NEWS RELEASE

Elixir Medical Completes Submission of DynamX Coronary Bioadaptor System to Japan's PMDA Agency for Regulatory Approval

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Once approved, the DynamX Coronary Bioadaptor System would become the first percutaneous coronary intervention (PCI) treatment available in Japan to demonstrate restoration of vessel motion and function

MILPITAS, Calif.--(BUSINESS WIRE)-- **Elixir Medical**, a developer of disruptive cardiovascular technologies, announced submission to Japan's Pharmaceutical and Medical Device Agency (PMDA) for the approval of the DynamX® Coronary Bioadaptor System for the treatment of coronary artery disease (CAD).

DynamX coronary bioadaptor was developed to overcome the limitations of drug-eluting stents (DES) and bioresorbable scaffolds (BRS). DynamX is a novel coronary implant designed to unlock the scaffold, uncage the vessel, and provide the essential dynamic support after uncaging to return normal vessel motion and function after percutaneous coronary intervention (PCI). In a randomized controlled trial versus DES, the unique mechanism of action has shown reduced target lesion failure (TLF) rates and restored vessel pulsatility, translating to increased blood flow, improved vessel lumen diameter, and reduced plaque progression.

"Our submission for approval in Japan is an exciting milestone for the company and industry. The DynamX coronary bioadaptor represents a culmination of major design and manufacturing breakthroughs and three clinical trials consistently demonstrating differentiated functional performance compared to the standard of care," said Motasim Sirhan, CEO of Elixir Medical. "Coronary artery disease treatment with stents has seen no major innovation in over 20 years, and we are thrilled to challenge the current standard of care by bringing our technology to physicians and patients around the world."

“Drug-eluting stents (DES) have served an important role in the treatment of coronary artery disease, but have yet to overcome many challenges, including restricting vessel motion and function, mechanical failure, and progression of plaque,” said Shigeru Saito, M.D., director of the Division of Cardiology and Catheterization Laboratory at Shonan Kamakura General Hospital in Kamakura, Japan, and principal investigator of the BIOADAPTOR RCT trial. “What we have seen with the DynamX in the **12-month BIOADAPTOR RCT data** exceeded our expectations against the current standard of care—the Resolute Onyx™ DES—in clinical outcomes, and for the first time ever demonstrated restoration of vessel pulsatility, motion and function by uncaging the vessel while providing the needed support after uncaging. The findings collectively point to a technology standard not seen before that I believe is of great benefit to patients.”

About DynamX® Coronary Bioadaptor System

DynamX coronary bioadaptor is the first coronary implant technology designed to unlock the scaffold, uncage the vessel, and restore sustained normal vessel motion and function after PCI by maintaining dynamic support of the diseased vessel after its uncaging. With this unique mechanism of action (MOA), it addresses the shortcomings of drug-eluting stents and bioresorbable scaffolds (BRS) with remarkably low clinical event rates.

The DynamX Coronary Bioadaptor System is CE marked. Not available for sale in the U.S.

About the BIOADAPTOR RCT Trial

The BIOADAPTOR RCT is an international, single-blinded, randomized controlled (1:1) trial comparing a sirolimus-eluting bioadaptor with a contemporary zotarolimus-eluting stent in 445 patients. Both arms included a large randomized multi-imaging modality subgroup of 100 patients powered to document standard effectiveness benchmarks, and the new effectiveness benchmarks of vessel motion and function. The primary and secondary endpoints were presented at a late breaking trial session at EuroPCR 2023.

The BIOADAPTOR RCT trial is the third trial of Elixir Medical’s robust DynamX bioadaptor clinical evidence program consisting of several clinical trials involving over 9,000 patients, including the INFINITY SWEDEHEART RCT (n=2400) which completed enrollment in July, and a global BIO-RESTORE registry with a target enrollment of up to 5,000 patients.

About Elixir Medical

Elixir Medical Corporation, a privately-held company based in Milpitas, California, develops disruptive platforms to treat coronary and peripheral artery disease. Our technologies have multiple applications across the cardiovascular space capable of delivering improved clinical outcomes for millions of patients. Visit us at **www.elixirmedical.com**

and on **LinkedIn** and X, formerly known as **Twitter**.

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