Medtronic News

Update on CoreValve Federal District Court Ruling; Court Agrees to Expedited Appeal

MINNEAPOLIS - April 21, 2014 - Medtronic, Inc. (NYSE: MDT) today issued an updated statement on the recent ruling by Federal District Court of Delaware. The ruling granted in part Edwards Lifesciences' motion for a preliminary injunction that prevents Medtronic from selling or offering to sell its CoreValve® System in the United States, except through a mechanism that Medtronic is pursuing with Edwards Lifesciences that would allow currently trained sites to treat patients with CoreValve based on a physician's medical judgment. The injunction will go into effect on April 23.

Medtronic has asked the U.S. Circuit Court of Appeals to postpone the injunction until it can determine if the injunction was properly issued. The Court has not yet ruled. Medtronic also requested, and the Court agreed to, an expedited appeal of the injunction ruling, and other underlying legal issues, with the last appeal brief to be submitted by June 19. Medtronic does not believe Edwards Lifesciences, which brought the motion for a preliminary injunction, has met the standards needed for an injunction, particularly with respect to the impact it will have on the public health interest.

As written in the District Court order, Medtronic and Edwards Lifesciences have entered into discussions in an effort to agree on a mechanism that will enable physicians at facilities currently trained on CoreValve 'to make clinical, patient-by-patient determinations as to whether to implant [CoreValve or the Edwards device] without being constrained by the number of CoreValve...available.' On May 21, Medtronic and Edwards are to report the status of these discussions to the District Court, but if an agreement is reached before that time, it may be implemented.

To date, Medtronic has made numerous offers to Edwards to ensure patients have continued access to this life saving technology. The Company is striving for a near term solution that addresses patient interest completely, but not one that selectively and arbitrarily controls who has access to a device they need and who does not, regardless of where they live in the United States. Medtronic is committed to this.

Medtronic will diligently work toward developing mechanism that will allow physicians to use their medical judgment to determine clinical use of CoreValve under the injunction.

Patient and Physician Support

During this uncertain time, Medtronic's greatest concern is to support patients and physicians. Patients and physicians in the U.S. who have questions about CoreValve System may contact the Medtronic LifeLine at 1-877-526-7890. Medtronic will actively work with them to ensure, to the greatest possible extent under the terms of the injunction, that patients' needs for the CoreValve System can be met under these dire and unusual circumstances.

Background on the Appeal

The patent in question in this case is the Andersen '552 patent. *This patent expired in May 2012* Medtronic's appeal is based on its belief that both Edward's and the trial court have inappropriately applied patent term extension provisions beyond what U.S. patent law allows.

The statutes and case law in this area clearly establish that a patent term extension does not apply to all claims of the expired patent. First, an extended patent only applies to the product upon which the extension was based, Sapien, and CoreValve is not a copy of Sapien, or even based on a similar design or concept. Therefore, the patent is not enforceable against CoreValve during this extension period. Second, during the extended term of a patent on a medical device, the only claims that are enforceable are those that apply to the specific U.S. Food and Drug Administration ("FDA") evaluated product and its approved indications for use available to customers at the time of patent expiration. At the time of the May 2012 patent extension, Sapien

was approved by the FDA for transfemoral procedures for patients with annulus sizes between 18mm and 25 mm inclusively, and who were determined to be inoperable for open aortic valve replacement.

Beyond the clear, clinically established differences between Medtronic's Nitinol based, self-expanding stent design and Edward's stainless steel based, balloon expandable design, Edwards did not at the time of Anderson patent expiration, nor does it today, have an FDA-approved product capable of serving patients with larger valves including annular sizes greater than 25mm.

Medtronic estimates that more than 50 percent of U.S. patients with aortic stenosis at extreme risk for surgery - a patient group with a one-year expected mortality of 50 percent - cannot be served by the currently approved Edwards device.

"It is highly unusual for an injunction to be enforced on a therapy that the patent-holder cannot replace, and it is virtually unheard of that an injunction would be enforced against a unique, life-saving therapy," said John Liddicoat, M.D., president of the Structural Heart business at Medtronic.

About CoreValve

The CoreValve System received approval from the FDA in January. Based on the strength of the clinical data, the FDA quickly reviewed and approved the CoreValve System for patients at extreme risk for surgical valve replacement in January. The CoreValve System is not yet approved in the U.S. for other patient groups.

Last month, data presented at the American College of Cardiology (ACC) annual meeting and simultaneously published in *The New England Journal of Medicine* showed that patient results with CoreValve System were superior to surgical aortic valve replacement (SAVR) at one year in patients at increased risk for surgery. This is the first time a prospective, randomized study has shown any transcatheter aortic valve to be superior to surgery.

Upon reviewing the CoreValve Trial's results for high risk patients, the FDA determined it has sufficient information to evaluate the safety and efficacy of the Medtronic CoreValve System for this patient group without the need for an external expert panel. As such Medtronic anticipates FDA approval of the CoreValve System for high risk patients sometime this summer.

The Courts' rulings have no impact on the sale or marketing of CoreValve outside of the United States or the use of CoreValve in the current U.S. clinical trials.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

Contacts:

Kathleen Janasz
Public Relations
+1-763-526-3676

Jeff Warren
Investor Relations
+1-763-505-2696

---

https://news.medtronic.com/2014-04-21-Update-on-CoreValve-Federal-District-Court-Ruling-Court-Agrees-to-Expedited-Appeal