

Biom'up HEMOBLAST™ Bellows full pivotal trial results published in Journal of Cardiac Surgery

- **Article provides full data set of pivotal clinical trial showing that HEMOBLAST Bellows is clinically and statistically superior to control at achieving hemostasis**

Saint-Priest, France, January 30, 2019, 8:00 am (CET) – Biom'up (the "**Company**"), a specialist in surgical hemostasis, today announced the publication of scientific and clinical data with the Company's lead product HEMOBLAST Bellows, a hemostatic product to control bleeding in a broad range of both traditional and laparoscopic surgical procedures in the January edition of the *Journal of Cardiac Surgery*.

The *Journal of Cardiac Surgery* is a peer-reviewed, international publication devoted to contemporary surgical treatment of cardiac diseases.

The clinical data, published in open access in the article entitled "*Evaluation of the safety and efficacy of a new hemostatic powder using a quantitative surface bleeding severity scale*", clearly demonstrates the outstanding superiority of HEMOBLAST Bellows in terms of effectiveness for patients and surgeons under the usage prerequisites versus a control agent. In comparison to absorbable gelatin sponge and thrombin, HEMOBLAST Bellows achieved hemostasis in 71.1% of patients within three minutes (45.8% in the control arm) and in 93.1% of patients within six minutes (73.5% in the control arm). No signs or symptoms of postoperative bleedings were observed with HEMOBLAST Bellows.

HEMOBLAST Bellows met all primary and secondary endpoints with high statistical significance prior to completion of the clinical trial at the scheduled interim analysis. This allowed the product to receive pre-marketing approval (PMA) by the FDA seven months ahead of the trial's scheduled end which in turn allowed the Class III medical device to be marketed in the United States in December 2017.

The results were assessed using the only quantitative bleeding severity scale (SPOT GRADE™ Surface Bleeding Severity Scale, SBSS) clinically validated by the FDA and another major Biom'up innovation. SBSS constitutes a method for reproducibly quantifying surgical wound bleeding developed under the coordination of Prof. William Spotnitz, itself published in *Spine Journal* on June 1, 2018.

"We are delighted to be able to share the data of this very important study with the scientific community by publishing it in such a distinguished scientific journal," said **Prof. William Spotnitz, Chief Medical Officer at Biom'up**. "The acceptance of an article to

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be published in Journal of Cardiac Surgery testifies not just to the prominence and the high quality of the study results but also to the scientific excellence and ambitions of the Biom'up research team."

The publication can be viewed here: onlinelibrary.wiley.com/doi/10.1111/jocs.13982

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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.

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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 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. 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. 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 during the first half of 2019.