Abbott Initiates New Intravascular Lithotripsy Clinical Trial To Improve Outcomes In Patients With Coronary Artery Disease

- Coronary Artery Disease (CAD) is the most common heart disease and most frequent cause of death in the U.S., with over 20 million adults affected by this condition
- Abbott's investigational Coronary Intravascular Lithotripsy (IVL) System offers a new potential treatment by using sound pressure waves to treat arterial calcium blockages
- Abbott offers a comprehensive vascular portfolio of technologies designed to assess, treat and manage calcium buildup in coronary arteries

ABBOTT PARK, Ill., March 24, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved an investigational device exemption (IDE) for its Coronary Intravascular Lithotripsy (IVL) System to evaluate the treatment of severe calcification in coronary arteries prior to stenting. The TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) clinical trial will enroll up to 335 people in 47 sites in the U.S.

Coronary Artery Disease (CAD) is the most common heart disease in the U.S., with more than 20 million adults impacted by the condition.[1,2] CAD also remains the single most frequent cause of death in America.[3] CAD develops when plaque builds up in the vessel blocking blood flow and oxygen supply to the heart requiring vessel interventions.

Currently, physicians often use several therapy approaches to clear calcified arterial blockages, including cutting balloons and atherectomy technology. IVL is a newer treatment for calcified coronary arteries that treats blockages by fracturing the calcium within the artery wall, potentially allowing for vessel expansion and better stent placement. Abbott's investigational Coronary IVL System uses high-energy sound pressure waves to treat calcium blockages prior to placing a stent.

"For people living with coronary artery disease, severe calcification can make treatment more challenging, often limiting the effectiveness of standard interventions like angioplasty or stenting," said Eric Secemsky, M.D., director of vascular intervention at the CardioVascular Institute, Beth Israel Deaconess Medical Center in Boston, MA and co-principal investigator for the TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) trial. "The TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) trial will evaluate a possible new treatment option to prepare the vessel prior to stenting and optimize stent placement."

Abbott's investigational Coronary IVL technology builds upon the company's existing vascular portfolio and is designed to address challenges of currently available IVL systems. Today, Abbott's portfolio of treatment solutions includes optical coherence tomography (OCT) imaging technology, which assesses coronary arteries and detects calcium buildup to help physicians identify the arteries that could benefit from plaque modification. The company's advanced technologies are designed to ensure complete vascular support including artery assessment, preparation, and treatment.

"Abbott is a leader in treating coronary artery disease, offering the best diagnostics and therapeutic options for calcium detection and treatment at every stage. Through our expansive portfolio of treatment offerings, we aim to make interventions safer and more effective for people who need them most," said Jennifer Jones-McMeans, Ph.D., divisional vice president of global clinical affairs at Abbott's vascular business. "Now, by working with physicians to evaluate Abbott's Coronary IVL System, we are exploring the next generation of calcium modification technology, advancing our portfolio of treatments for coronary artery disease."

Abbott's Coronary Intravascular Lithotripsy (IVL) system is an investigational device and not commercially available.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries.

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[1] Nowbar, A.N., et al., Mortality From Ischemic Heart Disease. Circ Cardiovasc Qual Outcomes, 2019. 12(6): p. e005375.

[2] Tsao, C.W., et al., Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association. Circulation, 2023. 147(8): p. e93-e621.

[3] Brown JC, Gerhardt TE, Kwon E. Risk factors for coronary artery disease. PubMed. Published January 23, 2023. https://www.ncbi.nlm.nih.gov/books/NBK554410/

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