Biom'up obtains CE Mark for its HEMOBLAST™ Bellows Laparoscopic Applicator

- **An additional device designed to deliver the HEMOBLAST Bellows powder in minimally-invasive procedures**
- **Biom'up ready to address a new European market segment where traditional hemostatic products are generally difficult to use or unusable**
- **Yet another important milestone enabling Biom'up to address a new market of approximately 500,000 surgeries per year in Europe**

Saint-Priest (France), July 12, 2018, 8:00 a.m. (CET) – Biom'up (the "**Company**"), specialist of surgical hemostasis, today announces having obtained CE Mark for its Laparoscopic Applicator and thus extends its indications by enabling European surgeons to use HEMOBLAST Bellows hemostatic powder for both open and laparoscopic surgery, while continuing to benefit from the same advantages in terms of efficacy, simplicity and rapidity. This CE Mark attests to the conformity of the device with the essential health and safety requirements laid down by the applicable European regulations and attests that it has followed the appropriate conformity assessment procedures.

The HEMOBLAST Bellows Laparoscopic Applicator is designed to deliver the HEMOBLAST Bellows hemostatic powder in cases of surgical bleeding through a trocar with a diameter of at least 5 mm. The 35 cm polycarbonate accessory is compatible with the existing HEMOBLAST Bellows applicator, already with CE Mark.

HEMOBLAST Bellows is additionally indicated for hemostasis when the control of minimal, minor and moderate bleeding in classical procedures is ineffective or impossible during laparoscopic procedures for the following specialties: vascular, abdominal, urology, gynecology, head and neck surgery (excluding ophthalmic and neurosurgical procedures).

The laparoscopy market is significant in the United States and Europe, with nearly 443,000 and 500,000 surgeries per year respectively[1]. Use of hemostatic products in this market remains however limited, notably due to the impact of traditional products on visibility in the surgical area and the difficulty of introducing them

[1] Global Data, DNA Ink, Company.

through trocars. HEMOBLAST Bellows, a hemostatic powder, is designed to overcome these obstacles by facilitating precision handling through its laparoscopic applicator.

As a reminder, HEMOBLAST Bellows, Biom'up's flagship product, obtained its CE Mark in December 2016 and its PMA (*Pre-Market Approval*) application was granted by the US FDA (*Food & Drug Administration*) in December 2017.

In addition, the Company filed a PMA (Pre-Market Approval) supplement on July 2, 2018, dedicated to obtaining approval for HEMOBLAST Bellows for all laparoscopic surgical procedures in the United States.

Etienne Binant, Chief Executive Officer, commented: "*We are very pleased to be able to announce today this CE Mark for our HEMOBLAST™ Bellows Laparoscopic Applicator, an important accessory which will further extend the use of our flagship product to laparoscopic surgery. This market potential for our product is significant as it is under-explored by existing technologies. It is thus with satisfaction that we are preparing to make this additional option available to surgeons and their patients in Europe. I would like to congratulate all our European regulatory teams for achieving this key milestone within a very short timeframe, illustrating our regulatory environment expertise*".

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About HEMOBLAST

Biom'up obtained FDA approval for HEMOBLAST Bellows in December 2017. The expedited approval arrived 7 months ahead of original plan, and led to a focus on industrial activities, as well as the recruitment of sales and marketing teams in the U.S. to prepare the mid-2018 commercial roll-out of our lead product in Europe and the U.S.

HEMOBLAST Bellows is an advanced hemostatic product to control bleeding in a broad range of surgical procedures, such as cardiac surgery, general surgery, and orthopedic surgery. Biom'up conducted a successful clinical trial in 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 after an interim analysis of the data, which allowed the company to accelerate the submission of its filing for premarket approval (PMA) to US regulatory authorities in June 2017.

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. Its flagship product, HEMOBLAST Bellows, is a unique hemostatic solution, ready to use (no preparation time needed, no need to mix, no heat required), usable once or several times during the surgery and offering unique efficacy features. Developed by a world-renowned scientific team, HEMOBLAST Bellows has obtained positive results for all the primary and secondary endpoints of Phase III of its pivotal study involving 412 patients in the United States. HEMOBLAST Bellows obtained its CE Mark in December 2016, and its PMA (Pre-Market Approval) application was granted by the FDA (Food & Drug Administration) in December 2017 with a view to the commercial launch in the United States in the summer of 2018. 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. In addition, the Company concluded a €16 million capital increase by means of a public offering without preferential subscription rights in February 2018 and in April 2018, concluded a €25 million bond with Athyrium Opportunities III Acquisition LP, a US fund specializing in innovative companies in the healthcare sector.