

Corporate News

October 13, 2021

MagForce AG: MagForce USA, Inc. has Received FDA’s Conditions for Approval of the Final Protocol of the Pivotal U.S. Study for the Focal Ablation of Prostate Cancer with the NanoTherm Therapy System

Berlin, Germany and Nevada, USA, October 13, 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 the U.S. Food and Drug Administration (FDA) has provided MagForce USA, Inc. with the conditions for approval of the final clinical protocol for the clinical study for the focal ablation of prostate cancer. These conditions consist of clarifications of definitions and additions of certain administrative measures to the protocol.

MagForce is pleased that the FDA’s conditions include using the final protocol in Stage 2b with targeted biopsy to assess effectiveness. MagForce believes the FDA conditions are reasonable, and files the necessary documentation with the authority. MagForce expects to receive final clearance to commence Stage 2b in November 2021. Until then patient screening will be expedited at MagForce’s NanoTherm treatment centers.

Stage 2b and the final protocol of the single-arm pivotal study are planned to evaluate the use of NanoTherm ablation as a method of treating prostate cancer patients with intermediate grade lesions, thereby allowing up to 100 patients to return to active surveillance without definitive treatment such as external beam radiation or prostatectomy. The subjects will have intermediate risk prostate cancer but their prostate cancer has progressed to a stage where a clinical review and treatment change is required. The trial is designed to demonstrate that the NanoTherm therapy system can focally ablate targeted prostate cancer lesions with minimal side effects. The streamlined procedure will continue to be used for the remainder of the clinical trial.

The Stage 2a findings affirmed the highly favorable safety and tolerability profile already demonstrated in Stage 1. As expected, treatment with the NanoTherm therapy system in Stage 1 and Stage 2a showed no unanticipated or serious adverse events and only minimal treatment-related side effects, which were tolerable and similar to those commonly associated with biopsies.

Also, Stage 2a was meant to improve the accuracy of instillation. This was successfully achieved to more than 90 percent coverage of the clinical target volume, resulting in a greater NanoTherm particle mass in the clinical target. Due to this good coverage, all subjects had sufficient deposit heating during the activation and pathologically confirmed ablation in the clinical target volume (CTV) including the cancer present in this CTV. At the same time, there were no indications of ablation beyond 1 mm to 2 mm of the NanoTherm deposit in the surrounding healthy tissue.

MagForce USA will continue to conduct the clinical trial in its own treatment centers and does currently not expect major delays in carrying out and completing the trial with the final protocol. MagForce will submit interim data packages at 15 and 30 patients treated for FDA review, whilst treatments continue.

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Based on the current plan and conditions set out by the FDA, the clinical trial is expected to be completed in summer 2022. Following trial completion, the interim data packages supplied will be updated and submitted to the FDA for their approval.

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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