Abbott's Breakthrough Dissolving Stent Receives FDA Approval For Arteries Below The Knee

- More than 20 million people in the U.S. are living with peripheral artery disease (PAD) yet there have been limited treatment options
- The first-of-its-kind Esprit™ BTK Everolimus Eluting Resorbable Scaffold dissolves over time after it has opened blocked arteries below the knee (BTK)
- The Esprit BTK System is a dissolving stent that offers the possibility of better outcomes for people with the most severe form of PAD

ABBOTT PARK, Ill., April 29, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit BTK System), a breakthrough innovation for people with chronic limb-threatening ischemia (CLTI) below-the-knee (BTK). The Esprit BTK System is designed to keep arteries open and deliver a drug (Everolimus) to support vessel healing prior to completely dissolving.

Until today, there were no stents or drug-coated balloons approved for use below the knee in the U.S. The standard of care has been 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.

The Esprit BTK System is a first-of-its-kind dissolvable stent and is comprised of material similar to dissolving sutures. The device is implanted during a catheter-based minimally invasive procedure via a small incision in the leg. Once the blockage is open, the Esprit BTK scaffold helps heal the vessel and provides support for approximately three years until the vessel is strong enough to remain open on its own.

"The FDA approval of Abbott's Esprit BTK System marks a significant milestone in our fight against peripheral artery disease below the knee and should usher in a new era of improved outcomes for people worldwide," said Sahil A. Parikh, M.D., Columbia University Irving Medical Center, and one of the principal investigators of the LIFE-BTK trial. "By introducing a treatment option that is superior to balloon angioplasty, Abbott is changing the landscape of CLTI therapy."

The LIFE-BTK trial, which evaluated Abbott's Esprit BTK System, was presented inOctober 2023 as a late-breaking clinical trial at the 35th Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco and simultaneously published in the *New England Journal of Medicine*. The results of the trial demonstrated that the Esprit BTK System reduces disease progression and helps improve medical outcomes compared to balloon angioplasty, the current standard of care.

PAD is highly prevalent, yet many people have never heard of the condition. More than 20 million people in the U.S. are living with this painful disease and only 10% of those people have been diagnosed.[1,2] CLTI is a serious form of PAD that occurs when arteries become clogged with plaque, preventing blood flow and oxygen from reaching the lower leg and foot. People living with CLTI often experience extreme pain, open wounds that don't heal and, in some cases, may have to resort to amputation. Over a five-year period, CLTI has a lower survival rate than breast, colorectal and prostate cancer combined.[3]

"At Abbott, we've recognized the significant burden of disease and limited treatment options available for people living with the most severe form of PAD. That's why we're revolutionizing treatments with resorbable scaffold technology below the knee," said Julie Tyler, senior vice president of Abbott's vascular business. "Our resorbable program is focused on meeting unmet needs in the peripheral anatomy to help people live better and fuller lives."

As part of Abbott's continued commitment to helping all people live healthier lives, PAD and CLTI education information can be found at www.PAD-info.com. Physicians can find more information atwww.CLEAR.abbott.

For U.S. important safety information on Esprit BTK System, visit: https://www.cardiovascular.abbott/us/en/hcp/products/peripheral-intervention/esprit-btk-resorbable-scaffold-system/important-safety-information.html.

About Abbott
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[1] Fowkes, F.G., et al., Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet, 2013. 382(9901): p. 1329-40——.

[2] Nehler, M.R., et al., Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. J Vasc Surg, 2014. 60(3): p. 686-95 e2.

[3] Li J, Varcoe R, Manzi M, Kum S, Iida O, Schmidt A, Shishehbor MH. Below-the-Knee Endovascular Revascularization: A Position Statement. *JACC: Cardiovascular Interventions*. 2024; ISSN 1936-8798

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