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Corporate News

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MagForce AG: Enrollment in Stage 2b of Pivotal U.S. Study for the Focal Ablation of Prostate Cancer with the NanoTherm Therapy System successfully underway following IRB approval

- *Stage 2b of the single arm study will enroll up to 100 men who have progressed to intermediate risk prostate cancer stage and are under active surveillance*
- *First patients enrolled; Patient recruitment proceeding well, treatments will be conducted at NanoTherm treatment centers owned and operated by MagForce*
- *The clinical trial is expected to be completed in summer 2022, the interim data packages supplied earlier will then be updated and submitted to the FDA for approval*

Berlin, Germany and Nevada, USA, December 20, 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., announced today that enrollment of patients in Stage 2b of its pivotal U.S. study with the NanoTherm therapy system for the focal ablation of intermediate risk prostate cancer is successfully proceeding.

Following FDA approval to initiate Stage 2b with the final study protocol in November, MagForce USA, Inc. has since received the green light from the ethics commission ("Institutional Review Board", IRB) to proceed with the study at the respective centers. After IRB approval, MagForce has now enrolled the first patients into the clinical trial while continuing to reach out to pre-identified potential study participants for updated testing and preparations. Up to 100 men diagnosed with intermediate risk prostate cancer that has progressed to a stage where a clinical review and treatment change is required will be enrolled at the NanoTherm treatment centers owned and operated by MagForce.

"We are happy that enrollment in Stage 2b of our pivotal US study has successfully commenced and that the recruitment process is progressing well, despite once again surging Covid-19 cases. Stage 2b builds on the positive findings of earlier studies which demonstrated safety and efficacy of our approach and importantly, showed no treatment-related side effects frequently experienced with other therapies, such as sexual, urinary or gastrointestinal dysfunction or loss of energy. We are excited about the trials' potential results and are hopeful to be able to provide prostate cancer patients with a minimally invasive and highly accurate treatment option," said **Ben Lipps, CEO of MagForce AG and MagForce USA, Inc.**

Stage 2b of the single-arm pivotal study is planned to evaluate the use of NanoTherm ablation for the treatment of prostate cancer patients with intermediate grade lesions and confirm the favorable results seen in Stage 2a in a larger patient population. The trial is designed to demonstrate that the NanoTherm therapy system can focally ablate targeted prostate cancer lesions with minimal side effects.

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Subsequently the patients should then be able to return to active surveillance without definitive treatment, such as external beam radiation or prostatectomy.

MagForce previously reported encouraging findings from Stage 1 and 2a of its pivotal study confirming a highly favorable safety and tolerability profile. Treatment with the NanoTherm therapy system showed no unanticipated serious adverse events but only minimal treatment-related side effects, which were tolerable and similar to those commonly associated with biopsies.

Based on the current plan and conditions set out by the FDA, the clinical trial is expected to be finished in summer 2022. Following the final protocol, MagForce will submit interim data packages at 15 and 30 patients treated for FDA review, whilst treatments continue, which will be updated and submitted for approval after trial completion.

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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