



News releases

Edwards Receives European Approval for Advanced SAPIEN 3 Valve

IRVINE, CA, January 27, 2014 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced that it has received CE Mark in Europe and is initiating the launch of its most advanced transcatheter aortic valve, the Edwards SAPIEN 3 valve.

The SAPIEN 3 valve builds upon Edwards' decades of experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves. The new valve has an outer skirt -- a cuff of fabric surrounding the valve frame -- providing a seal to address paravalvular leak. The effectiveness of this solution is supported by the limited clinical experience(1, 2), as detailed in two first-in-human feasibility studies, which demonstrated that significant paravalvular leak was eliminated during transcatheter aortic valve implantation (TAVI).

The SAPIEN 3 valve is the only commercial transcatheter heart valve that can be delivered through a low-profile 14 French expandable sheath (eSheath), which has shown through early clinical experience a low rate of complications(1, 2). The valve can be implanted through multiple approaches: transfemoral, transapical or transaortic. Once implanted, the discreet valve anchors in the aortic annulus.

"European physicians have been eagerly awaiting the launch of the Edwards SAPIEN 3 valve, and we are very excited to make it available today. It has a unique design intended to provide a simpler procedure, along with fewer post-procedural complications and a faster recovery for patients," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves. "Based on our clinical leadership in transcatheter heart valves, we believe the SAPIEN 3 valve's characteristics and procedural refinements have the potential to transform TAVI for both physicians and patients."

In the United States, the Edwards SAPIEN 3 valve is an investigational device being studied in the PARTNER II Trial and is not yet available for sale in the country.

About Edwards Lifesciences

Edwards Lifesciences is the global leader in the science of heart valves and hemodynamic monitoring. Driven by a passion to help patients, the company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring, enabling them to save and enhance lives. Additional company information can be found at www.edwards.com (<http://ctt.marketwire.com/?release=1084659&id=3826816&type=1&url=http%3a%2f%2fwww.edwards.com%2f>).

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements include, but are not limited to, Mr. Wood's statements and statements regarding the expected launch of the Edwards SAPIEN 3 valve, design features and expected product benefits and procedural outcomes. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement.

Forward-looking statements involve risks and uncertainties that could cause the roll-out and benefits of the technology to differ materially from those expressed or implied by the forward-looking statements based on a number of factors including but not limited to unexpected outcomes after more expanded clinical experience, unexpected changes or delays related to product supply, potentials for unexpected regulatory or quality developments, and customer acceptance. These factors are detailed in the company's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2012.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, SAPIEN XT, SAPIEN 3, eSheath, PARTNER and PARTNER II are trademarks of Edwards Lifesciences Corporation.

(1) Binder RK, Rodés-Cabau J, Wood DA, et al. Transcatheter Aortic Valve Replacement With the SAPIEN 3: A New Balloon-Expandable Transcatheter Heart Valve. *J Am Coll Cardiol Interv.* 2013;6(3):293-300. doi:10.1016/j.jcin.2012.09.019.

(2) Dvir D, Barbanti M, De Larocheiliere R, et al. TCT-787 Preliminary Clinical Experience using the SAPIEN 3 device. *J Am Coll Cardiol.* 2013;62(18_S1):B239. doi:10.1016/j.jacc.2013.08.1539.

#

Contact Information :

Media Contact: Sarah Huoh 949-250-5070

Investor Contact: David K. Erickson 949-250-6826

<input type="text" value="Search Edwards.com"/>

Follow Edwards on:



- (http://www.edwards.com/)
- About us (/aboutus/home)
- Careers (/careers/lifesciences)
- Investors (http://ir.edwards.com)
- MRI safety (/mri-safety)
- Contact us (/aboutus/contactus)
- Product ordering (/product-ordering)
- Site map (/sitemap)
- Legal terms (/legal/legalterms)
- Privacy policy (/legal/privacypolicy)

(/)

© 2020 Edwards Lifesciences Corporation.
All rights reserved.