Excellent 1-Year Safety and Efficacy Results for the CE-Marked Fully Bioresorbable DESolve Novolimus Eluting Coronary Scaffold System

Business Wire

Elixir Medical Corporation, a developer of products that combine state-of-the-art medical devices with advanced pharmaceuticals, announced excellent one-year results from the DESolve Nx international pivotal clinical trial for the CE Mark-approved, fully bioresorbable DESolve Novolimus Eluting Coronary Scaffold System.

At one year, the DESolve Nx trial demonstrated a low MACE (Major Adverse Cardiac Events) rate of 5.69% with no definite scaffold thrombosis. The results were presented by Stefan Verheye, M.D., Ph.D., ZNA Middleheim Hospital, Antwerp, Belgium, and Co-Principal Investigator of the DESolve Nx Trial at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco. The trial represents one of the largest multi-modality imaging studies in the industry for bioresorbable scaffolds with angiographic, IVUS, OCT, and MSCT follow ups.

Results using MSCT (Multi Slice Coherence Tomography), a noninvasive imaging modality to visualize coronary arteries and the manifestations of coronary artery disease, demonstrated a mean lumen area of 5.5 ± 2.2 mm 2 at one year, maintaining the results that were observed at 6 months using other imaging modalities.

“The 12-month results of the DESolve scaffold demonstrated sustained clinical outcomes at one year, further validating the scaffold as an excellent treatment option for coronary artery disease,” said Dr. Verheye. DESolve Nx pivotal trial enrolled 126 patients at 13 centers in Europe, Brazil and New Zealand. In addition to Quantitative Coronary Angiography (QCA) follow-up on all patients, a subset of 46 patients underwent Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT) imaging at baseline and 6-month follow-up.

At 6 months, Elixir’s DESolve demonstrated excellent mean late lumen loss of 0.21±0.34 mm as measured by QCA. IVUS imaging results demonstrated a statistically significant increase of 9% in the lumen area between post procedure and 6-month follow-up with no late acquired ISA (incomplete scaffold apposition). OCT imaging results demonstrated an impressive 99% strut coverage with a thin and uniform 0.10 mm neointimal layer and confirmed no late acquired ISA.

Successful Live Case follow-up of DESolve Nx patient at 18 months Professor Alexandre Abizaid, M.D., Ph.D., of The Instituto Dante Pazzanese de Cardiologia, Brazil, conducted a successful live case from Sao Paulo of a patient enrolled in the DESolve Nx trial undergoing 18-month follow-up. The angiographic, IVUS, OCT, and MSCT imaging of the coronary vessels treated with the DESolve Scaffold was projected live in the main arena at the 25th TCT conference. The coronary vessels

of the patient were widely patent with substantial scaffold resorption when viewed using the IVUS and OCT imaging modalities. These excellent results were well-received by an expert panel of cardiologists gathered in San Francisco.

“DESolve is the first product to degrade in about one year, demonstrate lumen area increase at six months, and maintain the lumen at 18 months as demonstrated during the live case follow up,” said Dr. Abizaid. “These impressive results can create a paradigm shift in the treatment of patients with cardiovascular disease.” Bioresorbable scaffold technology had thus far been a challenge in the industry because it required a level of strength and support that only permanent metallic stents had been able to provide while resorbing and maintaining excellent clinical outcomes. The DESolve Novolimus Eluting Bioresorbable Coronary Scaffold overcomes these challenges and achieves vascular restoration within six months. DESolve is the first scaffold to achieve this objective at such early time point.

“Elixir is fulfilling its commitment to providing the broadest and most innovative product portfolio for cardiologists to address their patients’ needs,” said Motasim Sirhan, Chief Executive Officer, Elixir Medical. “DESolve holds the promise to transform the interventional cardiology industry by raising the bar in clinical outcomes while leaving nothing behind.” The fully bioresorbable DESolve scaffold, developed from a proprietary and proven poly-L Lactide (PLLA)-based polymer, provides optimal strength and support to the artery while delivering the novel anti-proliferative drug, Novolimus. The unique attributes of the DESolve scaffold system include (a) Its ability to demonstrate lumen area increase at six months demonstrating vascular restoration; (b) its ability to self-appose up to the nominal vessel diameter resolving minor malapposition; (c) its ability to maintain radial strength and vessel support for the necessary period of vessel healing while degrading in about a year and (d) its ability to have a wide margin of expansion.

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