Boston Scientific

Boston Scientific Prevails In U.K. Edwards Lifesciences Litigation

U.K. Court Affirms that Edwards Lifesciences Infringes Boston Scientific Patent

MARLBOROUGH, Mass., March 28, 2018 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced the U.K. Court of Appeal dismissed Edwards Lifesciences' appeal and upheld a prior court decision that Edwards' Sapien 3™ device infringes Boston Scientific patent EP (UK) 2 926 766 and that all claims of that patent are valid.

"We are pleased with another positive ruling from the European courts which further substantiates our intellectual property," said Desiree Ralls-Morrison, senior vice president, general counsel and corporate secretary, Boston Scientific. "We see the U.K. court's decision as an important validation of our patents and supports our goal to bring differentiated solutions to patients suffering from severe and symptomatic aortic valve stenosis."

Separately, the company plans to appeal the U.S. Patent Office's recent Inter Partes Review finding that certain claims of the Boston Scientific U.S. patent 8,992,608 asserted against Edwards are invalid.

Boston Scientific currently offers the ACURATE *neo*™ Aortic Valve System in key European markets. The company is also seeking CE mark application for the next-generation valve system, the ACURATE *neo2*™, and intends to commercialize the new valve later this year as well as begin a pivotal clinical study for U.S. regulatory filing.

The ACURATE family of valve products is one of two valve systems in the Boston Scientific structural heart portfolio. The LOTUS™ Valve System features an adaptive seal, 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 continues to have a goal to return the LOTUS Valve to the European market and launch in the U.S. in 2019, pending its ability to clear certain technical and regulatory hurdles.

The ACURATE neo™ Aortic Valve Systems are not available for use or sale in the US.
The ACURATE neo2™ Aortic Valve System is not available for use or sale.
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.

CONTACTS:

Media:
Timette Nevala
Boston Scientific Corporation
763-494-1284 (office)
Timette.Nevala@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
(508) 683-5565 (office)
investor_relations@bsci.com

[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.

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/2018-03-28-Boston-Scientific-Prevails-In-U-K-Edwards-Lifesciences-Litigation