SonaCare Medical Receives FDA Clearance for its Sonablate® High Intensity Focused Ultrasound Prostate Ablation Device

SonaCare Medical Receives FDA Clearance for its Sonablate® High Intensity Focused Ultrasound Prostate Ablation Device

Charlotte, NC (PRWEB) October 13, 2015 -- SonaCare Medical, LLC, a pioneer in minimally invasive high intensity focused ultrasound (HIFU) technologies, announced today that it received de novo clearance from the U.S. Food and Drug Administration (FDA) to market the Sonablate® 450 in the U.S. for the ablation of prostate tissue. Sonablate® is the first High Intensity Therapeutic Ultrasound (HITU) device to receive FDA regulatory authorization for prostate tissue ablation. SonaCare Medical expects to begin U.S. distribution this October.

“The FDA regulatory authorization to market Sonablate® in the U.S. is a milestone for non-invasive prostate care and a tremendous gain for men’s health,” said Mark Carol, MD, Chief Executive Officer of SonaCare Medical. “Men all over the world, in the more than 49 countries where it has already been authorized for use, have had access to this technology for prostate ablation. There are numerous peer reviewed articles attesting to its value in ablating the prostate while minimizing the occurrence of side effects. Our company is appreciative of the collaborative efforts made on the part of the FDA to bring this technology to the U.S.”

Sonablate® trial investigator Michael Koch, MD, Chairman of the Department of Urology at Indiana University comments, “I believe that we are at a pivotal point in prostate care. Simultaneous advances in imaging, fusion technologies, and now more focused therapies are going to allow us to precisely diagnose prostate conditions, and ablate these targeted areas rather than perform whole gland prostate surgery, which carries a significant burden on quality of life. HIFU will become the work-horse of subtotal prostate therapy.”

Herbert Lepor, MD, Professor and Martin Spatz Chairman, Department of Urology NYU School of Medicine, who also participated in the Sonablate® trial, further comments, “HIFU is a novel technology that has been used worldwide to ablate prostate tissue. Until now, this technology was not available in the U.S. It is anticipated that ablative urological surgeons in the U.S. will quickly master and adapt this technology for their patients. HIFU offers the opportunity for the precise delivery of ablative energy to the prostate. Thus, it can be adapted to whole gland or focal gland ablation.”

“The FDA’s decision on Sonablate® is an important step in providing men with prostate conditions access to this less invasive approach. We hope that focused ultrasound will eventually become a standard of care for treating the prostate,” said Neal Kassell, MD, Chairman of the Focused Ultrasound Foundation.

Sonablate® is the Company’s second medical device to receive U.S. FDA regulatory authorization, complementing the 510(k) cleared Sonatherm® laparoscopic HITU ablation device. “With the authorization to sell Sonablate® in the U.S., we can now offer a full HIFU surgical suite of technologies working off of the same basic platform and providing benefits throughout health care centers,” said Mark Carol.

“In addition,” Dr. Carol continued, “this de novo clearance, together with the CE Mark for Sonablate®500, will facilitate additional regulatory authorizations in markets beyond Europe and North America, further strengthening our world-wide market leadership in therapeutic HIFU devices.”

About SonaCare Medical, LLC
SonaCare Medical is a world leader in minimally invasive focused ultrasound (HIFU) technologies. SonaCare Medical is committed to developing focused ultrasound related technologies that support precise and innovative procedures for the treatment of a range of medical conditions. SonaCare Medical, with its subsidiary Focus Surgery, Inc., designs and manufactures medical devices, including the following: Sonablate®, which has 510(K) clearance in the U.S. under a De Novo regulatory classification; Sonablate® 500, which has CE Marking and has obtained regulatory authorization in more than 49 countries outside the U.S.; Sonatherm® laparoscopic HIFU surgical ablation system, which has 510(K) clearance in the U.S., has CE Marking and has obtained regulatory authorization in more than 30 countries outside the U.S.

For additional information, visit www.SonaCareMedical.com

Forward Looking Statements. The Company's forward-looking statements are based on management's current expectations and assumptions regarding the Company's business and performance, the economy and other future conditions and forecasts of future events, circumstances and results. As with any projection or forecast, forward-looking statements are inherently susceptible to uncertainty and changes in circumstances. The Company's actual results may vary materially from those expressed or implied in its forward-looking statements. Any forward-looking statement made by the Company speaks only as of the date on which it is made. The Company is under no obligation to, and expressly disclaims any obligation to, update or alter its forward-looking statements, whether as a result of new information, subsequent events or other factors.
###

Contact Information
Sandra Stein
SonaCare Medical
http://www.sonacaremedical.com
+1 7048171167

Online Web 2.0 Version
You can read the online version of this press release here.