Abbott Aims To Optimize TAVI Implants With European Approval Of FlexNav™ Delivery System For The Company's Portico™ Valve

- New FlexNav™ delivery system improves control and delivery of the Portico™ TAVI valve even in complex clinical cases

- The minimally invasive Portico procedure allows doctors to treat severe aortic valve stenosis without invasive surgery

- Approval of the new delivery system follows first implants of the company's next-generation and investigational Navitor™ TAVI valve

ABBOTT PARK, Ill., March 5, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it has received CE Mark for the new FlexNav™ delivery system for the company's Portico™ transcatheter aortic valve implantation (TAVI) system, enabling marketing authorization in Europe. With the approval, physicians implanting Portico can benefit from improved delivery, flexibility and navigation during implant, even in complex cardiac anatomies.

The new FlexNav delivery system demonstrates Abbott's commitment to developing new tools for doctors to treat patients requiring a transcatheter aortic valve implant. The approval and launch of the FlexNav delivery system follow first global implants in a clinical study of Abbott's next generation Navitor™ TAVI system, which were recently conducted at Rigshospitalet in Copenhagen, Denmark, by a clinical team led by Prof. Lars Søndegaard, M.D., professor of Cardiology, Rigshospitalet, Copenhagen University Hospital in Denmark. Prof. Lars Søndegaard, M.D., also serves as co-principal investigator for the trial.

Transcatheter aortic valve replacement (TAVR) is a minimally invasive alternative to surgical aortic valve replacement for patients at high or extreme risk for open heart surgery who are diagnosed with severe aortic stenosis, a condition which restricts blood flow through the valve. While valve technology improvements have helped reduce adverse events and improve patient outcomes, improvements to delivery systems are critical to improving the placement and positioning of the valve. Based on physician feedback, Abbott developed the FlexNav delivery system to incorporate more stability, predictability and placement accuracy into the TAVI procedure.

"As a therapy, TAVR is now fairly mainstream and has helped countless patients around the world live better lives, but physicians have continued to seek improvements to how we deliver a valve to optimize outcomes for our patients," said Francesco Bedogni, M.D., interventional cardiologist and head of Cardiology at the IRCCS Policlinico San Donato in Italy, who served as principal investigator for the FlexNav sub-study within the Portico Global Investigational Device Exemption (IDE) Trial. "With Abbott's new FlexNav delivery system, the company has introduced a delivery system that improves the implant process even in incredibly complex cardiac anatomies."

Clinical experience with the FlexNav delivery system has yielded positive outcomes for patients to date. Data presented at the 31st annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in September 2019 showed that within the Portico U.S. IDE Study, patients who received a Portico valve implanted with the FlexNav Delivery System saw no deaths, no strokes and low rates of major vascular complications and new permanent pacemaker implants after 30 days.

"Within the field of TAVI, delivery systems often don't receive the attention of the evolving technology of the valves themselves, but improvements to a delivery system can result in substantial benefits to patients," said Neil Moat, M.D., chief medical officer of Abbott's structural heart business and a physician who has performed several hundred TAVI procedures. "If we look at the total TAVI procedure, innovation around both the valve itself and also how it's delivered during an implant are both central to improving outcomes."

The Portico Transcatheter Aortic Valve and FlexNav Delivery System are approved for investigational use only in the U.S.

The Navitor Transcatheter Aortic Valve is Abbott's next generation TAVI valve, currently under investigation in the United States. The Navitor valve is approved only for investigational use.

About Abbott:
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

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