MagForce AG: MagForce USA, Inc. Announces Completion of Patient Treatment in Stage 2a of Pivotal U.S. Single-Arm Study for the Focal Ablation of Intermediate Risk Prostate Cancer with the NanoTherm Therapy System

- Stage 2a confirms positive findings of stage 1 - only minimal and tolerable treatment-related side effects observed – also with streamlined procedure
- Preparations for stage 2b with three MagForce USA sites are underway, trial will focus on offering a treatment alternative to intermediate risk prostate cancer patients to that of definitive therapy
- Despite ongoing restrictions due to COVID-19, MagForce is hopeful that the next stage of the clinical trial will not be unduly delayed since MagForce USA will conduct the trial from its own treatment centers

Berlin, Germany, and Nevada, USA, February 8, 2021 - 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., announces that patient treatment in Stage 2a of its pivotal U.S. study with the NanoTherm therapy system for the focal ablation of intermediate risk prostate cancer has been completed.

Initial findings of Stage 2a showed in a 10-patients group that only the expected minimal treatment-related side effects, which are tolerable and similar to those observed in Stage 1 with an extended procedure, could be maintained in the streamlined procedure. The findings from Stage 1 demonstrated a favorable safety and tolerability profile as well as well-defined ablation and cell death in the region of the nanoparticle deposit. Upon FDA approval, this streamlined procedure will allow patient treatment to be completed within a single day.

“Although expected, we are very happy that the findings indicate the streamlined study procedure will benefit patients by completing the entire treatment within one day, thus minimizing the burden of repeated clinical visits. We experience the importance of this especially in times of the current pandemic with its heightened anti-infection protocols, and I am even more grateful for all patients participating in our clinical trial despite the increased effort due to testing and quarantine this means for every single one of them,” said Ben Lipps, CEO of MagForce AG and MagForce USA, Inc. “Now, we prepare the start of the final Stage 2b of our focal ablation study, which is expected in early Q2. Immediately upon FDA approval we will start commercialization, which is still expected for the second half of 2021, assuming that the COVID-19 situation eases in spring.”

The next and final Stage 2b of the clinical trial is being initiated with MagForce’s three Focal Treatment Centers in Texas, Washington and Florida. Stage 2b will focus on offering a treatment alternative to immediate risk prostate cancer patients to that of definitive therapy.
The purpose of this focal ablation registration study, which will enroll up to 120 men in a single arm study, is to demonstrate that the 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 reported in 2020 an estimated 191,930 new cases of prostate cancer in the United States. In spite of advances in diagnosis and treatment, an estimated 33,330 resulting deaths occurred. Clearly, early diagnosis and MagForce's focal therapy have 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,” exemptions exist for healthcare workers, such as MagForce’s USA staff at the Company’s clinical facilities. Clearly MagForce USA can conduct the trial in its out-patient facilities and has developed COVID-19 infection control protocols for staff and study subjects. These additional safety measures have caused a certain delay, but MagForce is hopeful that the next and final Stage of the clinical trial will not be unduly delayed since MagForce USA will conduct the trial from its own treatment centers.

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.

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