Biom’up announces first sales of HEMOBLAST™ Bellows in the United States and the nomination to its board of directors of an independent director and an observer to support the company’s growth

- The first batch of HEMOBLAST Bellows was shipped to the United States in June, offering a test run for the entire supply chain and customs for its flagship product
- A first supply agreement was signed with the UCLA Medical Center, a leading hospital in the Los Angeles area
- Master agreements are in the process of being negotiated with more than 75 hospitals throughout the United States
- The first deliveries to hospitals were made on July 2
- On July 2 the company filed a supplement to obtain FDA approval for HEMOBLAST Bellows for use in laparoscopic surgery
- An independent director and a non-voting observer are appointed at the company’s board of directors to support its development in North America

Saint-Priest (France), July 3, 2018, 8:00 am (Paris time) – Biom’up (the “Company”), specialist of surgical hemostasis, announces today its first commercial results in the North American market, early proof points of the strength of its US sales infrastructure.

A first shipment of its flagship product HEMOBLAST Bellows from the Company’s French production site in Saint-Priest to the Company’s central logistic hub in the US in June confirmed that the supply chain is operational, reliable and fully compliant with US regulations.

The UCLA Medical Center, a leading Los Angeles hospital, has already signed a supply agreement with Biom’up for HEMOBLAST Bellows. Medico-economic evaluations are currently being performed by Value Analysis Committees at more than 75 hospitals throughout North America.

The first commercial delivery of HEMOBLAST Bellows to a leading hospital in the south of the United States was made on July 2, 2018, confirming the Company’s plans for a product launch in the 2018 third quarter.
Finally, the Company announces the filing of a PMA (Pre-Market Approval) supplement on July 2, 2018, dedicated to obtaining approval for HEMOBLAST Bellows for all laparoscopic surgical procedures. The Company expects a response from the FDA within six months, in accordance with applicable laws.

In the wake of these announcements, and to strengthen its focus on the US market, Biom’up has reinforced its Board of directors by the addition of Ms. Caroline Lang as independent director and Ms. Janice Hogan as non-voting observer (censeur). Through their personal and professional qualities and wide-ranging expertise, Ms. Lang and Ms. Hogan will further strengthen Biom’up’s international development.

Ms. Lang will replace Mr. Laurent Higueret and Ms. Hogan will occupy the position of non-voting observer previously held by Mr. Thibaut Roulon as representative of Bpifrance Investissement. Biom’up expresses particular thanks to both for their years of collaboration and their valuable contributions to the Company’s strategic development.

Ms. Lang holds a Master – JD in Public Law and is pursuing an international career in sales and distribution. Senior Vice President and Managing Director at Warner Bros. International Television Distribution Inc. since 2010, Ms. Lang has occupied a number of senior positions at Warner Bros after previously working for Time Warner and the Maxwell-MacMillan Publishing Company in New-York. As a lawyer and talented negotiator with extensive management experience and knowledge of US companies, Ms. Lang will contribute to Biom’up’s expansion in North America.

Ms. Hogan holds an engineering degree from MIT. She has been working extensively in the pharmaceutical industry and has been involved in medical technology for over 25 years. A widely recognized leader in FDA regulation of devices, Ms. Hogan is today a partner of Hogan Lovells based in their Philadelphia and Washington, D.C. offices, where she leverages her technical background to help companies with cutting-edge technologies navigate and optimize the FDA approval process. As non-voting observer she will contribute her cross-cutting experience in the fields of technology, law and health.

Etienne Binant, Chief Executive Officer, commented: “The initial expressions of demand for HEMOBLAST Bellows are very encouraging and I congratulate the local sales and marketing teams led by David Clark and Steve Ford for their significant efforts in setting up our sales infrastructure in the United States. With a complete supply chain in place, we are now in an excellent position to meet this demand. Our company is fully focused on this challenge. This also applies to the Board which is continuing to reinforce its international profile. I express my sincerest gratitude to Mr. Laurent Higueret as director and Mr. Thibaut Roulon, representative of Bpifrance Investissement as non-voting observer, for their contributions over their years of service and I am proud to now welcome Ms. Caroline Lang and Ms. Janice Hogan who I am certain will provide us with valuable advice in this next phase of the Company’s development.”

Contacts

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

NewCap
EU Investor Relations
Tristan Roquet Montégon
biomup@newcap.eu
+33 1 44 71 00 16

LifeSci Advisors
US Investor Relations
Hans Herklots
hherklots@lifesciadvisors.com
+41 79 598 7149

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 pre-market approval (PMA) to 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.