Boston Scientific

Boston Scientific Prevails in U.S. Edwards Lifesciences Litigation

Delaware Court Rules Edwards Lifesciences Infringes Boston Scientific Patent

MARLBOROUGH, Mass., Dec. 11, 2018 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced that a jury in the United States (U.S.) District Court for the District of Delaware determined that the Boston Scientific U.S. patent 8,992,608 is valid and that Edwards Lifesciences' Sapien 3™ Aortic Valve infringes this patent and that Edwards owes Boston Scientific infringement damages through the end of 2016. Additional damages and interest incurred from 2017-2018 will be determined by the court in post-trial motions.

The jury also found that the Boston Scientific LOTUS™ Aortic Valve System does not infringe Edwards' Spenser patents U.S. 7,510,575, U.S. 9,168,133, or U.S. 9,339,383.

"We continue to be encouraged by the sustained record of positive legal rulings, first in European courts and now in the U.S., which upholds our company's intellectual property," said Desiree Ralls-Morrison, senior vice president, general counsel and corporate secretary, Boston Scientific.

The LOTUS system features an adaptive sealing technology, which creates an external seal to prevent leakage around the valve known as paravalvular leak or PVL, which is a proven predictor of mortality.[i,ii,iii] The company anticipates the LOTUS™ Edge Valve System will be commercialized in CE mark countries in Q1 2019 and in the U.S. in mid-2019, pending FDA regulatory approval timelines.

The LOTUS valve is one of two valve systems in the Boston Scientific structural heart portfolio. Boston Scientific currently offers the ACURATE *neo*™ Aortic Valve System in key European markets and is also seeking a CE mark application for the next-generation valve system, the ACURATE *neo*2™, which it intends to commercialize during the first half of 2019.

The LOTUS Edge Aortic valve system is an investigational device in the U.S. and is not available for sale. It is pending CE Mark.
The ACURATE neo™ and ACURATE neo2™ Aortic Valve Systems are not available for use or sale in the US.
The LOTUS Valve System is currently not available for use or sale.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains 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. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, clinical trials, regulatory approvals, litigation strategy and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

[i] Kodali SK et al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. *N Engl J Med* 2012; 366:1686-1695

[ii] Tamburino C et al. Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis. *Circ.* 2011;123:299.

[iii] Abdel-Wahab M et al. Aortic Regurgitation After Transcatheter Aortic Valve Implantation: Incidence and Early Outcome. Results from the German Transcatheter Aortic Valve Implantation Registry. *Heart* 2011;97:899-906.

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