Press Release

VEXIM: another major step towards the SpineJack® commercialization in the US

▶ Completion of patient enrollment in the international clinical trial to support 510(k) submission for the SpineJack® in the US.

▶ FDA 510(k) filing is planned by year-end leading to potential US launch in the first half of 2018, a market worth €500 million per year.

▶ This trial evaluates safety & effectiveness of the SpineJack® in comparison with balloon kyphoplasty in 152 patients with vertebral fractures.

Toulouse, February 21st, 2017 (8:00AM CET) – VEXIM (FR0011072602 - ALVXM), a medical device company specializing in the minimally-invasive treatment of vertebral fractures, today announces enrollment completion of its FDA clinical trial.

The VEXIM FDA trial is a European, prospective and randomized multicenter study. It aims to compare safety and efficacy of the SpineJack® vs balloon kyphoplasty on 152 patients with osteoporotic vertebral compression fractures. It is being conducted in 12 centers in Germany, France, Italy, Spain and Switzerland. The study is intended to provide clinical data to support a 510(k) submission in the United States, which is expected to be filed by the end of 2017.

« Vertebral Compression Fractures (VCF) represent a true concern in aging population with more than 1.5 million osteoporotic VCF reported each year globally, » explains Professor David Noriega, one of the study investigators.

« Those fractures are very crippling because patients experience acute and chronic back pain, as well as a progressive deformation of the spine that can lead to additional pathologies. Thanks to its jack mechanism, which is designed to restore vertebra from the inside through a mini invasive surgery, the SpineJack® is intended to provide a quick and efficient way of treating those fractures and to restore spine balance[1]. »

VEXIM's clinical trial compares improvements in terms of back pain, functional and physical capability, quality of life, device safety, analgesic usage and vertebral height restoration, on patients suffering osteoporotic vertebral compression fractures and treated with the SpineJack® and balloon kyphoplasty. Trial's success will be defined by showing the SpineJack®'s non-inferiority to balloon kyphoplasty on a primary endpoint which is a composite measure of pain reduction, maintenance or improvement in function and absence of device related serious adverse event.

[1] D. C. Noriega & R. H. Ramajo & I. S. Lite & B. Toribio & R. Corredera & F. Ardura & A. Krüger (2016) Safety and clinical performance of kyphoplasty and SpineJack® procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study. Osteoporos Int 27:2047-2045. Clinical data on SpineJack® second generation

As of today, all 152 patients planned have been randomized. Half of them within SpineJack® treatment group, the other half in the balloon kyphoplasty group. The finalization of patient enrollment represents an important milestone in the trial's schedule. SpineJack® 510(k) file is planned to be submitted to the FDA[2] before the end of year 2017.

« The finalization of our FDA clinical study enrollment is a key milestone on the path to commercialize the SpineJack® in the United States. We keep our target to submit our 510(k) in 2017 that would lead, subject to FDA clearance, to a SpineJack® commercialization in the US during the first half of 2018. This is also a demonstration of VEXIM's capacity to run a large international trial. In the name of VEXIM, I want to thank warmly all our site investigators and coordinators for their active participation that allowed us to achieve this phase of the trial, » concludes Vincent Gardès, VEXIM's CEO.

Financial reporting schedule:
2016 Full-Year Results: March 22nd, 2017[3]

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[4], 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 and the United Kingdom, as well as distributors in Turkey, Argentina, India and in the following countries where the product is currently being registered: Mexico, Brazil, Colombia, Venezuela, Chile, Ecuador and Peru. VEXIM has been listed on NYSE Alternext Paris since May 3rd 2012. For further information, please visit www.vexim.com

SpineJack®, an innovative implant for treating Vertebral Compression Fractures

The SpineJack® is designed 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, which is intended to enable 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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[2] Food and Drug Administration
[3] Indicative date, subject to changes.
[4] 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.