# Treatment With Abbott's Portico™ Transcatheter Aortic Valve Showed Portico Is Safe And Reduces Severe Aortic Stenosis At 30 Days In Real-World Setting

- Data presented at EuroPCR indicated excellent clinical outcomes for Portico in a real-world setting to treat common and life-threatening heart valve disease with minimally invasive option

- Portico is the first fully resheathable, repositionable and retrievable device – now with a sheathless delivery option – to replace a diseased or damaged aortic heart valve without major surgery

- Data are consistent with earlier study results used to support CE Mark

PARIS, May 22, 2018 – Abbott today announced treatment with the company's Portico™ transcatheter aortic valve replacement (TAVR) therapy was associated with excellent clinical outcomes at 30 days, including low rates of death, disabling stroke, and paravalvular leak. Additional benefits observed included reduction in New York Heart Association (NYHA) class severity, low rates of bleeding, and improvements in a six-minute walk test, allowing patients to return to their previous lifestyles and activity faster. Data from the PORTICO I study were presented during EuroPCR, the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), and showed favorable short-term clinical outcomes for safety and performance – consistent with the Portico CE Mark study results that granted European regulatory approval.

The Portico transcatheter aortic valve provides a minimally invasive treatment for patients diagnosed with severe aortic stenosis – a common and very serious valve disease – who are not candidates for open-heart surgery. More than one in eight people aged 75 and older have moderate or severe aortic stenosis,[1] which is caused by a narrowing of the aortic valve opening in the heart that restricts blood flow from the left ventricle to the aorta.

Most patients don't have symptoms for decades, but once symptoms appear, the prognosis is poor without surgical treatment.[2] The end result of severe aortic valve stenosis is the reduction in the heart's pumping ability, which can lead to shortness of breath, fatigue, and ultimately to heart failure[3]. Transcatheter aortic valve replacement provides a minimally invasive alternative to surgical aortic valve replacement, the treatment of choice for many patients affected by severe aortic stenosis.[2]

"Patients with severe aortic stenosis require timely treatment to reduce symptoms and improve clinical outcomes and quality of life," said principal investigator Francesco Maisano, M.D., Prof., UniversitätsSpital Zürich, Switzerland. "These new data reinforce that treatment with the Portico valve is safe in a real-world setting – with robust clinical results – and confirm that Portico is an excellent solution for patients at increased risk for surgery."

The PORTICO I study is a real-world, multicenter, prospective, single-arm study with independent adjudication of clinical events and independent echocardiography core-lab analysis. The study will follow patients annually through five years in a real-world setting after being treated with Portico to assess long-term clinical outcomes. In the study, 941 patients were treated at 61 centers across the EU, Canada and Australia. At 30 days, the study showed patients who received Abbott's TAVR therapy had very low rates of all-cause mortality (2.7 percent; 25/941) and disabling stroke (1.7 percent; 16/941).

At 30 days after implant, study patients had excellent hemodynamic performance (8.6 mm Hg), a measurement of forward blood flow resistance, and effective orifice area, or large valve opening, of (1.8 $cm^2$), allowing blood to easily flow from the left ventricle of the heart to the aorta. Nearly all patients (96.1 percent) experienced none-to-mild paravalvular leak which may result after a mitral or aortic valve replacement procedure. The percentage of patients in NYHA class III/IV significantly decreased from 64 percent to 13.1 percent, indicating improved mobility, and clinical measures showed a mean improvement of 26 meters in the six-minute walk test. No severe aortic valve regurgitation, or leak, based on Independent Core Lab-assessed echocardiographic analysis, was seen at 30 days.

"When developing the Portico valve, our goal was to provide physicians with new offerings that would improve deliverability, placement accuracy and performance when replacing a diseased or damaged aortic heart valve using a minimally invasive therapy," said Michael Dale, vice president of Abbott's structural heart business. "The findings of the PORTICO I real-world study corroborate those from our previous clinical trials, which showed that Portico is a life-saving valve that improves quality of life and helps patients resume their day-to-day activities."

Portico recently received regulatory approval in Europe for a sheathless introduction of the Portico valve, allowing physicians to deliver it without an arterial introducer sheath. Use of the Portico Transcatheter Aortic Valve system without an arterial delivery sheath reduces the valve profile further, making it easier for physicians to insert the device in patients with severe disease and complex anatomies. The smaller size of the valve may lower the risk of serious adverse events and vascular complications such as internal damage to the arteries. [4],[5],[6][7]

**About the Portico Transcatheter Aortic Valve:**

The Portico Transcatheter Aortic Valve received CE Mark in 2012 and is the first fully resheathable, repositionable and retrievable TAVR device.[8] Portico offers excellent hemodynamic stability, or continued blood flow during deployment of the device, enabling more precise placement for physicians and improving patient outcomes. Portico has the lowest profile of other TAVR systems and an optimized delivery system for trackability and flexibility to deliver the valve in complex anatomies. The self-expanding Portico valve is designed to preserve coronary artery access for future interventions. The device is currently

under clinical study in the U.S.

*The Portico Transcatheter Aortic Valve  is approved for investigational use only in the U.S.*

**About Abbott:**

At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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