

Biom'up announces completion of the 2018 scale-up of its manufacturing facility to meet commercial demand for HEMOBLAST™ Bellows

- **2018 scale-up of Biom'up's manufacturing facility near Lyon (France) completed, allowing for a larger throughput and increased shipments of devices to the US and EU markets**
- **Six key manufacturing processes upgraded, thoroughly reviewed and approved by the FDA and EMA; a strong validation of the Company capability to efficiently execute a comprehensive and demanding regulatory plan**
- **Biom'up reaches a new important milestone in its growth strategy and continues to execute in line with commitments made at IPO**

Saint-Priest (France), November 08, 2018, 8:00 am (Paris time) – Biom'up (the “Company”), a specialist in surgical hemostasis, announces today the completion of the 2018 scale-up of its manufacturing facility to meet commercial demand for HEMOBLAST™ Bellows, in the US and selected national markets in the EU.

Approved in Europe in December of 2016, HEMOBLAST Bellows received US Food and Drug Administration (FDA) approval in December 2017, 7 months prior to the anticipated approval date. It was made available to a limited number of hospitals in France and Germany in 2018 and launched onto the US market in July of the same year with a list price of \$270.

To meet the encouraging market demand, the Company efficiently executed a rigorous scale-up of its manufacturing facility in France, including upgrading and fully validating 6 key internal and outsourced processes allowing for a much larger throughput and increased shipments of devices to the US and EU markets.

As a consequence, the Company's product output grew to more than 4,000 units of HEMOBLAST Bellows in October 2018. This number is expected to grow to 7,000 units per month by H1 2019, fulfilling the Company's production commitment to investors made at the time of their IPO in October 2017.

PRESS RELEASE

All updated processes were thoroughly reviewed and ultimately approved by the FDA and the European Medicines Agency (EMA), allowing for the release of the products manufactured under said upgraded processes to the US and EU markets.

Philip Corcoran, M.D., surgeon at Johns Hopkins Community Physicians and one of the area's "Top Doctors" in cardiovascular and thoracic surgery according to Washingtonian magazine, said: "As one of the surgeons involved in the pivotal clinical trial that led to HEMOBLAST Bellows approval in the US market in December 2017, I am excited that Biom'up has now fully launched this hemostat onto the US market. Requiring almost no preparation time, effective in just minutes, and the sole hemostat approved for up to and including moderate bleeding, HEMOBLAST Bellows is a dramatic change in how surgeons will manage bleeding in the operating room."

Etienne Binant, Chief Executive Officer, commented: "This is a watershed moment in the history of Biom'up. The increased availability of HEMOBLAST Bellows, in line with the business plan communicated at time of the IPO, demonstrates the Company's ability to execute a comprehensive and demanding plan, including meeting manufacturing, human resources, regulatory and financial challenges quickly and successfully. For this, my gratitude and congratulations go to the entire Biom'up staff and, in particular, to our Manufacturing, Industrialization and Quality teams who invested so much time and energy to ensure as many devices as possible could be provided quickly to patients and surgeons in the US and EU."

Contacts

Biom'up

Chief Financial Officer
Jean-Yves Quentel
investisseurs@biomup.com
+33 4 86 57 36 10

MC Services AG

International Investor and Public Relations
Anne Hennecke
anne.hennecke@mc-services.eu
+49 211 529252-22

Alizé RP

Investor Relations
Caroline Carmagnol
biomup@alizerp.com
+33 6 64 18 99 59

About HEMOBLAST

HEMOBLAST Bellows is an innovative hemostatic product to control bleeding in a broad range of surgical procedures, such as cardiac surgery, general surgery, and orthopedic surgery. The product is available in select European markets and was approved in the United States in December 2017, seven months prior to the anticipated approval date. The early FDA approval was based on Biom'up's 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

PRESS RELEASE

before the initially planned date after an interim analysis of the data. This allowed the Company to accelerate the submission of its filing for premarket approval (PMA) to regulatory authorities in June 2017.

After obtaining FDA approval Biom'up's efforts have been focused on industrial and commercial activities including the recruitment of sales and marketing teams in the US to prepare the commercial roll-out of the Company's lead product in the United States.

On July 12, 2018, Biom'up also 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 annually 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 also in the United States.

About Biom'up

Founded in 2005 and based in the Lyon suburb of Saint-Priest (France), Biom'up designs innovative 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. This was followed by a €16 million capital increase in February 2018 and a €25 million bond financing agreement with Athyrium, a US fund specializing in innovative companies in the healthcare sector in March 2018.

Forward looking statement

This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.