Press Release
For immediate release

Biom’Up: a first clinical study demonstrates the potential of COVATM+ CARD membrane in pediatric cardiology & heart surgery

- This collagen membrane forms a resorbable barrier to provide the guided healing of organs and tissues along distinct anatomical planes
- The clinical study that included 36 patients demonstrates the good tolerance of the membrane and its benefit for the patient: no severe adherence was observed, contrary to the usual practice
- These results have been reviewed and published in “Archives of Cardiovascular Diseases”, the official review of the French Society of Cardiology

Lyon, France, December 02, 2013 - Biom’Up, a specialist manufacturer of absorbable medical implants, today announces the results of a first clinical study in pediatric cardiac surgery. The study aims to evaluate the use of COVATM+, a collagen membrane that prevents the formation of postoperative adherences, these anarchistic fibroses or wound healings, by maintaining anatomical and physiological plans.

The membrane developed by Biom' Up acts like a biocompatible barrier between the heart and other tissues, guiding the tissue healing. Naturally resorbable, this new membrane allows surer and simpler re-interventions, in particular on these pediatric patients who often are subject to iterative surgeries.

This clinical study led in the children who had an initial cardiac intervention using the collagen membrane COVATM (group 1) was managed by Dr. Roland HENAINE (Hospices Civils de Lyon, Inserm U1060) between January 2010 and December 2011. This group was compared to other patients not treated with a membrane (group 2).

Thus, 36 patients (the mean age of the patients at the time of the first intervention was 13.8 months) with congenital cardiopathy received a collagen membrane and were selected in-group 1. Nineteen re-interventions were undertaken within a mean delay of 169 days. Neither severe adhesions nor troubles in tolerability of the membrane were observed in the group 1 treated with COVA™+. For the re-interventions after 30 days, the durations of dissection and intervention were respectively of 34 and 160 minutes against 39 and 171 minutes in-group 2.

This feasibility study shows the potential of the new membrane in a pediatric population as well as in
regard to the prevention of severe adhesions as of the tolerance. The complete results of this first study are published in “Archives of Cardiovascular Diseases”, the official review of the French Society of Cardiology. (1)

Patricia FOREST, Chief Scientific Officer and Deputy CEO of Biom’Up declared: “We are very proud of these first results in pediatric cardiac surgery, a field where the needs are unfortunately significant in comparison with the frequency of the re-interventions for treating congenital cardiopathies. Representing more than 1% of the births, these malformations are extremely diversify, from the simple benign anomaly up to severe forms engaging the survival of the newborn or the psychomotor development of the child. Our COVA™+ membrane, already used for several years in the cardio-thoracic field, has shown once again its potential and its benefit for the patients but also for the surgical community thanks to a simplicity and an increased security of its pratices”.

The medical device COVA™, dedicated to the preservation of cleavage planes and the prevention of adhesions, is marketed since 2009 and obtained its first FDA clearance in 2011. The Company intends to launch an exploratory controlled study to confirm the superiority of COVA™, in the field of the pediatric surgery on the usual therapeutic strategies. The COVA™ technology was developed in collaboration with the Department of Cardiovascular Surgery of Assistance Publique - Hôpitaux de Paris, Hôpital Européen Georges Pompidou and the INSERM unit U 633 (Paris, France - Prof. Menasché and Dr. A Bel).

Preclinical results of performance were in particular published in the review the “Interactive CardioVascular and Thoracic Surgery” (ICVTS). (2) (3)


About Biom’Up

Since its inception in 2005, Biom’Up is specialized in the development of innovative implantable devices for various surgical applications, from nervous regeneration to cardio-thoracic surgery. Expert of biomaterials and the processing of the resorbable biopolymers as collagen, Biom’Up markets a complete range of innovating “bio surgery” (COVA™, MATRIBLE™, HEMOSNOW™ and COVAMESH™) to improve of medical treatments and reinforce patient wellbeing by decreasing post-operative continuations.
Directed by Sylvain Picot and Dr. Patricia Forest, Biom' Up is based in Saint-Priest (France, Rhône). The Company employs 40 people.

For more information: www.biomup.com

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