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Edwards Adds To Wide Range Of Approaches To Mitral Repair

by Reed Miller

Harpoon is a minimally invasive surgery device that complements Edwards pipeline of transcatheter mitral and septal valve repair and replacement technologies, which now includes at least six technologies at various stages of development, and is one of the company's top R&D priorities.

Less-invasive mitral valve and tricuspid valve repair is the next major for valve technology now that transcatheter aortic valve replacement (TAVR) systems, like Edwards' market-leading *Sapien* line, are rapidly taking market share from surgical valves, and is being pursued both by the major surgical valve companies, Edwards and *Medtronic PLC* as well as small start-ups like 4C Medical Technologies and MVRx, Inc. But *Abbott Laboratories Inc.*'s *MitraClip* is the only FDA-approved transcatheter mitral repair device. (Also see "*Starts & Stops: Medtronic's TMVR News Closes Big Month For Trial Announcements*" - Medtech Insight, 3 Nov, 2017.)

"We are aggressively pursuing a whole toolbox of therapies for mitral and tricuspid therapies," Edwards CEO Michael Mussallem said during Edwards' Dec. 8 investors conference. "This is a group of patients that's underserved. They just don't have great answers today. And even though it's not clear that we have all the answers, we're optimistic about it, that some of this is underpinned by our success in TAVR, some of it is just because of the enthusiasm we feel from the clinical community, but we're as optimistic as ever about the opportunity here and we're excited about the challenges ahead and what we might be able to do to tackle those."

Bernard Zovighian will lead Edwards' new transcatheter mitral and tricuspid therapies unit. John Barry, who is currently VP-Sales and

Marketing for Surgical Heart Valve Therapy in Europe, will take over as the new head of the Surgical Heart Valve unit.

To help the development of these mitral and tricuspid therapies, Edwards is creating a new Transcatheter Mitral and Tricuspid Therapies unit, to be led by Zovighian. The unit will officially begin operations on Jan. 1, 2018, Mussallem said. Taking over from Zovighian as head of the Surgical Heart Valve unit will be John Barry, who is currently VP-Sales and Marketing for Surgical Heart Valve Therapy in Europe, Mussallem said.

Edwards' mitral repair pipeline includes two mitral valve replacement devices, *Sapien M3* and *CardiAQ*. Sapien M3 is a version of Edwards wildly successful Sapien transcatheter aortic valve repair (TAVR) system adapted for the mitral valve with a proprietary docking device that provides a novel valve anchoring approach. During the investors call, Edwards' Corporate VP for Transcatheter Heart Valves Larry Wood said over 1,700 mitral procedures have already been performed with the Sapien platform, so the company is confident it can be adapted to the mitral valve.

The CardiAQ transseptal mitral valve replacement system, acquired when Edwards bought *CardiAQ Valve Technologies Inc.* for $350m, is undergoing enhancements that will significantly reduce the valve profile and a new transseptal delivery system to make delivery simpler, Edwards' Corporate VP for Strategy & Corporate Development, Donald Bobo, said during the investors meeting. (Also see "*Starts & Stops: Abbott's Inherited Products Add To Spike In Suspensions*" - Medtech Insight, 10 Feb, 2017.)

Also, as a condition of the Valtech deal, Edwards has an option to acquire Valtech's *Cardiovalve* transfemoral mitral valve, which is currently under investigation in the *AHEAD* trial.

Edwards acquired the *Cardioband* transcatheter mitral annulus repair technology when it bought *Valtech Cardio Ltd.*, $690m in 2016. (Also see "*Edwards To Pay Up To $690m For Cardioband-Maker Valtech*" - Medtech Insight, 28 Nov, 2016.) One-year follow-up from 38 patients with significant secondary mitral regurgitation at high-risk for surgery was presented by Francesco Maisano of the Unversity Hospital Zurich at the Transcatheter Cardiovascular Therapeutics meeting in Denver. The results showed that 94% of the patients treated with Cardioband had no worse than moderate mitral regurgitation one year after the procedure. The *ACTIVE* US pivotal trial of Cardioband for mitral regurgitation is currently enrolling patients.

Based on *promising "first-in-human" compassionate-use experience*, Edwards expects to launch the *Pascal* transcatheter mitral leaflet repair system in Europe in 2019. The 120-patient *CLASP* trial of Pascal is currently enrolling patients and Bobo expects it to complete enrollment in 2018.

Edwards is sponsoring trials of Cardioband for tricuspid repair. The 30-patient *TRI-REPAIR* trial of Cardioband to treat tricuspid regurgitation is ongoing in Europe and Edwards expects to earn a CE mark for this indication in 2018. The company is also planning to begin an early-feasibility trial in the US in 2018, Bobo said. (Also see "*Starts & Stops: Valve Repair And Replacement Tech Continues To Attract R&D Investment*" - Medtech Insight, 28 Aug, 2017.) The company is also developing the *Forma* tricuspid valve repair system. So far, 75 patients have been treated with Edwards' *Forma* tricuspid repair system, consisting of a polymer "spacer" and a "rail" delivered to the right ventricular apex via catheter. It reduces tricuspid regurgitation by occupying the regurgitant orifice area while providing a new surface for the coaptation of the valve's native leaflets.

So far, 30-day data from 75-patient treated with Forma, presented at the TCT meeting by Martin Leon of Columbia University showed it can create significant improvements in heart failure functional class and quality of life, but there were a few cases of distal anchor dislodgements and right ventricular perforations. Bobo said the company is working on enhancements for Forma and will resume clinical trials of the device in 2018.

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