

CANCER ABLATION BY WATER VAPOR.

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Francis Medical Announces Completion of Enrollment in the VAPOR 2 Pivotal Study for Vanquish Prostate Cancer Treatment

MINNEAPOLIS (February 25, 2025) – <u>Francis Medical, Inc.</u>, a privately held medical device company developing an innovative and proprietary water vapor ablation therapy for the treatment of prostate, kidney, and bladder cancer, today announced completion of enrollment and initial treatments in the company's VAPOR 2 pivotal clinical study.

VAPOR 2 is a prospective, multicenter, single-arm study treating 235 patients with intermediaterisk, localized prostate cancer at 26 U.S. clinical sites. Data gathered from the VAPOR 2 study will support 510(k) clearance of the Vanquish device, which the company expects to file for in July 2025. Patients will continue to be followed for a period of five years to gather longer-term cancer outcomes. Dr. Samir Taneja from NYU Langone and Dr. Arvin George from Johns Hopkins are coprincipal investigators on the study.

"We are thrilled to announce the completion of enrollment in the VAPOR 2 study ahead of our expected timeline," said Dr. Taneja. "For a study of this scale to finish enrollment early is a remarkable achievement and speaks to the dedication of our participating investigators and the level of excitement surrounding this promising technology."

As the second most common cancer in U.S. men, the American Cancer Society estimates 1 in 8 American men will be diagnosed with prostate cancer during their lifetime. Prostate cancer is a serious disease often treated with therapies that cause complications, such as urinary incontinence and erectile dysfunction. Francis Medical's Vanquish device's thermal water vapor energy technology is a breakthrough therapy designed to use phase shift energy stored in sterile water vapor to convectively transfer thermal energy to cancerous tissue, causing cell death. Through this process, damage to surrounding structures can be minimized or eliminated by respecting the prostate's natural boundaries. Vanquish aims to be a revolutionary cancer therapy that is tough on cancer yet gentle on patients.

"We are incredibly proud of the entire team for achieving this key milestone," said Michael Kujak, president and CEO of Francis Medical. "This success is the result of seamless collaboration between our employees, investors, investigators, research coordinators, and, most importantly, the patients. The entire Francis Medical team extends its heartfelt thanks to all the VAPOR 2 participants for partnering with us to help move closer to a kinder, gentler treatment for prostate cancer."

"Francis Medical's primary focus has always been on creating a better experience for patients," said Michael Hoey, founder and chief technology officer of Francis Medical. "It's extremely rewarding to see the years of hard work and dedication from so many people beginning to make a tangible difference in the quality of life for men suffering from prostate cancer."

About Francis Medical:

Francis Medical is committed to developing urological cancer treatments that are tough on cancer and gentle on patients, with a compassionate belief that minimally invasive therapies can effectively treat cancerous tissue. The inventor, Michael Hoey, founded Francis Medical as a tribute to and legacy of his father, Francis Hoey, who endured prostate cancer treatments that had harsh implications on his everyday life before he died from the disease in 1991. Unfortunately, current prostate cancer treatments, which come with side effects like urinary incontinence and erectile dysfunction, are not much different than what Francis Hoey encountered. In contrast, water vapor technology applies the thermal energy stored in sterile water vapor to treat cancerous tissue via a simple transurethral procedure, potentially minimizing life-altering side effects. For more information on Francis Medical, visit www.francismedical.com or call (763) 951-0370.

Vanquish Water Vapor Ablation System is currently an investigational device for treating prostate cancer.