

ABBOTT ANNOUNCES START OF TRIAL TO EVALUATE THE NEW ESPRIT™ BTK DRUG-ELUTING RESORBABLE SCAFFOLD

- The LIFE-BTK trial will evaluate the company's new drug-eluting resorbable scaffold (DRS), known as the Esprit BTK System, for the treatment of blocked arteries below-the-knee (BTK)
- Esprit BTK was granted breakthrough device designation by the U.S. FDA
- There are no stents or drug-coated balloons currently approved for use below the knee in the U.S.

ABBOTT PARK, Ill., Sept. 3, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the start of the LIFE-BTK clinical trial to evaluate the safety and effectiveness of the company's new Esprit™ BTK Everolimus Eluting Resorbable Scaffold System. This is the first Investigational Device Exemption (IDE) trial in the U.S. to evaluate a fully resorbable device to treat blocked arteries below the knees, or critical limb ischemia (CLI), in people battling advanced stages of peripheral artery disease (PAD). The first patient was enrolled by Danielle Bajakian, M.D., a vascular surgeon at New York-Presbyterian/Columbia University Irving Medical Center.

"Far too many people are impacted by peripheral artery disease, and this new drug-eluting resorbable scaffold is needed to offer meaningful improvements in how this disease is treated," said Nick West, M.D., divisional vice president, Medical Affairs, and chief medical officer in Abbott's vascular business. "Patients treated with balloon angioplasty often require repeat procedures on treated arteries, and therefore a drug-eluting resorbable device is ideally-suited to provide mechanical support for the vessel, reduce the chance of vessel re-narrowing and then gradually disappear over time."

For people with CLI, blocked vessels impair blood flow to the lower extremities, which can lead to severe pain, wounds, and in some cases, limb amputation. Globally, more than 200 million¹ people suffer from PAD, disproportionately affecting people in underserved communities. Worse, up to 40% of patients with CLI currently undergo amputations,² many of which could be prevented by eliminating health care disparities.

Currently, the standard of care for patients battling CLI is balloon angioplasty, which relies on a small balloon delivered via a catheter to the blockage to compress it against the arterial wall, opening the vessel and restoring blood flow. However, blockages treated only with balloon angioplasty have poor short- and long-term results, and in many instances the vessels become blocked again, requiring additional treatment.

There are no drug-eluting stents (DES), drug-coated balloons (DCB) or bare-metal stents (BMS) approved for use below the knee (BTK) in the U.S. With the limited options for BTK, new treatment options are needed. The U.S. Food and Drug Administration (FDA) has granted Esprit BTK breakthrough device designation, which streamlines review and pre-market approval timelines.

Unlike traditional metal stents, Abbott's Esprit BTK System is not a permanent implant; it provides support to an artery immediately after a balloon angioplasty, preventing the vessel from reclosing. Once implanted, the scaffold delivers a drug over a few months that promotes healing and keeps the artery open. The scaffold is naturally resorbed into the body over time, like dissolving sutures, and ultimately leaves only a healed artery behind. Abbott is a pioneer in bioresorbable scaffolds. Long-term clinical data from a meta-analysis of randomized Absorb trials suggested that bioresorbable scaffolds might be an acceptable alternative to metallic DES for many patients with coronary artery disease.³

"After a five-year feasibility study in assessing treatment of arteries below the knee with a different version of this technology, the outcomes suggest resorbable devices have significant potential to become the favored therapy for CLI patients," said Ramon Varcoe, MBBS MS FRACS Ph.D., University New South Wales, Sydney, Australia, and one of the principal investigators in the trial. "This technology offers the best of both worlds. The device provides a strong scaffold structure and delivers antiproliferative drugs, then disappears and is not an impediment for future interventions, surgery or imaging."

Once fully enrolled, the LIFE-BTK trial will evaluate the Esprit BTK resorbable scaffold in 225 patients at centers around the world. The study is the first of its kind and an evolution of prior studies examining resorbable technology in treating diseased vessels and blocked arteries.

About the LIFE-BTK Trial

The LIFE-BTK trial is the first Investigational Device Exemption trial in the U.S. to evaluate a fully dissolvable device to treat critical limb ischemia in people battling advanced stages of peripheral artery disease (PAD). To date, the trial has sites in Australia, Japan, New Zealand, Singapore and the United States.

The LIFE-BTK trial is a prospective, randomized controlled clinical trial comparing Esprit BTK to Percutaneous Transluminal Angioplasty (PTA). The study objective is to evaluate the safety and efficacy in CLI patients with up to two lesions in separate infrapopliteal vessels, one of three types of vessels found below the knee and the type most commonly affected by CLI.

The trial will be led by principal investigators Brian DeRubertis, M.D. (vascular surgeon, UCLA), Sahil Parikh M.D., (interventional cardiologist, New York-Presbyterian/Columbia University Irving Medical Center, who serves on the medical advisory board for Abbott's vascular division), and Ramon Varcoe MBBS MS FRACS Ph.D., (University New South Wales, Sydney, Australia).

About the Esprit BTK System

The Esprit BTK System consists of a thin strutted scaffold which measures 99 microns made from poly-L-lactide (PLLA), a semi-crystalline bioresorbable polymer engineered to resist vessel recoil and provide a platform for drug delivery. The scaffold is uniformly coated with poly-D, L-lactide (PDLLA) and the cytostatic drug, everolimus. PDLLA is an amorphous bioresorbable polymer coating designed to allow controlled drug release. The controlled release of everolimus, a drug that acts to retard cell proliferation, reduces scar tissue growth in the affected area, which can cause vessel blockage. The Esprit BTK System is an investigational device only in the U.S.

About Critical Limb Ischemia

Critical limb ischemia is a severe form of PAD that is characterized by chronic pain, even at rest, as well as ulcers and gangrene (tissue death) that develop as a result of chronically poor blood flow to the lower limbs. The most common endovascular treatment of below-the-knee arteries is balloon angioplasty, which opens narrowed arteries with a catheter-guided balloon. For some patients, surgical bypass procedures are performed. If left untreated, the disease can eventually lead to amputation and limb loss.

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 107,000 colleagues serve people in more than 160 countries.

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¹ Fowkes, Lancet 2013; 382: 1329-40

² <https://www.amputee-coalition.org/resources/limb-loss-statistics/>

³ JAMA Cardiol 2019 Dec 1;4(12):1261-1269. doi: 10.1001/jamacardio.2019.4101.

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For further information: Abbott Media, Alicia Swanson, (669) 210-7204; Abbott Financial, Mike Comilla, (224) 668-1872

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