Late-Breaking Data Shows Sustained Benefits Of Abbott's Esprit™ BTK System For People Battling Peripheral Artery Disease Below The Knee

- Two-year LIFE BTK data demonstrates sustained safety and efficacy of Abbott's Esprit BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK) in treating peripheral artery disease (PAD) below the knee
- Late-breaking data presented at the VIVA 2024 conference showed that people treated with Esprit BTK required 48% fewer repeat procedures at two years compared to people treated with balloon angioplasty
- Esprit BTK is a recently FDA-approved treatment option for people with PAD

LAS VEGAS – Nov. 4, 2024 – Abbott today announced late-breaking data from the second year of the LIFE-BTK clinical trial demonstrating the long-term effectiveness of the FDA-approved Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit BTK) in people with the most severe form of peripheral artery disease (PAD) below the knee (BTK). The data showed that Abbott's Esprit BTK System offered sustained benefits over balloon angioplasty (a common treatment for PAD) with fewer repeat procedures at two years.

PAD is a highly prevalent disease affecting one in 20 Americans over the age of 50. In severe cases of PAD, blocked vessels reduce blood flow to the lower extremities, often leading to severe pain, non-healing wounds, and, in some cases, the need for limb amputation. Historically, the condition has been challenging to treat due to the anatomy below the knee, leaving many patients with limited or less effective therapy options.

The Esprit BTK System is a first-of-its-kind dissolvable stent to treat PAD below the knee. It is comprised of material similar to dissolving sutures that helps heal the vessel once the blockage is opened and provides support until the vessel is strong enough to remain open on its own.

The two-year data from the LIFE-BTK trial, which evaluated Esprit BTK in more than 260 people worldwide with PAD below the knee, was presented as a late-breaking clinical trial at VIVA 2024 in Las Vegas.

"PAD is a dangerous condition that is complex to treat, with limited approved treatment options," said Brian DeRubertis, M.D., FACS, New York Presbyterian-Weill Cornell Medical Center, and one of the principal investigators in the trial. "Abbott's Esprit BTK System offers a new option for treating people with the most severe forms of PAD, helping to heal blood flow and potentially salvage limbs."

The LIFE-BTK trial evaluated whether the Esprit BTK could offer greater long-term benefits than balloon angioplasty, the current standard of care for PAD below the knee. Balloon angioplasty offers poor short- and long-term outcomes and can result in the vessels becoming blocked again, requiring additional interventions.

The data from the trial also showcases strong two-year results when compared to other therapies. The trial's primary efficacy endpoint evaluated the ability of the vessel to stay open and lengthen the time until another intervention is needed.

Results after two years of the LIFE-BTK clinical trial showed:

- 90.3% of patients in the Esprit BTK arm did not require a reintervention at 24 months.
- The trial showed sustained efficacy at 24 months, demonstrating that Esprit BTK's long-term durability is effective in reducing reclosures and promoting the vessel to stay open.
- Compared to balloon angioplasty, people treated with Esprit BTK had significantly greater freedom from chronic limb-threatening ischemia (a severe form of PAD), which was the primary efficacy clinical event, 61.5% vs 32.8%.
- At one year, the trial's powered secondary endpoints revealed that Esprit BTK had a higher rate of reducing vessel re-narrowing (35.2% improvement) compared to balloon angioplasty.

"The positive results at two years reinforce Esprit BTK's potential to revolutionize the treatment of peripheral artery disease below the knee," said Jennifer Jones-McMeans, divisional vice president of global clinical affairs at Abbott's vascular business. "We're proud to be at the forefront of developing innovative treatment options for the millions of people living with PAD. By eliminating the need for multiple interventions and in some cases, amputation, we're ultimately helping people live fuller, better lives."

Additionally, Abbott launched the Esprit BTK Post-Approval Study (PAS) to assess the continued safety and effectiveness of Esprit BTK in treating chronic limb-threatening ischemia (CLTI) patients with blocked arteries below the knee in a real-world setting. The first patient was enrolled by Bernardino L. Rocha, M.D., vascular surgeon at SSM Health Heart & Vascular Care in Oklahoma City, Oklahoma.

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

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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]Get a Pulse on PAD: 1 in 20 Americans over 50 years of age experience PAD. https://www.secondscount.org/get-a-pulse-pad. 2024 August 22.

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