

Biom'up granted FDA IDE approval for HEMOSNOW™

Saint-Priest, France, April 24, 2019 - 8h00 (CET) - Biom'up (the « **Company** »), specializing in surgical hemostasis, announced today that the U.S. Food and Drug Administration (FDA) approved the IDE (Investigational Device Exemption) application for HEMOSNOW, a hemostatic dry powder made from porcine collagen and bovine-derived chondroitin sulfate developed by the Company for managing minimal and mild levels of bleeding during surgical procedures. The Company initially submitted the IDE application to FDA for HEMOSNOW in January 2019.

This approval demonstrates once again Biom'up's ability to meet all IDE requirements set by the U.S. regulatory process.

HEMOSNOW will complement Biom'up's flagship product, HEMOBLAST™ Bellows, as a hemostatic solution for use in minimal (oozing) to mild (pooling) bleeding. HEMOSNOW contains the same components as HEMOBLAST Bellows, but without human pooled plasma thrombin. It will thus be available at a lower cost and targeted at less severe bleedings. HEMOSNOW uses the exact same applicator system as HEMOBLAST Bellows, making it ready for use on focal bleeding sites as well as bleeding surfaces of up to 50 square centimeters per bellows.

*«The approval of the IDE application for HEMOSNOW by the FDA represents another significant milestone in Biom'up's portfolio expansion, potentially providing surgeons with a wider range of ready-to-use hemostatic products once it is approved » declared **Etienne Binant, Chief Executive Officer of Biom'up**, « We are now preparing the start of the clinical testing required to obtain marketing approval in the U.S, which we expect in 2020.»*

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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 the surgeons practices for open surgical procedures in numerous specialties such as cardiac, general and orthopedic as well as in laparoscopic surgeries. The Company's lead product, HEMOBLAST™ Bellows and its laparoscopic applicator are marketed in Europe and the United States.

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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 Bellows

HEMOBLAST Bellows is a hemostatic product designed to control bleeding in a broad range of open surgical procedures, such as cardiac, general and orthopedic surgeries, as well as in laparoscopic surgeries.

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. On the basis of compelling preliminary results (93% effectiveness at 6 minutes, compared with 74% for the control arm) in a major clinical trial, 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 the 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 US 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 second half of 2019.