Innovative back microsurgery

Press release

VEXIM Obtains FDA Approval to Market Masterflow™ Injection System in the United States

Innovative solution for mixing and injecting orthopedic cement enhances accuracy and optimizes each stage of critical process

Toulouse, December 10, 2014 - VEXIM (FR0011072602 - ALVXM / PEA-PME eligible), a medical device company specializing in the minimally invasive treatment of vertebral fractures, today announced that the U.S. Food and Drug Administration (FDA) has approved the marketing in the United States of the Company's innovative Masterflow™ Injection System for mixing and injecting orthopedic cement. This achievement follows nearly two years of development on this innovative system.

The Masterflow™ Injection System is revolutionary in terms of its simplicity, accuracy and control of the injection of ultra-high-viscosity cement to treat vertebral fractures where reducing and stabilizing the fracture is the priority. Combined with VEXIM's Cohesion® Bone Cement, FDA-approved since 2011, this fully integrated system optimizes each stage of the injection process allowing a complete focus on the surgical case:

- precise control of the cement injection with immediate halting of the flow,
- safe and secure technique for the physician and the patient,
- user friendly: enhances clinical performance.

VEXIM acquired an exclusive worldwide license for Masterflow in January 2013. The Masterflow™ technology is protected by international patents granted in the United States, Europe and China.

The Masterflow™ Injection System enables VEXIM to efficiently target the U.S. back trauma market (vertebral augmentation market), which is estimated to total $500 million, or 60% of the global market[1]. VEXIM plans to commence marketing this system through a network of specialized regional sales agents and distributors in the coming weeks and also plans to launch this Masterflow™ Injection System in Europe during the first half of 2015.

Vincent Gardès, CEO of VEXIM, commented: "*Following the establishment of an effective local distribution network via the creation of our U.S. subsidiary staffed with the right leadership, this FDA registration of the Masterflow™ Injection System marks the next milestone in our U.S. strategy that is perfectly suited to this complex market: to quickly break into the vertebral augmentation segment and establish a positive track record and reputation in advance of delivering of our flagship SpineJack® product, the registration of which is in process. Thanks to the Masterflow™ Injection System, we possess an immediately available, innovative solution that can be offered to U.S. patients who suffer from vertebral fractures, thereby laying the groundwork for even broader-based success in the U.S. market in the future.*"

[1] Source: Millennium Research Group 2012 data

About VEXIM, the innovative back microsurgery specialist

Based in Balma, near Toulouse (France), VEXIM is a medical device company created in 2006. The Company has specialized in the creation and marketing of mini-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of its longstanding shareholders, Truffle Capital and Banexi Venture, and from Bpifrance 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 59 staff. It has its own sales teams in France, Germany, Italy, Spain, Switzerland and the United Kingdom, as well as distributors notably 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 Alternext Paris since May 2012.

For further information, please go to www.vexim.com

SpineJack®[2] 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 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. 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
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[2] 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.