Boston Scientific

Boston Scientific Prevails In European Patent Dispute With Edwards Lifesciences

European Patent Office Revokes Edwards Lifesciences '550 Patent

MARLBOROUGH, Mass., April 16, 2018 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it, along with several other opponents, successfully opposed Edwards Lifesciences Corporation's European patent EP 2,399,550 ('550) in the European Patent Office (EPO), resulting in a revocation of the patent.

The '550 patent was the only Edwards patent that Boston Scientific was found to infringe in the March 2017 German District Court litigation between the companies and is also the sole basis of Edwards' infringement action against Boston Scientific in Ireland. While Edwards has the right to appeal the EPO's decision, Boston Scientific believes the Edwards patent revocation will have a positive impact on both suits. As to the Boston Scientific patents that Edwards was found to infringe in March 2017 – EP 2 749 254 B1 ('254) and EP 2 926 766 B1 (766) – the German Court of Appeal will hear arguments in May and June of this year.

Following last month's U.K. Court of Appeal's decision confirming that Edwards' Sapien 3™ device infringes the Boston Scientific '766 patent and that all claims of that patent are valid, the U.K. High Court has scheduled a hearing for the week of May 14, 2018 to determine what, if any, exception or limitation should be made to allow for Edwards to continue to supply the Sapien 3 valve in the U.K.

Boston Scientific currently offers the ACURATE *neo*™ Transcatheter Aortic Valve System in key European markets. The company is also seeking CE mark application for the next-generation transcatheter aortic valve implantation (TAVI) 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 TAVI 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.

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[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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