Abbott Receives European And Canadian Approval For Amplatzer™ Steerable Delivery Sheath To Optimize Left Atrial Appendage Closure Procedures For People At Risk Of Stroke

- First-of-its-kind steerable delivery system designed for left atrial appendage (LAA) occluder to seal the LAA in people who are at increased risk of stroke due to atrial fibrillation

- New delivery system works with Abbott's leading Amplatzer Amulet™ LAA Occluder device to enable better access to the LAA and seals off a broad range of LAA anatomies

- Steerable sheath gives physicians enhanced flexibility and precise placement when implanting Amplatzer Amulet

ABBOTT PARK, Ill., June 7, 2021 — Abbott today announced it has received CE Mark and Health Canada approval for its Amplatzer™ Steerable Delivery Sheath, which is used with the company's market-leading Amplatzer Amulet™ Left Atrial Appendage (LAA) Occluder. Now available in Europe and Canada, the new device is the first steerable delivery sheath that has been developed specifically for minimally invasive LAA occlusion (or closure) procedures to treat patients diagnosed with atrial fibrillation who are at risk of ischemic stroke.

Often referred to as AF or AFib, atrial fibrillation is the most common sustained cardiac arrhythmia. It occurs when the upper chambers of the heart (atria) beat out of coordination with the lower chambers (ventricles) and contract rapidly and irregularly. The LAA is a small pocket (or recess) connected to the upper left chamber of the heart that, in people with AF, can allow blood to pool and increase the likelihood of a clot forming and traveling to the brain to cause a stroke. For patients with AF who are unable to take blood thinning medication long term, physicians may perform closure procedures where the device is threaded through a vein in the leg and then implanted in the heart where it seals off the LAA, preventing blood clots from forming in the LAA and reducing the risk of stroke.[1,2]

"Abbott's Amplatzer Amulet has long been the LAA occlusion device of choice in Europe and Canada to reduce the risk of stroke and eliminate the need for blood thinning medication in patients with atrial fibrillation," said Réda Ibrahim, M.D., Montréal Heart Institute, who completed one of the first global procedures with the new system. Jacqueline Saw, M.D., Vancouver General Hospital, who completed additional first procedures, added, "Physicians performing occlusion procedures on the LAA can now easily and precisely place the device in a broad range of anatomies with an enhanced delivery system that shortens procedure time and enhances efficiency."

To improve physician ease-of-use, the Amplatzer Steerable Delivery Sheath features bi-directional steering and an "auto-lock" setting for more accurate alignment with the LAA. The sheath also includes a hemostasis valve designed to stabilize blood flow and minimize blood loss during the procedure. The new design additionally reduces the need for catheter manipulation or exchanges, which can slow down procedure time or cause further blood loss.

"This innovation advances the performance of our Amplatzer Amulet device and offers patients a much-needed treatment option to help manage stroke risk from atrial fibrillation," said Michael Dale, senior vice president of Abbott's structural heart business. "At Abbott, we are continually looking for new and better ways to address structural heart diseases, and this approval is another step forward in helping people achieve better health."

For more information on the Amplatzer Amulet LAA Occluder, please visit:http://abbo.tt/Amulet.

The Amplatzer Steerable Delivery Sheath and Amplatzer Amulet LAA Occluder are not approved for use in the U.S.

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 109,000 colleagues serve people in more than 160 countries.

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[1] Landmesser U, et al. *EuroIntervention* 2017;13:867-876.

[2] Lewalter T. *Europace* 2013; 15:652-656.

For further information: Abbott Media: Cynthia Kong (669) 400-6879 Abbott Financial: Mike Comilla (224) 668-1872