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# Medtronic presents Evolut EXPAND TAVR II trial design and baseline characteristics of patients with moderate aortic stenosis at TCT 2026

Featured clinical science presentation highlights global randomized trial investigating TAVR intervention alongside guideline-directed medical therapy

**SAN DIEGO, Calif., October 31, 2026** – Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today presented the study design and baseline characteristics of patients enrolled in the Evolut™ EXPAND TAVR II Trial as Featured Clinical Science at the Transcatheter Cardiovascular Therapeutics (TCT) annual conference in San Diego, Calif.

EXPAND TAVR II is the first prospective, randomized trial evaluating the self-expanding, supra-annular Evolut TAVR platform in patients with moderate aortic stenosis. The trial investigates whether transcatheter aortic valve replacement (TAVR), combined with guideline-directed medical therapy (GDMT), can improve clinical outcomes compared with GDMT alone.

Moderate aortic stenosis is associated with significant adverse cardiac events, heart failure hospitalizations, [1,2] and increased mortality. EXPAND TAVR II addresses an important clinical question: whether patients with moderate aortic stenosis, and features that place them at increased risk, may benefit from aortic valve intervention before their disease becomes severe.

“Moderate aortic stenosis can be accompanied by symptoms and cardiac damage, yet important questions remain about when to intervene,” said Paul Sorajja, MD, interventional cardiologist and co-principal investigator of the study. “Understanding the clinical and anatomic characteristics of the EXPAND TAVR II population will provide essential context for interpreting the trial’s future results and determining whether earlier TAVR can improve outcomes in these patients.”

The international, multicenter trial includes 692 patients randomized at 96 sites across 16 countries. Participants are aged 65 years or older, have core-laboratory-confirmed moderate aortic stenosis and at least one at-risk feature.

At enrollment, the mean age of participants was 78.4 years, 42.3% were female, and more than 90% were New York Heart Association functional class II or higher.

"EXPAND TAVR II is designed to generate rigorous evidence to help clinicians address meaningful gaps in patient care and make informed decisions about when to intervene in moderate aortic stenosis," said Kendra Grubb, MD, vice president and chief medical officer of Medtronic Structural Heart. "EXPAND II investigates whether intervening earlier in the progression of aortic stenosis can make a difference for patients at increased risk. The presentation today establishes the foundation by defining who is enrolled and detailing the trial designed to assess safety and effectiveness."

The trial is designed to assess safety at 30 days and effectiveness at two years, with patient follow-up planned through 10 years. As part of the study protocol, patients were managed by a heart failure cardiologist in strict accordance with guideline-directed medical therapy. The primary effectiveness endpoint is a composite of all-cause mortality, heart failure hospitalization or event, or medical instability leading to aortic valve replacement or reintervention. This endpoint will be evaluated for superiority between the two treatment groups.

**Investigational use:** Use of the Evolut TAVR system to treat moderate aortic stenosis is investigational. Safety and effectiveness for this use have not been established.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

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Contacts:
Kimberly Powell
Public Relations
+1-202-498-2601

Ingrid Goldberg
Investor Relations
+1-763-505-2696

**References:**

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[2] Jean G, Van Mieghem NM, Gegenava T, et al. Moderate aortic stenosis in patients with heart failure and reduced ejection fraction. *J Am Coll Cardiol*. 2021;77(22):2796–2803. doi:10.1016/j.jacc.2021.04.014.

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