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06/05/2019 – GBC Management interview with Dr. Ben Lipps, CEO of MagForce AG

Company: MagForce AG[*5a,5b,11]
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**catalogue of potential conflicts of interests on page 6*

MagForce AG, which is specialized in the field of nanomedicine with a focus on the treatment of malignant brain tumors (glioblastoma) and prostate cancer, has made further progress in recent months. The Company currently has EU-wide certification for glioblastoma treatment and is also seeking approval in the US for the treatment of prostate cancer. MagForce CEO Dr. Ben Lipps spoke to GBC analyst Cosmin Filker about the latest company development.

Cosmin Filker: In early 2018 the FDA approved a clinical trial for the treatment of prostate cancer and in July 2018 the first patient was already recruited. What is your assessment regarding the current clinical trial progress?

Dr. Ben Lipps: The trial you are referring to is our pivotal, staged, single-arm study that will enroll up to 120 men. We want to demonstrate that NanoTherm therapy can focally ablate prostate cancer lesions with minimal side effects.

As background, this is the very first time that MagForce is applying NanoTherm therapy as a focal treatment. Although the NanoTherm therapy is recognized and approved as a device, the FDA considered our nanoparticles as a drug in 2015. During 2016 and 2017, MagForce re-conducted the ten-year-old studies to the latest FDA preclinical standards. MagForce demonstrated to the FDA, that the nanoparticles remain at the injection site and do not wander in the patient's body, and thus can be classified as medical device rather than as drug, as opposed to a classification as a drug, which would have required years of very expensive clinical testing to obtain approval.

After having reviewed all the safety data and new preclinical data that MagForce provided in 2016 and 2017, the FDA granted us Investigative Device Exemption (IDE), which allowed us to start patient recruiting at the first clinic in July 2018. This was a major achievement for MagForce in bringing our innovative prostate cancer treatment to the patients.

As part of Stage I of this clinical trial, we took the required time and focused our work during the past months on precisely injecting our NanoTherm particles into the targeted human prostate Region of Interest (ROI).

In this context, MagForce diligently worked to quantify the effect of prostate perfusion and optimized the nanoparticle infusion process with the latest, cutting-edge biopsy technology that is available for surgeons. We introduced a standardized process for the instillation of the particles, to ensure that it is equal across all study physicians. Based on

our experience so far, we anticipate to show with successful completion of Stage 1 that there are only minimal treatment-related side effects which are tolerable and similar to those commonly associated with biopsies.

Cosmin Filker: You previously mentioned, that you had to show to the regulators that you can precisely instill the nanoparticles into the lesions. Could you explain this in more detail?

Dr. Ben Lipps: Of course. 10 years ago, the technology to conduct targeted biopsies did not exist. Today, we are using this cutting-edge technology (MRI-ultrasound fusion biopsies technology) to instill the NanoTherm particles but we are utilizing a different injection needle. However, contrary to the isolated whole prostate gland studies that were conducted 10 years ago, our objective is to contain the nanoparticles in the 2-4 cc of the suspected cancerous region – the lesion. This focal application required an injection speed of about 1/5 of the speed used in the old whole gland study to allow for the NanoTherm particles to conjugate in the region of interest, which ensures they will remain in that region. During the treatments so far, we have shown that NanoTherm particles can be accurately instilled in the targeted treatment area in the minimally invasive procedure.

Cosmin Filker: This means that the original timetable for the planned marketing authorization as of late 2019 is not valid anymore? What could an updated possible schedule look like?

Dr. Ben Lipps: After the extensive work over the past months, I do not think it is realistic for us to commercially launch NanoTherm therapy in the US in 2019. Please keep in mind that this is the very first time that such an innovative focal treatment approach to ablate prostate cancer lesions has been tested on patients in the US. In Stage I, MagForce has to proceed diligently with the first 10 patients, as we define the therapy to be used in the next 100-patient stage. This process cannot and should not be rushed in the very best interest of the physicians but most importantly the patients.

However, in 2019 we will proceed with introducing the ambulatory NanoActivator chair to select urology programs, so called Active Surveillance Programs, to allow gaining experience with training phantoms, which are commonly used for new urological procedures. My new target for commercialization is 2020. The delay is due primarily to the extra effort MagForce USA had to perform to achieve device status for our nanoparticles – like I said before: as opposed to a classification as a drug, which would have required years of very expensive clinical testing to obtain approval. However, our nanoparticles are the only nanoparticles with a device status.

Cosmin Filker: So, patient recruitment is key. Are you confident to be able to successfully enroll the requested amount of prostate cancer patients?

Dr. Ben Lipps: Yes, absolutely. As mentioned before, we have now extended patient enrollment to three urological centers - Texas Urology Group, University of Texas, San Antonio and University of Washington, Seattle. All three of them are currently continuing to actively enroll male patients aged 40-85 that are diagnosed with intermediate risk prostate cancer to be treated at one of the two US study sites, the University of Washington Medical Center in Seattle and the CHRISTUS Santa Rosa Hospital - Medical Center in San Antonio. We are very fortunate to be working together with such well-respected partners for the recruitment with their extensive reach.

Within the near future, we will be setting up a third site in the Eastern region of the United States.

The University of Washington (UW) Medicine group consists of a network of hospitals and clinics that reach from Olympia to Bellingham, Washington, a catchment area housing of as well nearly six million people. Through their extended network, e.g. partnerships with the Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center, one of the top ten cancer research facilities in the country, and the willingness of patients to travel for cancer care, this number is even significantly higher. An initial evaluation of the electronic health records system at UW Medicine shows 30,000 patients with prostate cancer diagnoses currently being cared for by UW. The San Antonio/Austin and South Texas region alone has a similar catchment area housing nearly six million people.

The therapy procedure in the next stage is projected to require a one-day stay at one of MagForce's NanoActivator facilities. Therefore, patients can be recruited from across the USA in addition to the catchment areas surrounding the MagForce facilities.

Cosmin Filker: The MagForce technology is already certified in Europe for the treatment of glioblastoma. Recently, you announced the installation of the first mobile treatment center in Poland. How is the response so far?

Dr. Ben Lipps: Immediately when we began treating patients commercially in Germany in late 2015 and early 2016, we saw an elevated interest for the therapy in patients from Poland. In 2018, MagForce had over 700 inquiries and about 40% of these inquiries were from Poland. With our NanoActivator in Poland, these patients have a significantly reduced economic burden to receive treatment since non-NanoTherm therapy procedures are all reimbursed in Poland and they receive the treatment in their home country.

Consequently, only the NanoTherm therapy must be funded by private pay or crowdfunding until MagForce can get reimbursement for the NanoTherm patients.

Cosmin Filker: What is the rollout strategy for Europe and Germany?

Dr. Ben Lipps: Due to the aggressive nature of glioblastoma, there is a narrow window for patients to receive treatment. In order for patients to benefit from our NanoTherm therapy, access has to be fast. To this end, the goal of our European roll-out plan is to establish treatment centers in selected European countries to allow patients to be treated in their homeland. Mobile treatment center enable us to place the devices more quickly and cost-effectively by avoiding protracted construction and allowing for easy integration into existing hospital infrastructure. Although the highest interest in our therapy stems from patients from Poland we also register high numbers of patient inquiries from Italy and Spain and are currently in negotiations with an Italian and a Spanish clinic. In addition, we are delighted to report, that additional hospitals in Germany have displayed strong interest in our therapy and we expect to open another treatment center in Germany, too.

Cosmin Filker: To what extent is achieving reimbursement by health insurances in Europe and in the USA decisive for the use of the MagForce technology?

Dr. Ben Lipps: Achieving reimbursement is of course an important factor when it comes to selecting a treatment plan. The reimbursement in Germany so far was achieved in a rather lengthy process for each individual patient/case. As previously communicated, we now have the number of cases necessary for the NanoTherm treatment centers to be able to negotiate their budgets with the health insurance providers. These negotiations are currently ongoing and we support the clinics in every way we can in order to achieve the best possible result and facilitate the reimbursement process.

Cosmin Filker: MagForce AG entered into a financing agreement with the European Investment Bank (EIB) totaling € 35 million. Will the EIB financing ensure sufficient funding until the comprehensive market entry in the USA and Europe?

Dr. Ben Lipps: Over the past two years, we have secured the necessary funding to drive MagForce through our next inflection points and execute our strategy. Moreover, the EIB loan offers us financial flexibility to pursue our goals. With that said, I would still never rigorously exclude any financial transaction as we need to remain flexible to operate successfully and continue to evaluate all options open to us.

Cosmin Filker: Finally, another question for investors with a long-term investment horizon: Where do you see MagForce AG in five years?

Dr. Ben Lipps: With the encouraging results we have seen so far from our pivotal study, our confidence in our NanoTherm technology and unique therapy feature remains high. I am positive that, after approval in the US, MagForce will generate revenues north of 200 million Euro in five years from now with a very favorable profit margin.

Cosmin Filker: Dr. Lipps, thank you for your time.

ANNEX

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