

Corporate News

August 27, 2019

MagForce AG: MagForce USA, Inc. Completed Enrollment and Treatment for Stage 1 and Prepares for Next Stage of its Pivotal, Single-Arm Study for the Focal Ablation of Intermediate Risk Prostate Cancer with NanoTherm Therapy

- *Successful validation of standardized clinical procedure for instillation of nanoparticles in first patient cohort*
- *Initial findings in this cohort show only minimal treatment-related side effects which were tolerable and similar to those commonly associated with biopsies*
- *Next stage of clinical trial is being initiated with three well-respected urological centers in the US who actively enrolled patients in Stage 1*

Berlin, Germany, and Nevada, USA, August 27, 2019 - MagForce AG (Frankfurt, Scale, Xetra: MF6, ISIN: DE000A0HGQF5), a leading medical device company in the field of nanomedicine focused on oncology, together with its subsidiary MagForce USA, Inc., today announced the successful completion of the first stage of its pivotal clinical US study for the focal ablation of intermediate risk prostate cancer. MagForce has defined the clinical procedure and standardized the NanoTherm particles instillation process. Initial findings from the first patients have shown that with the changes to the NanoActivator and the defined instillation procedure, MagForce has observed only minimal side effects that have not only significantly improved over the studies in Germany, but are very similar to those associated with a routine biopsy. The Company will now proceed with the next stage of its study in a larger patient cohort.

"We are pleased that NanoTherm therapy continues to show great potential for the treatment of intermediate risk prostate cancer. After working diligently with the study investigators, medical technicians and patients, we were not only able to successfully develop a standardized clinical procedure but also demonstrate a favorable safety and tolerability profile that now allows us to expeditiously proceed with the next stage," **said Ben Lipps, CEO of MagForce AG and MagForce USA, Inc.** *"We are more confident than ever, that the registration trial will prove that NanoTherm therapy can focally ablate prostate cancer lesions and allow men diagnosed with prostate cancer to maintain a higher quality of life, while delaying or even avoiding definitive treatment and known side effects."*

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High medical need for a new less invasive, effective and well-tolerated treatment option

The purpose of this focal ablation registration study, which will enroll up to 120 men in a single arm study, is to demonstrate that NanoTherm therapy can focally ablate cancer lesions with minimal side effects for patients who have progressed to intermediate risk prostate cancer stage and are under active surveillance. By destroying these cancer lesions, it is anticipated that patients will be able to remain in Active Surveillance Programs and avoid definitive therapies such as surgery or whole gland radiation with their well-known side effects as long as possible.

“Even as the treatment landscape for prostate cancer has evolved, there remains an important unmet need for patients who have progressed to the medium-risk stage and for whom the benefits of treatment with current methods come with a significant risk of related side effects. NanoTherm therapy has the potential to significantly change the way we treat prostate cancer, because it allows for a less invasive, less aggressive treatment modality that could cure the cancer or, at a minimum, reduce a patient’s chances of needing a more aggressive treatment in the future,” **Dr. Thompson III of the Texas Urology Group said.** *“About 30,000 men die of prostate cancer every year in the US. With NanoTherm therapy, we hope we can continue to reduce those numbers while avoiding the cost of surgery or radiation for some of those men.”*

Building on previously conducted whole gland studies in Germany more than 10 years ago, the first stage of the study, conducted in a relatively small patient cohort with 10 patients, was designed to develop a standardized clinical focal procedure for humans with normal perfusion within the prostate. The procedure allows for accurate instillation of the NanoTherm particles with the latest, cutting-edge biopsy technology available into the targeted human prostate Region of Interest at the required concentration to destroy the cancerous cells with minimal side effects.

Based on the positive findings from Stage 1, MagForce will now proceed with the next stage of the study with urological specialist centers – Texas Urology Group, University of Texas, San Antonio, and University of Washington, Seattle. To further bolster recruitment and ensure broader geographic coverage as well as allow for more patients to be treated simultaneously, MagForce has added a third study site in the Eastern region of the United States in Sarasota, Florida at the Sarasota Inverventional Radiology Center lead by Dr. Gerald Grubbs.

To minimize the time needed for patient treatment, MagForce USA will streamline the focal procedure and with FDA approval, MagForce will offer the streamlined focal therapy to the patients who enroll in the next stage of MagForce’s pivotal study.

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About MagForce AG and MagForce USA, Inc.

MagForce AG, listed in the Scale segment of the Frankfurt Stock Exchange (MF6, ISIN: DE000A0HGQF5), together with its subsidiary MagForce USA, Inc. is a leading medical device company in the field of nanomedicine focused on oncology. The Group's proprietary NanoTherm® therapy enables the targeted treatment of solid tumors through the intratumoral generation of heat via activation of superparamagnetic nanoparticles.

NanoTherm®, NanoPlan®, and NanoActivator® are components of the therapy and have received EU-wide regulatory approval as medical devices for the treatment of brain tumors. MagForce, NanoTherm, NanoPlan, and NanoActivator are trademarks of MagForce AG in selected countries.

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