Abbott Strengthens Left Atrial Appendage Closure Leadership With U.S. Availability Of Amplatzer™ Steerable Delivery Sheath For The Company's Amulet™ Device

- First and only steerable delivery system designed to help seal the left atrial appendage (LAA) in people with atrial fibrillation who are at an increased risk of stroke
- Now available in the U.S., Abbott's steerable sheath offers precise and flexible placement when used with the company's Amplatzer Amulet LAA Occluder

ABBOTT PARK, Ill., April 28, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced U.S. availability of its Amplatzer™ Steerable Delivery Sheath, which is used with the company's Amplatzer Amulet™ Left Atrial Appendage (LAA) Occluder to treat people with atrial fibrillation (AFib) who are at risk of ischemic stroke. The latest addition to Abbott's comprehensive structural heart portfolio, this first-of-its kind delivery system demonstrates the company's commitment to innovating across heart conditions, including in LAA occlusion (closure).

The LAA is a small pouch connected to the upper left chamber of the heart. The most common persistent arrhythmia, or irregular heartbeat, AFib disrupts the heart's ability to effectively pump blood. If this condition is left untreated, blood can pool and collect in the LAA and increase the likelihood of a clot forming and traveling to the brain to cause a stroke. For patients with AFib who are unable to take blood-thinning medication long term, physicians may opt for a minimally invasive procedure using devices like Abbott's Amulet to seal off the LAA entirely and reduce the risk of stroke.

"Since its FDA clearance last year, doctors have been utilizing Abbott's Amulet device to help patients reduce their risk of stroke from atrial fibrillation without the need for blood-thinning medication," said Vivek Y. Reddy, M.D., director of electrophysiology, Mount Sinai Hospital, who completed the first U.S. procedure with the delivery system. "With the Amplatzer Steerable Delivery Sheath, U.S. physicians now have more flexibility and precise placement when implanting the Amulet device, in simple and complex anatomies. It allows doctors to close left atrial appendages in challenging cases, when otherwise it might not be possible."

About Amplatzer Amulet and the Steerable Delivery Sheath
Abbott's Amulet with dual-seal technology (consisting of a lobe or piece to fill the cavity of the LAA and a disc to close off the opening into the LAA) offers immediate and complete closure of the LAA. This reduces the risk of stroke and – unlike competitive devices – does not require blood-thinning medication following the procedure, which is significant since these medicines often carry bleeding risks.

To improve physician ease-of-use when implanting the Amulet device, the Amplatzer Steerable Delivery Sheath features bi-directional steering and an "auto-lock" function that provides confidence the sheath will remain in its desired position. The delivery system also includes a valve designed to stabilize blood flow and minimize blood loss during the procedure.

Strong Clinical Evidence for Amplatzer Amulet
The availability of the Steerable Delivery Sheath follows recent back-to-back achievements for Abbott's LAA offering, including:

- Strong clinical evidence from the Amulet IDE trial, the largest randomized LAA occlusion study to date, confirmed that the Amplatzer Amulet offers durably superior LAA closure compared with the Watchman‡ device (Boston Scientific) at 45 days (presented at ESC Congress 2021) as well as at 12 months (presented at the 33rd Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium in 2021).
- Analysis presented at the International Stroke Conference 2022 demonstrated that device-related adverse events (peri-device leak and device-related thrombus) were seen more frequently in the Watchman device than Amulet.
- Data presented at TCT in 2021 confirmed the advantage of Amplatzer Amulet vs. Watchman (including Watchman FLX) in relation to the rate of occlusion of the LAA (SWISS-APERO), and peri-device leak with Amulet at both the disc and the lobe was lower than Watchman FLX (SEAL FLX).

"The Amulet LAA Occluder and Amplatzer Steerable Delivery Sheath are examples of Abbott's commitment to helping people with structural heart diseases live their best lives, and we remain committed to the continued innovation of our technology for the benefit of physicians and patients worldwide," said Michael Dale, senior vice president of Abbott's structural heart business. "Abbott is focused on advancing technology for LAA occlusion devices as well as how they are delivered to optimize the physician experience and improve outcomes for patients."

Abbott's Amplatzer Steerable Delivery Sheath is approved in Europe and Canada and cleared for use in the U.S. Receiving initial CE Mark approval in 2013, the Amplatzer Amulet LAA Occluder has been approved for use in more than 80 countries and is the market leader in Europe, the Middle East and Asia.

For U.S. important safety information on the Amplatzer Steerable Delivery Sheath, visithttps://abbo.tt/SS_ISI.

For U.S. important safety information on the Amplatzer Amulet LAA Occluder, visithttps://abbo.tt/AmuletISI.

About Abbott:
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nutritionals and branded generic medicines. Our 113,000 colleagues serve people in more than 160 countries.

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