which encompasses several surgical specialties. I want to again thank our U.S.-based regulatory affairs team, led by our Chief Medical Officer, Pr. William Spotnitz, who have consistently demonstrated their ability to execute flawlessly on our regulatory roadmap.»*

¹ Global Data, DNA Ink, Company

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About Biom'up

Founded in 2005 and based in the Lyon suburb of Saint-Priest (France), Biom'up develops and commercializes hemostatic products based on patented biopolymers designed to simplify traditional and laparoscopic surgical procedures in numerous specialties such as cardiac, general and orthopedic, and give patients a better quality of life. The Company's lead product, HEMOBLAST Bellows, is marketed in Europe and the United States.

Since its creation, Biom'up has benefited from the support of prominent European and US investors. The Company's shareholders include Bpifrance (including its Innobio fund), Gimv, Lundbeckfond, Athyrium Capital and Invesco, as well as all the Company's management team. Biom'up successfully completed its IPO on Euronext Paris, raising €42.5 million in October 2017.

Since then, the Company carried out a €16 million capital increase in February 2018 and a €7.7 million capital increase by means of a private placement in December 2018. It also entered into a €25 million bond financing agreement with Athyrium, a U.S. fund specializing in innovative companies in the healthcare sector, in March 2018, brought to €28 million in December 2018.

About HEMOBLAST

HEMOBLAST Bellows is a hemostatic product to control bleeding in a broad range of both open and laparoscopic surgical procedures, such as cardiac, general and orthopedic surgeries, and give patients a better quality of life.

Uncontrolled bleeding is a major surgical complication associated with higher mortality, longer hospitalization and higher rates of transfusions and reoperations. Beyond its impact on patient's health, this major complication causes excess costs in all surgical specialties and is a burden for hospital budgets across the globe. HEMOBLAST Bellows is the only surgical hemostatic agent approved by the FDA based on the validated Spot Grade™ Surface Bleeding Severity Scale (SBSS), which demonstrates the ability to control a range of bleeding from minimal (oozing), mild (pooling) and moderate (flowing) bleeding. HEMOBLAST Bellows is proven to control bleeding with flow rates up to 117 mL per minute. Due to its efficacy, versatility and ease of use, HEMOBLAST Bellows is quickly becoming a popular choice amongst U.S. surgeons looking for new options to control surgical bleeding challenges.

Biom'up obtained CE Marking for HEMOBLAST Bellows in December 2016 and, on the basis of compelling preliminary results (93% effectiveness at 6 minutes, compared with 74% for the control arm) in the pivotal trial, expedited FDA approval for HEMOBLAST Bellows in December 2017, seven months ahead of the original plan. This allowed for the commercial roll-out of its lead product in the U.S. in summer of 2018. The Company's successful pivotal clinical trial in the U.S. included 412 patients admitted to cardio-thoracic, abdominal or orthopedic (lower limb) surgeries and met all of its primary and secondary endpoints.

In July 2018, Biom'up additionally obtained CE Marking for its HEMOBLAST Bellows Laparoscopic Applicator designed to deliver the HEMOBLAST Bellows powder in all minimally-invasive procedures. This has opened up new market segments, representing approximately 500,000 surgeries per year in Europe.

Currently the Company is working to expand the range of applications for HEMOBLAST Bellows. In addition, the approval from the Australian health authorities for the Company's lead product is expected during the first half of 2019.