

Cardioband Annuloplasty System for transcatheter mitral repair show promising preliminary results

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Valtech Cardio Ltd, a medical device company that develops solutions for mitral valve repair and replacement, announced today that 11 patients have been treated with the company's transcatheter Cardioband Annuloplasty System in three leading European medical centers.

The Cardioband device enables transcatheter Mitral Regurgitation (MR) repair, thereby avoiding open heart surgery and the use of cardiac bypass machine. Another advantage is that the size of the Cardioband is fitted while the heart is beating which optimizes the results of the repair. Importantly, the form and clinical function of the Cardioband closely replicates that of the annuloplasty rings that are today the standard-of-care in surgery.

The patients were treated as part of an ongoing multi-center study at the Asklepios Klinik St. George Heart Center in Hamburg, Bichat-Claude Bernard Hospital in Paris and San Raffaele Hospital in Milan. The objective is to study the safety of Valtech's Transfemoral Cardioband Annuloplasty from functional MR who are at high risk for open heart surgery. The study focusses on overall rate of Major cardiovascular adverse events (MACE) until hospital discharge and at post-operative 30 days.

Dr. Francesco Maisano, Valtech's Chief Medical Officer, commented: "The safety profile of the device is impressive. Throughout these eleven procedures, the Cardioband device has demonstrated an excellent safety profile with no MACE to

date." Dr. Maisano added, "Cardioband is the most promising valve repair technology. Early outcomes are extremely favorable with profound reduction of MR in most patients."

All patients that have been implanted with the Cardioband system have experienced a reduction in the mitral valve annular size and an increase in coaptation length. To date, two patients have completed 6 months follow-up demonstrating a stable improvement from severe MR to mild MR; while nine patients were discharged with mild or even no MR.

Prof. Vahanian, Principal Investigator at Bichat-Claude Bernard Hospital, Paris, who planted five patients noted, "We have been waiting for a long time for a transcatheter treatment for mitral regurgitation that can reproduce an effective surgical technique. The preliminary results we now have with Cardioband suggest that the Cardioband can do it."

Valtech Cardio plans to expand the study in the next few months by recruiting additional leading heart centers throughout Europe. Data from the trial will be used to support and obtain the CE Mark and other international regulatory approvals. Enrollment is expected to be completed in the first half of 2014.