

Achievement of two major development milestones

- **IDE application submitted to the FDA for HEMOSNOW™**
- **Renewal of the supply agreement for human-derived thrombin, a key component of its flagship product, HEMOBLAST™ Bellows**

Saint-Priest, France, January 7, 2019, 8:00 am (CET) – Biom'up (the "**Company**"), a specialist in surgical hemostasis, today announces an IDE (Investigational Device Exemption) application submitted to the FDA for HEMOSNOW, a hemostatic dry powder made from porcine collagen and bovine-derived chondroitin sulfate for managing minimal and mild levels of bleeding during surgical procedures. The Company now plans to prepare the launch of the clinical studies required to obtain approval in the United States in 2020.

HEMOSNOW will complement its flagship product, HEMOBLAST Bellows. HEMOSNOW contains the same components as HEMOBLAST Bellows, but without human pooled plasma thrombin and is therefore effective against lesser degrees of bleeding at lower cost. The applicator systems are exactly the same as for HEMOBLAST Bellows permitting HEMOSNOW to be immediately ready for use and highly versatile with the ability to stop bleeding at focal bleeding sites as well as large area bleeding up to 50 square centimeters.

This submission to the FDA is a major step to the approval of a second hemostatic device with substantial development potential to compliment HEMOBLAST Bellows already on the market. Biom'up is thereby strengthening its position in the sector of hemostasis and will thus be able to fulfill the expectations of surgeons providing them with a wider range of ready-to-use hemostatic products. This portfolio of devices will be capable of managing minimal to moderate levels of bleeding and assuring a safer surgical procedure for the patient at rationalized costs.

In addition, the Company announces the renewal, for the next seven years, of its supply agreement for human-derived thrombin, a key component of HEMOBLAST Bellows, only available from a limited number of suppliers. With this new agreement, the Company ensures an adequate supply of its key component to meet its goals.

Etienne Binant, Chief Executive Officer of Biom'up, commented: *"The achievement of these two major milestones ensures that we have an ongoing capacity to deliver our flagship product, HEMOBLAST Bellows, and expand our portfolio of hemostatic products towards a diversified hold in this sector. It illustrates our determination to meet our strategic goals."*

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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.

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 in October 2017.

Since then, the Company carried out a €16 million capital increase in February 2018 and a €7.67 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 US fund specializing in innovative companies in the healthcare sector, in March 2018.

About HEMOBLAST

HEMOBLAST Bellows is a hemostatic product to control bleeding in a broad range of surgical procedures, such as cardiac surgery, general surgery, and orthopedic surgery, etc.. Biom'up conducted a successful clinical trial in the United States with 412 patients admitted to cardio-thoracic, abdominal or orthopedic (lower limb) surgeries which met all of its primary and secondary endpoints. Given the compelling preliminary results (93 % effectiveness at 6 minutes, compared with 74 % for the control arm), the Independent Data Monitoring Committee (IDMC) unanimously recommended to stop the study before the initially planned date after an interim analysis of the data, which allowed the company to



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accelerate the submission of its filing for premarket approval (PMA) to regulatory authorities in June 2017 for the United States.

After obtaining expedited FDA approval for HEMOBLAST Bellows in December 2017, 7 months ahead of original plan, Biom'up's efforts are focused on industrial and commercial activities and the recruitment of sales and marketing teams in the U.S. to prepare the planned commercial roll-out of our lead product in the United States.

On July 12, 2018, Biom'up obtained CE Marking for its HEMOBLAST Bellows Laparoscopic Applicator designed to deliver the HEMOBLAST Bellows powder in minimally-invasive procedures. This has opened the way for the Company in a new market segment representing approximately 500,000 surgeries per year in Europe. In addition, on July 2, 2018 the Company filed a PMA supplement to obtain approval for HEMOBLAST Bellows for all laparoscopic surgical procedures in the United States.