



## **Biom'up announces a first distribution agreement in Europe and the filing of a reimbursement dossier with Australian health authorities**

- **The Company signed a first exclusive distribution agreement in Europe with Spain's Palex Medical SA, a leading distributor of medical devices. A first shipment to Spain is expected at the end of 2018 with an official market launch scheduled in Q1 of 2019.**
- **In Australia, the Company filed a reimbursement dossier for HEMOBLAST™ Bellows in the Prostheses list. Feedback from the Australian health regulators is expected in H1 2019.**

**Saint-Priest (France), October 16, 2018, 8:00 am (Paris time)** – Biom'up (the “Company”), a specialist in surgical hemostasis, announces today the coming availability of its leading product, HEMOBLAST™ Bellows, in Spain, as well as the achievement of a key milestone towards its introduction and reimbursement in the important Australian market.

The Company has signed the first distribution agreement ever for HEMOBLAST Bellows to cover the key Spanish market, in exclusivity with Palex Medical, a leading medical device distributor in the Iberian Peninsula. Based in Barcelona and Madrid, Palex, through its comprehensive sales network covering Spain's main hospitals, will allow the use of HEMOBLAST Bellows in a wide range of surgical procedures, such as cardiac surgery, general and abdominal surgery and orthopedic surgery. After market tests earlier this year, the first shipment is due at the end of 2018 and the official market launch is expected in the first quarter of 2019. The Spanish market for topical hemostats is one of the largest in the European Union, estimated to have reached €75m and growing at 5% annually (source: Grand View Research), making this agreement an important commercial breakthrough for the company.

Biom'up is also making substantial progress in Australia where the company has submitted a reimbursement dossier for HEMOBLAST Bellows in the Prostheses list. This dossier comes in addition to the regulatory submission for approval of the product, which was initially filed on March 15<sup>th</sup>, 2018. The final decision of the Australian authorities is expected in the first half of 2019. To prepare for the launch of HEMOBLAST Bellows in the Australian market, the Company is already in advanced negotiations with one of the leading independent medical device distributors in the country.

Australia has a well-established use of hemostatic devices, with a market for hemostats forecasted to reach US\$ 50 m in 2020, with an annual growth of 7% (source: Grand View Research). Alongside Japan, Australia is one of the few markets in the world where hemostatic products used in surgery are reimbursed, giving patients and healthcare providers better access to these technologies.

**Etienne Binant, Chief Executive Officer, commented:** *“The entire Biom’up team continues to remain focused on bringing our flagship product, HEMOBLAST™ Bellows, to market. Spain being one of our top targets in Europe, we are honored to have been able to partner with Palex Medical, a major distributor of medical devices to hospitals in the Iberian markets and one of the most experienced companies of its kind. This, together with the recent filings in Australia and continued progress in the US, demonstrates that we continue to lay the foundations for the long-term commercial development of HEMOBLAST Bellows.”*

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## 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 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 et commercial activities and the recruitment of sales and marketing teams in the U.S. to prepare the commercial roll-out of our lead product in the United States planned for the 2018 third quarter.

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.

## **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. This has been 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.