CANCER ABLATION BY WATER VAPOR.

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FOR IMMEDIATE RELEASE

Francis Medical Receives U.S. FDA Breakthrough Device Designation for Vanquish Minimally Invasive Prostate Cancer Therapy

MINNEAPOLIS (August 1, 2023) – Francis Medical, Inc., 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 that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its Vanquish minimally invasive water vapor ablation therapy.

Breakthrough Device Designation expedites the review of innovative technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. To qualify for a Breakthrough Device Designation, a device technology must show that it has the potential to provide a more effective treatment than current standards of care. The goal of the program is to help patients have more timely access to these medical devices by expediting their development, assessment and review.

As the second most common cancer in U.S. men, the American Cancer Society estimates one in eight 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 water vapor technology applies the thermal energy stored in a few drops of sterile water to deliver targeted treatments to the cancerous tissue through a simple transurethral procedure. The therapy is designed to ablate cancer cells while protecting surrounding structures, lessening the likelihood of life-altering side effects common with other prostate cancer treatments.

"The goal of Francis Medical is to become the first line therapy of choice for patients with prostate cancer," said Michael Kujak, Francis Medical president and chief executive officer. "We are excited that the FDA has recognized the potential of our technology to be a breakthrough for patients who today face the difficult choice between addressing their cancer and avoiding the debilitating morbidities often associated with current standards of care."

The company is currently in the process of initiating their VAPOR 2 pivotal study in support of an FDA submission for U.S. market clearance. The VAPOR 2 study will treat 235 patients with

localized, intermediate-risk prostate cancer at up to 30 centers in the U.S. Further information on the VAPOR 2 clinical study can be found at clinicaltrials.gov (NCT05683691).

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 company's foundation is a tribute to and legacy of the inventor's father, Francis Hoey, who endured prostate cancer treatments that had harsh implications on his everyday living before the disease took his life in 1991. Unfortunately, current prostate cancer treatments are not much different from what Francis Hoey encountered, with the typical side effects including urinary incontinence and erectile dysfunction. In contrast, water vapor technology applies the thermal energy stored in sterile water vapor to 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.