Biom’up announces first US sales in laparoscopy for HEMOBLAST™ Bellows and the signing of an exclusive distribution agreement for HEMOBLAST™ Bellows in Australia

• Successful launch of the HEMOBLAST Bellows Laparoscopic Applicator in the US, first sales booked in March 2019

• Major framework agreement signed with Life Healthcare Distribution (“LHC”) for the exclusive distribution of HEMOBLAST Bellows in the sizeable and growing Australian market

Saint-Priest, France, April 15th, 2019 - 8h00 (CET) - Biom’up SA (the “Company”), specializing in surgical hemostasis, announces today first sales on the US market of its HEMOBLAST Bellows Laparoscopic Applicator.

The first kits have been shipped overseas from Saint-Priest (France) production unit and delivered to hospitals earlier in March. The U.S. surgeons are now able to use the hemostatic powder for both open and laparoscopic surgeries with the same patient and surgeon benefits of efficacy, simplicity and rapid availability. The U.S. laparoscopy market, in a growing phase, is estimated at nearly 443,000 surgeries per year1.

The HEMOBLAST Bellows Laparoscopic Applicator offers a quick and simple delivery of the HEMOBLAST powder to bleeding sites in minimally invasive surgeries. The 35 cm long polycarbonate applicator fits easily into the existing applicator and delivers HEMOBLAST powder in seconds. 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 5 mm to 10 mm instead of a much larger field of operation in open surgery.

Biom’up also announces today the signature of an important exclusive agreement with LHC, a leading independent distributor of medical devices and healthcare solutions in

1 Global Data, DNA Ink, Company
PRESS RELEASE

Australia, for future distribution of its medical device pending approval for sale in Australian market. LHC wide footprint in and network creates a broad platform for launching HEMOBLAST Bellows with its indications in many surgical specialties. LHC and Biom’up have defined clear milestones for the market development with an initial focus on spine and cardiac surgeries.

The regulatory submission for approval of the product, was initially filed on March 15th, 2018. The final decision of the Australian authorities is now expected in the second half of 2019. Australia has a well-established use of hemostatic devices, with a market for hemostats forecasted to reach US$ 50 million in 2020, with an annual growth of 7%.

“Biom’up continues to execute its commercial plan and to establish the foundation for robust growth in the coming years. Minimally invasive surgeries are challenging procedures for traditional hemostats, and a space where HEMOBLAST Bellows stands out amongst the competition with its combination of efficacy, versatility and ease of use while preserving a surgeon’s field of vision.” declared Etienne Binant, Chief Executive Officer of Biom’up. “These first sales of our Laparoscopic Applicator in the U.S. alongside the conclusion of a major, strategic agreement with LHC in Australia demonstrate our total focus on commercial expansion in 2019 forward”.

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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.

2 Source: Grand View Research
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 Bellows

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 cardiothoracic, 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. In January 2019, the Company obtained the respective approval for HEMOBLAST Bellows Laparoscopic Applicator in the U.S. This has opened up new market segments, representing approximately 500,000 and 443,000 surgeries per year in Europe and the U.S. respectively.

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 in the second half of 2019.