



Innovative back microsurgery

Press release

Vexim Reports Six Month Results of Comparative Study of SpineJack® versus Balloon Kyphoplasty

Study demonstrated SpineJack is highly effective in treating vertebral compression fractures and resulted in:

- *Near-perfect restoration of vertebral height*
- *Greater, faster relief of vertebral pain*
- *Shorter intervention period*

Toulouse, September 30th, 2014 - VEXIM (FR0011072602 – ALVXM / Eligible PEA-PME), a medical device company specializing in the minimally invasive treatment of vertebral fractures, announced today the positive preliminary results at six months of an investigator-initiated study comparing the safety and performances of SpineJack® to the Medtronic balloon in the treatment of vertebral compression fractures in patients with osteoporosis. These two devices are differently composed but achieve the same purpose.

This pilot feasibility study was initiated by Dr. David Noriega, of the Hospital Clinico Universitario in Valladolid, Spain, supported by Vexim and after receiving approval from the hospital's Ethical Committee to treat 30 patients. Of the 30 patients, 15 were treated with SpineJack® and 15 were treated with the Medtronic balloon. Patients were monitored post implantation and results were assessed at six months and will be reassessed at 12 months.

The Company is pleased to report it has confirmed excellent near-term outcomes with SpineJack® compared to the Medtronic balloon at six months post implantation. Patient groups treated with SpineJack achieved:

- Near-perfect restoration of vertebral height (evolution of anterior vertebral angle ratio: pre-op/post op from 71% to 76% for the balloon and from 66% to 82% for SpineJack®), as well as perfect restoration of the physiological angle of the spine (evolution of the treated vertebra angle pre-op/postop: 5.4 degrees for Spinejack® compared to 1.7 degrees for the balloon).
- A strong and rapid decline in pain (92% at 6 months for SpineJack® compared to 81% for the balloon);
- A significantly shorter intervention period (23 minutes) compared with the balloon (32 minutes);
- No serious device-related adverse events, and it was not necessary to re-operate on any of the treated vertebrae.

Doctor David Noriega, Principal Investigator, commented: *“This randomized clinical study which has been realized during the last months has allowed us to confirm the great potential of SpineJack® implant compared to another well-known technique used for balloon kyphoplasty. The results obtained have allowed us to observe a greater fracture reduction capacity in the treated vertebra, as well as an improved segmental angular correction, providing better clinical benefits for the patients. The results*

obtained from patients with osteoporotic compression fractures confirm the results obtained in previous studies on traumatic fractures, increasing the use of this fracture reduction technique. This confirms that the vertebral reduction technique with SpineJack® can be used independently of the quality of the bone”.

2014 provisional financial reporting schedule*:

2014 annual sales: January 19, 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 mini-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of longstanding shareholders, Truffle Capital and Banexi Ventures Partners, 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, Chile, Panama and in the following countries where the product is currently being registered: Mexico, Brazil, Venezuela, Ecuador and Peru. VEXIM has been listed on NYSE Alternext Paris since May 2012. For further information, please go to www.vexim.com

SpineJack®¹ 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. Specialized instruments and guided by X-ray allow the implants into the vertebra to be carried out by mini-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 all patient morphologies. SpineJack® technology benefits from the support of international scientific experts in the field of spine surgery and worldwide patent protection until 2029.

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



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.