Innovative back microsurgery

Press release

VEXIM to Initiate Clinical Study to Support Planned 510(k) Application to Market SpineJack® in the United States

Safety and effectiveness of SpineJack® will be compared with balloon kyphoplasty in 150 patients in Europe

Toulouse, October 13th, 2014 - VEXIM (FR0011072602 – ALVXM / Eligible PEA-PME), a medical device company specializing in the minimally invasive treatment of vertebral fractures, today announced it will initiate a new clinical study that will support its planned application for 510(k) regulatory clearance to market SpineJack® in the U.S. The Company expects to complete the study in 2 years' time in support of a 510(k) submission in 2017.

Following recent and ongoing discussions with the U.S. Food and Drug Administration, the Company will conduct a prospective multicenter, randomized study that will compare the safety and effectiveness at one year follow-up of the New Generation SpineJack® device with Medtronic's balloon on 150 patients suffering from vertebral compression fractures due to osteoporosis.

Based on existing clinical data and the positive preliminary results of VEXIM's comparative study currently taking place in Europe (cf. press release of September 30th, 2014), the company presented the current study design to FDA and sought FDA feedback on the design, sample size, and duration. In combination with the previously collected clinical data, FDA concurred that the new study conducted on 150 patients solely in Europe is appropriate to support 510(k) clearance, streamlining the study initiation and execution, as well as reducing the cost to the Company. VEXIM already has selected five European centers to treat with SpineJack® and those surgeons are expected to begin patient recruitment in the first quarter of 2015.

Vincent Gardès, VEXIM's CEO, stated: *"Our discussions with the FDA have enabled us to make meaningful progress toward driving VEXIM's future growth and development, as it relates to targeting the United States, which is the world's largest market for vertebroplasty and kyphoplasty. Based on the excellent results obtained in clinical studies to date with SpineJack®, particularly as evidenced by the 30 patients suffering from osteoporosis whose success we recently reported, we are fully confident in achieving a positive outcome from this new study, which once completed, will support our application for clearance to market our device in the U.S. Furthermore, the fact that we will follow a 510(k) pathway, rather than PMA, combined with the possibility of only conducting the study in Europe, makes its timetable and cost very attractive for VEXIM."*

2014 provisional financial reporting schedule*:
2014 annual sales: January 19th, 2015
**Indicative date, subject to potential modifications*

About VEXIM, the innovative back microsurgery specialist

Based in Balma, near Toulouse (France), VEXIM is a medical device company created in 2006 that specializes in creating and marketing minimally invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of longstanding shareholders, Truffle Capital and Banexi Venture, and OSEO public subsidies, VEXIM has designed and developed the SpineJack®, a unique implant capable of repairing a fractured vertebra and restoring the balance of the spinal column. The Company has its own sales teams in France, Germany, Italy, Spain, Switzerland and the United Kingdom, as well as distributors in Argentina, India, Taiwan, Belgium, South Africa, Colombia, Panama, Venezuela, Chile and Ecuador and in the following countries where the product is currently being registered: Mexico, Brazil and Peru. VEXIM has been listed on NYSE Alternext Paris since May 2012. For further information, please go to www.vexim.com

SpineJack®[1] implant for treating Vertebral Compression Fractures

An important advantage of SpineJack® lies in its ability to restore a fractured vertebra to its original shape, restore the spinal column's optimal anatomy and thus remove pain and enable the patient to recover their functional capabilities. Specialized instruments and guided by X-ray allow the implants into the vertebra to be carried out by minimally invasive surgery in approximately 30 minutes enabling the patient to be discharged shortly after surgery. The SpineJack® range consists of three titanium implants with three different diameters, thus covering 95% of vertebral compression fractures and a wide range of patient morphologies. SpineJack® technology benefits from the support of international scientific experts in the field of spine surgery and worldwide patent protection until 2029. The SpineJack® is an investigational device in the United States and is not available for U.S. sale.

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- **Name:** VEXIM
- **ISIN code:** FR0011072602
- **Ticker:** ALVXM

ELIGIBLE PEA PME

[1] This medical device is a regulated health product that, with regard to these regulations, bears the CE mark. Please refer to the Instructions for Use.