Abbott To Initiate Trial To Study MitraClip As An Option For Moderate Surgical Risk Patients

- New clinical trial will assess first-of-its-kind MitraClip™ transcatheter mitral valve repair against current standard of care surgery in a new, expanded patient population

- If successful, the REPAIR MR study has potential to expand MitraClip's current indication (patients at prohibitive risk for surgery) to also include patients at moderate risk

ABBOTT PARK, Ill., Jan. 13, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved a first-of-its-kind clinical trial that will compare the effectiveness of Abbott's minimally invasive MitraClip™ device – which has now treated 100,000 patients worldwide – to open heart mitral valve surgical repair in people with primary mitral regurgitation (MR) who are eligible for open-heart surgery. If successful, the trial has the potential to expand treatment options for patients who are suffering from leaking mitral valves and whose current options are limited to open-heart surgery.

The prospective, randomized REPAIR MR clinical trial will enroll approximately 500 patients at 60 sites in the U.S.,Canada and Europe to evaluate the effectiveness of the MitraClip device in moderate-surgical-risk patients with severe primary MR who are candidates for open-heart surgery, which is the current standard of care today. The trial's design addresses the issue that, despite symptoms and increased mortality for people suffering from MR, patients are often undertreated by open-heart mitral valve surgery. Currently, only an estimated 15% of patients who are eligible for the standard-of-care surgery for their primary MR receive surgical treatment. In some cases, this may be because the MR goes undiagnosed, but in others, patients may forgo surgery due to prolonged recovery time or fear of possible surgical complications.[1] [2]

"The REPAIR MR trial seeks to evaluate the MitraClip device in treating a new patient population who currently undergo the standard surgical treatment, but are at moderate surgical risk," said Patrick McCarthy, M.D., chief of cardiac surgery, Northwestern Medicine, executive director, Bluhm Cardiovascular Institute and co-principal investigator of the REPAIR MR trial. "This is an important question since approximately 70% of people diagnosed with primary mitral regurgitation aren't treated with open-heart mitral valve surgery today yet are in need of treatment and symptom relief." The trial will also be led by co-principal investigator Saibal Kar, M.D., director of structural heart disease and research, Los Robles Hospital and Medical Center.

Mitral regurgitation (MR) is a debilitating, progressive and life-threatening disease in which the heart's mitral valve does not close completely, causing blood to flow backward and leak into the atrium of the heart. The condition is the most common valve disease worldwide and can lead to reduced quality of life, recurrent hospitalizations and decreased survival.

Abbott's MitraClip system has been commercially available in the U.S. since 2013 and in Europe since 2008 and has shown significant impact for patients with both primary and secondary MR who are at high risk for open-heart surgery. The MitraClip therapy – now on a fourth generation of innovation – has shown improved clinical outcomes and quality of life through a minimally invasive option that reduces MR's debilitating symptoms.

"Abbott is leading the way in the structural heart space. We're pushing the field forward by making clinical investments to examine whether new, minimally invasive treatment options are suitable, or even preferable, to what has been the standard of care," said Neil Moat, M.D., chief medical officer of Abbott's structural heart business. "Devices that can be delivered through a minimally invasive method to close or repair a significant structural issue in the heart are in high demand, and we are committed to continuing our efforts to bring the benefits of these devices to patients who need them."

For more information on MitraClip, visitwww.structuralheartsolutions.com.

For U.S. Important Safety Information about MitraClip, visit:https://www.structuralheartsolutions.com/us/mitraclip-isi.

About Abbott:
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[1] Mirabel et al. European Heart Journal 2007;28(11):1358-1365; Dziadzko et al. Lancet 2018; 391:960-69

[2] Hendrix, et al. Annals of Thoracic Surgery 2019; 107:747-53

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