REAL-WORLD STUDY RESULTS SUPPORT USE OF ABBOTT'S AMPLATZER™ AMULET™ TO REDUCE STROKE IN PATIENTS SUFFERING FROM ATRIAL FIBRILLATION WITHOUT THE NEED FOR LIFETIME BLOOD THINNERS

- Study confirms safety of treatment with AMPLATZER Amulet device and reduction in stroke risk by nearly 60 percent

- Post-implant, AMPLATZER Amulet successfully sealed left atrial appendage in 99 percent of patients

- In patient population at high risk for stroke – and major bleeding – need for blood-thinning medication reduced

PARIS, May 24, 2018 – Abbott today announced real-world results that showed treatment with the company's AMPLATZER™ Amulet™ left atrial appendage (LAA) occlusion device in patients with irregular heart beats, known as atrial fibrillation (AF), reduced the risk of stroke, transient ischemic attack (TIA) and systemic embolism (SE) without the need for blood-thinning medication. The study follows a patient population in which 83 percent of patients are contraindicated for blood thinners – importantly, the AMPLATZER Amulet device was shown at one year to reduce stroke risk by 57 percent as compared to the predicted stroke risk.

Results from the study with follow-up through one year were presented at EuroPCR, the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), in Paris, and simultaneously published in *EuroIntervention.*

The AMPLATZER Amulet occlusion device is used to seal off the left atrial appendage (LAA), a small pocket connected to the left atrium of the heart, in patients diagnosed with non-valvular atrial fibrillation. While the LAA may function as a de-pressurizing chamber of the heart in healthy patients, blood clots may form in the LAA in patients with atrial fibrillation[1]. Atrial fibrillation (AF) is a quivering or irregular heartbeat (arrhythmia) that affects 33.5 million people worldwide[2] and can lead to blood clots, stroke, heart failure and other heart-related complications.[3]

The Abbott device works by blocking the LAA at its opening into the left upper chamber of the heart, minimizing the opportunity for blood clots that may form in the LAA to migrate into the bloodstream – where they can travel to the brain and cause a stroke. Currently, patients with AF at risk of stroke are often prescribed blood-thinning medication to reduce risk for formation of blood clots, but this treatment approach requires a lifetime of taking medication and comes with risk of major bleeding. By closing the LAA with the AMPLATZER Amulet occluder, physicians can "seal off" the LAA to reduce the risk of stroke.

"Managing atrial fibrillation in patients who are at high risk of bleeding with blood thinning medicines is complex, and physicians must carefully weigh a patient's risk for life-threatening bleeds versus stroke," said Ulf Landmesser, M.D., presenter of the latest data and director, Department of Cardiology, Charité Universitätsmedizin in Berlin, Germany. "These real-world prospective data provide important information on the clinical use and safety of left atrial appendage occlusion with the AMPLATZER Amulet device, and demonstrate excellent occlusion of the left atrial appendage over time."

The AMPLATZER Amulet occluder is a second-generation, minimally invasive LAA occlusion device designed to allow for easier and more stable placement than the previous generation, and can result in shorter procedure times and complete sealing or closure of the LAA. The device is offered in eight sizes to accommodate varying anatomies and is designed to address a wide range of complex patient anatomies.

"The results of our observational post-market study provide important information about the efficacy and safety of the AMPLATZER Amulet device for stroke prevention in atrial fibrillation patients in a real-world setting," said Michael Dale, vice president of Abbott's structural heart business. "These findings support LAA occlusion as the preferred method for the prevention of stroke in people with atrial fibrillation."

About the Study:

The AMPLATZER Amulet Observational Post-Market Study enrolled 1,088 non-valvular AF patients from 61 centers in 17 countries. Of those enrolled, the Amulet device was successfully implanted in 99 percent of patients (1,078/1,088). The mean age of the patients was 75 ±8.5 years; 64.5 percent were male; 82.8 percent of patients were considered to have an absolute or relative contraindication to long-term anticoagulation; and 72.4 percent had experienced a previous major bleed.

Follow-up visits will occur at designated times through 24 months post-device implant for assessment. Transesophageal echo (TEE) was utilized to take detailed pictures of the heart at the end of the procedure and between one and three months afterwards. The study reported results through one year of follow-up. Unique to the study, an independent echocardiography core lab analyzed the data and an independent Clinical Events Committee adjudicated serious adverse events.

The observed ischemic stroke rate was compared to the predicted risk based on the CHA2DS2-VASc score[4], which is a key measure to assess stroke risk in AF. In the first year, patients treated with AMPLATZER Amulet had a 57 percent reduced risk for ischemic stroke and 60 percent reduced risk for ischemic stroke, transient ischemic attack or systemic embolism.

To assess residual flow – the remaining amount of blood flow around the device – which indicates the degree of complete closure, the study utilized a <3mm measurement versus the typical <5mm measurement used in other LAA trials. Adequate sealing of the LAA was achieved in 99.3 percent of patients with residual flow less than 3mm at the end of the procedure, and in 98.4 percent of follow-up studies between one and three months post-implant, as assessed by the echocardiolgraphic core laboratory.

Key one-year clinical events adjudicated by the independent Clinical Events Committee included: Ischemic stroke rate of 2.9 percent per year (29 events in 27 patients) versus a predicted rate of 6.7 percent; and, device-related thrombus rate of 1.7 percent (18 events in 17 patients).

The AMPLATZER Amulet LAA occluder is an investigational device 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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[1] http://heart.bmj.com/content/82/5/547

[2] Chugh S et al. Worldwide Epidemiology of Atrial Fibrillation. A Global Burden of Disease 2010 Study. Circulation. 2014;129:837-847

[3] American Heart Association. What is Atrial Fibrillation? Available on https://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/What-is-Atrial-Fibrillation-AFib-or-AF_UCM_423748_Article.jsp?appName=MobileApp. Accessed on May 15, 2018

[4] Friberg L, Rosenqvist M and Lip GY. Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182 678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study. *Eur Heart J*. 2012;33:1500-10.

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