BD Strengthens Leadership in Peripheral Vascular Innovation with Positive AGILITY Trial Results

Data through 9 months of follow-up from this ongoing 36-month study demonstrate high vessel patency, low reintervention rates and meaningful improvements in mobility and symptoms, providing evidence supporting the treatment of complex iliac artery disease.

FRANKLIN LAKES, N.J., Oct. 7, 2026 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced positive nine-month results from the iliac cohort of the AGILITY Investigational Device Exemption trial evaluating the Revello™ Vascular Covered Stent. Presented at VIVA 2026 by Sean Lyden, M.D., global lead principal investigator for AGILITY, the results demonstrated strong safety and effectiveness outcomes in patients with iliac artery disease, a common form of peripheral artery disease (PAD). The findings mark an important milestone in the efforts by BD to expand clinical evidence supporting innovative solutions for chronic vascular disease and reinforce its commitment to advancing care for patients with PAD.

The study met its primary composite endpoint for the treatment of iliac artery disease and adds to the growing body of clinical evidence supporting the continued evaluation of the Revello™ Vascular Covered Stent. The device is designed to combine the flexibility of a nitinol self-expanding stent with the radial resistive force tailored for the iliac arteries.

Iliac artery disease can reduce blood flow to the legs and feet and potentially cause symptoms such as leg pain, cramping, impaired mobility and reduced quality of life. As treatment options evolve, physicians continue to seek durable solutions that provide sustained vessel patency and favorable long-term outcomes, particularly for patients with complex iliac artery anatomy.

The AGILITY iliac cohort enrolled 120 patients at 28 investigational sites in the United States, Europe, Australia and New Zealand. Through nine months of follow-up, treatment with the Revello™ Vascular Covered Stent resulted in:

- Composite safety and effectiveness endpoint met with a failure rate of 2.8%, significantly below the 19% prespecified performance goal
- 97.2% primary patency
- 98.3% freedom from clinically driven target lesion revascularization
- No device- or procedure-related deaths, target limb major amputations (at or above the ankle), or unanticipated serious adverse device effects

Patients experienced meaningful gains in daily function and mobility, with mean Rutherford category improving from 3.0 at baseline to 0.3 and mean WIQ score improving by 31.7 points from baseline to 9 months. Women represented approximately 41% of enrolled patients, and slightly more than half of lesions showed moderate-to-severe calcification.

"These latest data showed high primary patency and low clinically driven target lesion revascularization in a patient population that included both straightforward and complex iliac lesions," said Sean Lyden, M.D., chairman of the Department of Vascular Surgery at Cleveland Clinic and global lead principal investigator for AGILITY. "Results showed the treated arteries remained open in a high percentage of patients, and at nine months, patients also showed changes in disease severity and walking ability."

"These results reflect the continued commitment of BD to advance evidence-based innovation in peripheral vascular care," said Rob Righi, vice president and general manager of the Vascular Platform, Peripheral Intervention at BD. "As follow-up continues, the AGILITY study will help further characterize the Revello™ Vascular Covered Stent's performance across patients with peripheral artery disease."

Clinical follow-up in the iliac cohort is ongoing through 36 months. BD also completed enrollment in the study's superficial femoral and proximal popliteal artery cohort this past August, marking another milestone in the AGILITY study.

The Revello™ Vascular Covered Stent is CE marked. In the United States, the Revello™ Vascular Covered Stent is an investigational device limited by U.S. law to investigational use only.

About BD

BD is one of the world's largest pure-play medical technology companies with a Purpose of *advancing the world of health™* by driving innovation across medical essentials, connected care, biopharma systems and interventional. The company supports those on the frontlines of healthcare by developing transformative technologies, services and solutions that optimize clinical operations and improve care for patients. Operating across the globe, with more than 60,000 employees, BD delivers billions of products annually that have a positive impact on global healthcare. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase clinical efficiency, improve safety and expand access to healthcare. For more

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