Elixir Medical Receives CE Mark Approval for the DESyne® BD Novolimus Eluting Coronary Stent System With Biodegradable Polymer Coating

The Associated Press

SUNNYVALE, Calif.--(BUSINESS WIRE)--Aug 28, 2012--Elixir Medical Corporation, a developer of product platforms that combine state-of-the-art medical devices with advanced pharmaceuticals, announced that it has received CE (Conformité Européenne) Mark approval for its DESyne BD Novolimus Eluting Coronary Stent System for the treatment of coronary artery disease.

“The CE Mark approval validates the impressive clinical results demonstrated with this stent system, including excellent efficacy and no cases of stent thrombosis through the one-year endpoint,” said Alexandre Abizaid, M.D., Ph.D., from the Instituto Dante Pazzanese de Cardiologia in Sao Paulo, Brazil, co-principal investigator for the EXCELLA BD clinical trial. “The combined attributes of lowest polymer load, lowest drug dose, and thin stent struts provides physicians with a state-of-the-art workhorse product that raises the bar for treating patients with coronary artery disease.” The Elixir DESyne BD stent uses a proprietary technology to enable an ultrathin (< 3 microns) polymer coating without the need for an underlying primer layer. The biodegradable, polylactide-based polymer enables the sustained release of Elixir’s novel therapeutic compound, Novolimus, to the coronary vessel wall and degrades within 6-9 months, leaving behind the cobalt chromium alloy metal stent surface to achieve excellent clinical outcomes.

The Elixir DESyne BD Novolimus Eluting Coronary Stent System was evaluated in the EXCELLA BD randomized clinical trial as compared to the control Endeavor Zotarolimus Eluting Coronary Stent System. The study enrolled patients in Europe and Brazil.

At six months, the Elixir DESyne BD stent demonstrated not only non-inferiority ($p<0.001$) but also superiority ($p<0.001$) over the Endeavor stent for the primary endpoint of in-stent late lumen loss (0.12 ± 0.17 vs. 0.67 ± 0.47, $p<0.001$). Similarly, there was a statistical difference in favor of DESyne BD for the secondary end point of binary restenosis (0% vs. 7.9%, $p=0.003$). In a subset of patients who underwent intravascular ultrasound (IVUS) imaging, the findings mirrored the angiographic results demonstrating a statistically significant reduction in percent neointimal obstruction for the DESyne BD stent versus the Endeavor stent ($3.6 \pm4.2\%$ vs. 20.7 ± 14.2, $p<0.001$). Clinical events measured using the device-oriented composite endpoint (DoCE) were low for both DESyne BD and Endeavor (2.7% vs. 3.2%), with DESyne BD sustaining its excellent performance at 12 month follow-up.

“The CE Mark approval for the DESyne BD system is a major milestone for Elixir. It reinforces the excellent safety and effectiveness achieved with the CE Mark approved DESyne system, and positions Elixir as the only company to offer both

durable and biodegradable polymer DES systems," said Motasim Sirhan, chief executive officer of Elixir Medical. "Elixir remains committed to providing interventional cardiologists with the broadest and most innovative product portfolio to advance patient care. Elixir intends to launch the DESyne BD system in a broad range of sizes." About Elixir Medical Elixir Medical Corporation, a privately held company headquartered in Sunnyvale, California, develops products that combine state-of-the-art medical devices with advanced pharmaceuticals to provide innovative treatment solutions to patients worldwide. The company's next-generation drug-eluting stent and bioresorbable scaffold systems are designed to optimize local drug delivery to provide a safe and effective treatment for cardiovascular disease. For more information about the company, its products and clinical data, please visit http://www.elixirmedical.com.

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