Update: Clinical Trial Establishes Catheter-based Aortic Valve Replacement As New Standard of Care for Patients Who Cannot Undergo Surgery

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WASHINGTON, Sept. 23 /PRNewswire/ -- One-year data from the PARTNER clinical trial, published yesterday in the New England Journal of Medicine, demonstrate that transcatheter aortic-valve implantation, compared with standard therapy, resulted in significantly lower rates of death among patients who cannot undergo surgery for aortic stenosis. The results will be presented today as a Late Breaking Trial at the 22nd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium.

Transcatheter aortic-valve implantation (TAVI) is a new procedure in which a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve. The Placement of AoRtic TraNscathetER valves (PARTNER) trial is a multicenter, randomized clinical trial comparing TAVI with standard therapy in high-risk patients with severe aortic stenosis. The co-principal investigators are Martin B. Leon, M.D., and Craig R. Smith, M.D., at NewYork-Presbyterian Hospital/Columbia University Medical Center. The data published today reflect a prespecified cohort of patients who were considered to be unsuitable candidates for surgery.

The primary end point was the rate of death from any cause over the duration of the study. A total of 358 patients with aortic stenosis who were considered to be unsuitable candidates for surgery underwent randomization at 21 centers, including 17 in the United States. Patients randomized for standard therapy received a combination of watchful waiting, medications, and balloon aortic valvuloplasty, which can provide transient clinical benefit but does not alter long-term outcomes.

At one year, based on the Hazard Ratio of 0.55, patients who underwent TAVI showed a reduction in mortality from 50.7 percent to 30.7 percent. In addition, there was a reduction in the combined endpoint of death from any cause or repeat hospitalization from 71.6 percent with standard therapy to 42.5 percent with TAVI. Among
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