Boston Scientific

Boston Scientific Prevails in German Edwards Lifesciences Litigation

Court Rules Edwards Lifesciences' Next-Generation Valve Infringes Boston Scientific Patent and Grants Right to Enjoin Sales in Germany

MARLBOROUGH, Mass., Oct. 23, 2018 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced the District Court of Dusseldorf, Germany has determined that Edwards Lifesciences Corporation's Sapien 3 Ultra™ device infringed a patent – established by Symetis SA, a subsidiary of Boston Scientific – specific to the fabric used on the valve seal, specifically the German part of European Patent (EP) 2 949 292 B1. The Dusseldorf Court ruled in preliminary injunction proceedings that Boston Scientific has the right to enjoin Edwards and its German subsidiary from offering and selling Sapien 3 Ultra in Germany. The infringement and injunction decision can be appealed by Edwards.

In 2017, Edwards' currently-available Sapien 3™ device was found to infringe two Boston Scientific patents (EP 2 749 254 B1 and EP 2 926 766 B1) by the same Court. Those rulings, which have been appealed by Edwards, enable Boston Scientific to enjoin Sapien 3 from the German market. The company has not yet exercised that option.

"We are pleased with the steady cadence of European court rulings which uphold and validate our TAVR intellectual property against competitive encroachment," said Desiree Ralls-Morrison, senior vice president, general counsel and corporate secretary, Boston Scientific. "Defending our patents is a core necessity which allows us to continue to innovate and offer differentiated technologies to hospitals, physicians and their patients."

Boston Scientific currently offers the ACURATE *neo*™ Transcatheter Aortic Valve System in key European markets and is seeking a CE mark for the next generation system – ACURATE *neo*2™ Transcatheter Aortic Valve System – which it intends to commercialize during the first half of 2019. The company expects to begin a pivotal clinical study of the ACURATE *neo*2 system in the U.S. later this year.

The ACURATE family of valve products is one of two TAVI valve systems in the Boston Scientific structural heart portfolio. The Company anticipates the LOTUS™ Edge Valve System will be commercialized in CE mark countries in Q1 2019 and FDA approval to be secured in mid-2019, pending regulatory approval timelines.

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 Edge™ 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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