

Corporate News

April 28, 2020

MagForce AG: MagForce USA, Inc. has received FDA Approval to proceed with its Streamlined Trial Protocol for the next Stage of Pivotal U.S. Single-Arm Study for the Focal Ablation of Intermediate Risk Prostate Cancer with the NanoTherm Therapy System

- *Following the FDA's approval of a streamlined trial protocol, the next stage of the U.S. focal ablation study can now commence*

Berlin, Germany, and Nevada, USA, April 28, 2020 - 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., announced that FDA approval for a streamlined trial protocol, for the next stage of the Company's pivotal U.S. study with the NanoTherm therapy system for the focal ablation of intermediate risk prostate cancer was received. The next stage of the clinical trial is being initiated with three well-respected urological centers in Texas, Washington and Florida who actively enrolled patients in Stage 1.

The streamlined procedure will allow patient treatment to be completed within one day at one of MagForce's three out-patient treatment facilities. This is possible because of the limited side effects that were observed at each step of the procedure in Stage 1.

The next stage of the study will be conducted in phases to ensure early on that the minimal side effects observed in Stage 1, with a drawn out procedure, are maintained in the streamlined one day procedure. Treatment of the first 5 to 10 subjects should be sufficient to affirm the minimal side effects as expected.

MagForce USA has completed Stage 1 and the results have shown the following important successes:

The development and validation of a standardized clinical procedure: MagForce USA had to develop a new procedure, parts of which will be patented. The new procedure places the NanoTherm in a clinical targeted volume (CTV) of less than 2 to 4cc of volume in the human prostate and provides for a true focal ablation therapy. By modifying the thixotropic nature of the NanoTherm, an increase in viscosity of 100 times was achieved, which allowed NanoTherm to remain at the reverse biopsy instillation site and allow time for the NanoTherm conjugation to occur stabilizing the NanoTherm particles in the CTV. Initial findings show only minimal treatment related side effects, which were tolerable and similar to those commonly associated with biopsies. The ablation analysis showed very well-defined ablation and cell death in the region of the nanoparticle deposit as it was observed with the previous pre-clinical studies.

"We are very pleased to have received FDA approval for the next stage our pivotal U.S. prostate cancer study," said Ben Lipps, CEO of MagForce AG and MagForce USA, Inc. "Initial findings shown in Stage 1 were encouraging demonstrating a favorable safety and tolerability profile as well as well-defined ablation and cell death in the region of the nanoparticle deposit. Our positive experience from this initial phase resulted in a streamlined trial protocol for the next stage of our trial."

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The purpose of the focal ablation registration study, which will enroll up to 120 men in a single arm study, is to demonstrate that NanoTherm therapy system 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.

The American Society of Clinical Oncology reports that in 2019, it was estimated that there were 174,000 new cases of prostate cancer in the United States and in spite of advances in diagnosis and treatment an estimated 31,000 deaths occurred. Clearly, early diagnosis and MagForce's Focal Therapy has a strong chance to reduce the death rate for prostate cancer.

COVID-19 impact: While there are many restrictions that have been applied such as "Shelter at Home" and eliminating state to state travel via car or via plane; however, MagForce is still working diligently with its physician investigators. Exemptions exist for healthcare workers, such as MagForce's USA staff at MagForce USA clinical facilities. Clearly MagForce USA can conduct the trial in its out-patient facilities and has developed COVID-19 infection control procedures for staff and study subjects. All this effort has caused a certain delay but MagForce is confident the next stage of the clinical trial will not be unduly delayed since MagForce USA will conduct the trial from its facilities.

MagForce is still hopeful that the COVID-19 pandemic will not cause significant delay beyond 2020 to complete this single-arm clinical trial.

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 system 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.

For more information, please visit: www.magforce.com

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assumptions, which may be subject to a variety of risks and uncertainties. The results actually achieved by MagForce AG may substantially differ from these forward-looking statements. MagForce AG assumes no obligation to update these forward-looking statements or to correct them in case of developments, which differ from those, anticipated.

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