CANCER ABLATION BY WATER VAPOR.

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FOR IMMEDIATE RELEASE

Francis Medical Announces Positive Data from VAPOR 1 IDE Study for Water Vapor Ablation of Prostate Cancer

MINNEAPOLIS (June 8, 2021) – 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 positive results from the company's VAPOR 1 clinical study evaluating the safety and efficacy of the company's minimally invasive water vapor ablation therapy for treating prostate cancer.

VAPOR 1 is a prospective, multicenter, single-arm study that treated 15 patients with intermediate-risk, localized prostate cancer at four U.S. clinical sites. The data is from the six-month primary endpoint, including safety and efficacy outcomes, and VAPOR 1 study patients will continue to be followed to one year. Study participants had unilateral cancer (one side of the prostate), with a treatment intent of ablating only the impacted side (hemi ablation). The VAPOR 1 six-month data reported no serious adverse events, no device-related adverse events, and no unanticipated adverse device effects. Additionally, the effectiveness results support findings that demonstrate water vapor technology can reach and treat all prostate regions (apex, mid, base, anterior, and posterior) and eradicate intermediate risk, Grade Group 2 (GG2, Gleason Score 3+4), prostate cancer. In 87% of patients, six-month biopsy results indicate no ≥ GG 2 (clinically significant) disease on the treated side. In three patients, results on the treated side showed a single positive biopsy core with ≤ 5% involvement (low volume) of GG1 (Gleason Score 3+3) disease.

The safety profile reflects low levels of adverse events for the patient population treated, with no patients reporting urinary incontinence requiring pad usage and one (6.7%) patient reporting moderate erectile dysfunction (with medication indicated). These promising results support the intent of this therapy to manage clinically significant disease while decreasing morbidities associated with currently used prostate cancer treatments. Francis Medical will use the safety and efficacy data from the VAPOR 1 study to support a pivotal trial with its next-generation device and U.S. regulatory approval.

"I am excited to be participating in the VAPOR 1 trial," said Dr. Christopher Warlick, head of the Department of Urology at the University of Minnesota and principal investigator in the VAPOR 1 study. "Currently, urologists commonly use water vapor to successfully treat benign prostatic hyperplasia (BPH). The VAPOR 1 results are very encouraging and suggest the viability of water

vapor technology to treat prostate cancer as well. This approach has the potential to provide appropriate men a simple outpatient procedure to manage their prostate cancer with minimal risk of the debilitating side effects often seen with other therapies."

As the second most common cancer in U.S. men, the American Cancer Society estimates one in nine American men will be diagnosed with prostate cancer during their lifetime. Prostate cancer is a serious disease for which current treatment options often cause complications such as urinary incontinence and erectile dysfunction. Francis Medical's water vapor energy technology applies the thermal energy stored in a few drops of sterile water to deliver targeted treatments to the cancerous tissue in 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.

"We are thrilled with the results from VAPOR 1," said Michael Kujak, Francis Medical president and chief executive officer. "We want to thank all of the VAPOR 1 investigators, their support staff and the patients suffering from prostate cancer who volunteered to participate for the extraordinary efforts required to execute this study through the worst of the COVID-19 pandemic. The excellent results of VAPOR 1 confirm our belief that this groundbreaking technology will ultimately become the first-line treatment of choice for men and their doctors."

"The VAPOR 1 results are the culmination of the hard work and shared vision of the entire Francis Medical team," said Michael Hoey, Francis Medical founder and chief technology officer. "At Francis Medical, the patient is always first and foremost in our minds. Therefore, it is extremely gratifying to provide the patients in VAPOR 1 with not only an effective treatment for their cancer, but also one that produced minimal pain and side effects, allowing them to quickly return to their normal activities. We continue to work hard every day to realize our shared goal to bring this therapy to every man who can benefit from it."

On the heels of these results, Francis Medical is currently in the process of raising Series B financing to fund their VAPOR 2 pivotal study.

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.