Innovative back microsurgery

Press release

VEXIM Initiates International Clinical Study with First Patient Treated to Support Planned 510(k) Application to Market SpineJack® in the United States

Study will assess the safety and efficacy of SpineJack® compared with balloon kyphoplasty in 160 patients in Europe

Toulouse, 4th June 2015 - VEXIM (FR0011072602 – ALVXM / Eligible PEA-PME), a medical device company specializing in the minimally invasive treatment of vertebral fractures, today announced the initiation of a new clinical study intended to support the Company's application for 510(k) regulatory clearance to market SpineJack® in the U.S.

Based on discussions with the U.S. Food and Drug Administration, Vexim will supplement its regulatory submission for the use of SpineJack® in the U.S. with a prospective European multicentric randomized study that compares the safety and efficacy at one year follow-up of the New Generation SpineJack® device with Medtronic's balloon in 160 patients suffering from vertebral compression fractures due to osteoporosis.

Vincent Gardès, CEO of VEXIM, said: *"The initiation of this clinical study is a significant milestone for Vexim. This is another important step towards the intended commercialization of our Spinejack® technology in the United States. We continue to expect that we will submit a 510(k) application in 2017."*

This comparative study recently received approval from Ethical Committees and Health authorities in each country and is being conducted in 8 European centers. Additional patients are expected to be enrolled over the coming weeks in France, Switzerland, Germany, and Spain.

The study will document and compare improvements in back pain, back function, narcotic medication usage, height restoration and quality of life, as well as safety profiles, in patients with osteoporotic vertebral compression fractures undergoing the SpineJack procedure and Medtronic's balloon kyphoplasty. Patients will be monitored post-implantation and followed up with through 12 months post-surgery.

All radiographic images will be assessed by an independent imaging core laboratory. The assessment of the device condition and performance will be performed by a blinded 2-reader system, with a third reviewer as adjudicator for readings that differ between the two independent reviewers. The reviewers are board-certified, practicing specialist radiologists with no financial interest in the company. The reviewers are blinded to the patient visit interval, treatment group and other reader(s) result.

This results of this study are expected to be included within a 510(k) submission in 2017.

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Upcoming events

About Vexim, the innovative back microsurgery specialist

Based in Balma, near Toulouse (France), Vexim is a medical device company created in February 2006. The Company has specialized in the creation and marketing of minimally-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of it longstanding shareholder, Truffle Capital[1] and from 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 currently has 60 members on its staff. It has its own sales teams in France, Germany, Italy, Spain, Switzerland, the United Kingdom and United States, as well as distributors in Turkey, Argentina, Taiwan, Belgium, Estonia, Poland, Portugal, South Africa, Saudi Arabia, Colombia, Panama, Venezuela, Chile, Peru and Ecuador and in the following countries where the product is currently being registered: Mexico, Brazil. Vexim has been listed on NYSE Alternext Paris since May 2012.
For further information, please visit www.vexim.com

SpineJack®, a revolutionary implant for treating Vertebral Compression Fractures

The revolutionary aspect of the 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. Thanks to a specialized range of instruments, inserting the implants into the vertebra is carried out by minimally-invasive surgery, guided by X-ray, in approximately 30 minutes, enabling the patient to be discharged shortly after surgery. The SpineJack® range consists of 3 titanium implants with 3 different diameters, thus covering 95% of vertebral compression fractures and all patient morphologies.
SpineJack® technology benefits from the support of international scientific experts in the field of spine surgery and worldwide patent protection through to 2029.

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

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[1] Founded in 2001 in Paris, Truffle Capital is a leading independent European private equity firm. It is dedicated to investing in and building technology leaders in the IT, life sciences and energy sectors. Truffle Capital manages €550m via FCPRs and FCPIs, the latter offering tax rebates (funds are blocked during 7 to 10 years). For further information, please visit www.truffle.fr and www.fcpi.fr.