LANDMARK STUDY PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE SHOWS ABBOTT'S AMPLATZER™ DEVICE SIGNIFICANTLY REDUCES RISK OF RECURRENT STROKE FOR PEOPLE LIVING WITH A HOLE IN THEIR HEART

- One in four people live with a small opening between the upper left and right chambers of the heart, called a patent foramen ovale (PFO), that increases their risk for recurrent stroke

- Long-term follow-up data from the largest study of PFO and strokes of unknown origin shows AMPLATZER™ PFO Occluder significantly reduces the risk of recurrent stroke over medication

ABBOTT PARK, Ill., Sept. 14, 2017 — Abbott today announced that long-term follow up in a landmark clinical trial showed that its AMPLATZER™ PFO Occluder device – designed to close a hole-like opening in the heart – cut the risk of recurrent ischemic stroke by 45 percent compared to the standard of care medications. The study was published today in The New England Journal of Medicine.

Everyone is born with a small opening in their heart, the foramen ovale, between the upper left and right chambers, which plays an important role prior to birth in the development of the fetal circulatory system. While the flap-like opening transports highly oxygenated blood in a developing fetus, it should close shortly after birth. However, in about 25 percent of people, the opening doesn't close, and may go unnoticed for years to come. Left untreated, the opening allows blood to flow directly from the right to left atrium of the heart, potentially allowing a thrombus, or dangerous blood clot, to pass through, travel up to the brain and cause a stroke.

"In many cases, people with a PFO are at increased risk for recurrent stroke, and may be otherwise young and healthy individuals," said lead investigator Jeffrey L. Saver, M.D., director of the stroke center at UCLA and professor of neurology at David Geffen School of Medicine. "This study carefully followed patients almost twice as long as early PFO trials, and ultimately showed that using the AMPLATZER device reduced patients' risk for stroke by 45 percent when compared to medication alone, allowing them to return to a more normal life."

The study involved 980 patients with median follow-up of almost six years, and found that AMPLATZER PFO Occluder reduced the risk for recurrent ischemic stroke by 45 percent versus medication alone (p=0.046). Additionally, the device showed a 62 percent reduction in risk for recurrent ischemic stroke of unknown cause, known as cryptogenic stroke (p=0.007). The prevalence of PFO in patients who have cryptogenic stroke is 25 to nearly 50 percent.[i]

"Many patients in this study are younger than the general stroke population and have their whole lives ahead of them," said Michael Dale, vice president of Abbott's structural heart business. "The AMPLATZER PFO Occluder - a first-of-its kind, minimally-invasive offering - can help people with PFOs return to health and peace of mind, with a reduced risk of stroke, and without having to take daily medication for the condition."

Data showed that closure with AMPLATZER PFO Occluder had a low risk of device- or procedure-related complications. Serious adverse events were comparable between the device and medication groups. The trial showed no increased risk of serious atrial fibrillation in patients who received the AMPLATZER device, and no device embolization, aortic erosion/dissection or thrombus formation.

The rate of venous thromboembolism in both groups, which includes deep vein thrombosis (DVT) or pulmonary embolism, exceeded that in healthy populations, with the PFO closure group having a higher rate than the medication group. Researchers believe that this was due to lower use of anti-clotting medicines in the PFO closure group.

About the Study:

Beginning in 2003, the RESPECT trial, a multicenter, open-label, randomized, controlled clinical trial, enrolled 980 patients at 69 centers across the U.S. and Canada. Patients were between the ages of 18 and 60, had a PFO, and previously suffered a cryptogenic ischemic stroke. Patients received either the AMPLATZER™ PFO Occluder (499 patients) or medication (481 patients), which included aspirin, warfarin, clopidogrel, and aspirin combined with extended-release dipyridamole, and were followed for a median of 5.9 years. The primary endpoint was recurrent nonfatal ischemic stroke, fatal ischemic stroke or early death.

About AMPLATZER PFO Occluder:

The AMPLATZER PFO Occluder was approved by the U.S. Food and Drug Administration (FDA) in October 2016, and is the first and only device indicated to reduce the risk of cryptogenic ischemic stroke in patients with a PFO. The procedure takes less than one hour to complete and can be performed under conscious sedation. Patients are released within 24 hours. For important safety information on AMPLATZER PFO Occluder, please visit https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/amplatzer-pfo-accluder-isi.pdf.

About Ischemic Stroke:

Ischemic stroke accounts for 85 percent of all stroke, and is caused by blockages or narrowing of the arteries that provide blood to the brain, resulting in ischemia - severely reduced blood flow that damages brain cells. While ischemic strokes may happen for a variety of reasons, the blockage that causes the stroke is often due to a blood clot, and in patients with a PFO, that blood clot may be allowed to pass through the arteries from the heart to the brain. When a person suffers an ischemic stroke without an identifiable cause, physicians run tests to assess any underlying risk factors, which should include an echocardiogram test to determine if the patient has a PFO.

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, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

Connect with us at http://www.abbott.com, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

---

[i] http://www.heart.org/HEARTORG/Conditions/More/CardiovascularConditionsofChildhood/Patent-Foramen-Ovale-PFO_UCM_469590_Article.jsp#.WbQm1bKGPI

For further information: Abbott Media: Mary Kokkinen, (408) 845-0808 Abbott Financial: Mike Comilla, (224) 668-1872