Evaluate Vantage

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Neovasc soars as mitral valves head to Europe

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Since December 1 shares in mitral valve group Neovasc are up 340%. A lucrative deal with Boston Scientific last week caused the stock to pop, but the fact that this deal excluded Neovasc's flagship technology, the Tiara valve, and that new clinical data on Tiara are promising, pushed the shares up a further 70% yesterday.

This climb in value is pretty large considering the earliness of the data. The new results are from a pilot study in 30 patients, and with other transcatheter mitral technologies more advanced (see table), shareholders might be a little too enthusiastic.

Neovasc's feasibility study, Tiara-1, is to assess the device's safety in 30 patients with severe symptomatic mitral regurgitation. So far 22 patients have been treated with a technical success rate of 86%. In all 19 patients with technically successful implantations, paravalvular leak levels were reported as mild, trace or absent.

Sparkling

The all cause 30-day mortality rate so far is 15.7%. But this is only part of the primary endpoint, a composite of all-cause mortality and major adverse events, defined as disabling stroke, heart attack, renal failure requiring dialysis, life-threatening bleeding, and cardiac surgical or transcatheter reintervention.

There have been no reported adverse events related to the valve performance. Neovasc said that no device performance issues have observed with Tiara in any patient follow-up. However, analysts from Evercore ISI point out that there have been three cases of device malposition and three cases that were converted to open surgery in Tiara-1, and wrote that they were "unsure if this is a design issue".

The trial is being conducted in very ill patients: those with NYHA Class III and IV heart failure. Around 26% of them had left ventricular ejection fraction (LVEF) of less than 30% – less than a third of the blood in these patients' left ventricles was being pumped out of the chamber with each heartbeat. Medical consensus is that LVEF needs to be above 30% for transcatheter mitral valve procedures.

Race to Europe

No transcatheter valve replacement devices are approved yet anywhere in the world, and as is usual in medtech, European CE mark is the first target.

A 115-patient CE mark approval study of Tiara is due to start early next year. But here Neovasc is likely to trail at least two other technologies.

The European approval trial of Edwards Lifesciences' CardiAQ valve is due to conclude in October 2017 and that for Abbott's Tendyne product in May 2018. Both these companies acquired their valves by buying the companies that initially developed them – the same is true for Medtronic's Twelve device, which has not yet reached the pivotal stage.

Selected active transcatheter mitral valve trials				
Company	**Device**	**Trial description**	**Primary completion date**	**Trial ID**
Edwards Lifesciences	CardiAQ	Relief: Phase I/II, Europe and Canada, 200 patients *	October 2017	NCT02722551
Edwards Lifesciences	CardiAQ	Phase I, US, 28 patients	December 2016	NCT02718001
Abbott Laboratories	Tendyne	US, Europe and Australia, 110 patients *	May 2018	NCT02321514
Neovasc	Tiara	Tiara II: Europe, 115 patients *	Unknown; trial starts Q1 2017	-
Neovasc	Tiara	Tiara I: US, Europe and Canada, 30 patients	August 2017	NCT02276547
Medtronic	Twelve	Europe, 10 patients	July 2017	NCT02428010
* *CE mark approval trials*				

Neovasc is one of the few remaining independent mitral valve companies. And it has recently narrowed its focus, selling its biotissue business to Boston last week; Tiara is almost the only thing it has left.

This deal was reminiscent of the one signed by Edwards Lifesciences a few days earlier, in which it bought all the assets of Valtech Cardio except its mitral valve, Cardiovalve, for $340m (*Edwards gets everything but the valve, November 29, 2016*). Cardiovalve does not appear to be in any active clinical trials, however, and in any case Edwards already has CardiAQ.

But transcatheter mitral valve replacement is forecast to take off in a huge way, with Leerink analysts saying the addressable market is worth $9bn. Even if Neovasc's technology is third to the European market it might still be worth having. That said, potential acquirers – and it is perhaps of note that Boston is the only major CV company without a horse in the mitral race – might wish to wait until the full data from Tiara-I are available.

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