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## 02/09/2022 – GBC Management interview with Dr. Ben Lipps, CEO of MagForce AG

Company: MagForce AG<sup>\*5a,5b,11</sup> ISIN: DE000A0HGQF5 Analyst: Cosmin Filker Date (time) of completion: 09/02/2022 (12:30 pm) Date (time) of first distribution: 09/02/2022 (1:30 pm) \*catalogue of potential conflicts of interests on page 6

In the past fiscal year 2021, MagForce AG made progress in both business segments. Of particular note here is the approval granted by the FDA for the start of Stage 2b for the treatment of prostate cancer patients. This means that the pivotal study could be concluded as early as summer 2022. In parallel, the treatment capacities for the indication glioblastoma are to be expanded in Europe. GBC analyst Cosmin Filker spoke to MagForce CEO Dr Ben Lipps about the latest development:

### Cosmin Filker: In December 2021, you reported that patient recruitment for Stage 2b is successfully underway. What is the current status on this?

**Dr Ben Lipps:** Yes, that is correct. We are thrilled, that the first men have been enrolled and the patient recruitment is proceeding well.

Let me elaborate on this: In November we received FDA approval to initiate Stage 2b with the final study protocol. This was a necessary pre-condition to also receive the green light from the ethics committees ("Institutional Review Board", IRB) in the respective states to proceed with the study at each center.

In preparation for Stage 2b, we already pre-identified eligible patients in the areas around the treatment centers owned and operated by MagForce so that we could start the trial immediately. With both FDA and IRB approvals having been granted, those pre-selected candidates are currently being invited into the clinics for updated testing and preparations and for official recruitment into the study. In addition, we are of course continuing screening activities. We are looking to enroll men with intermediate risk prostate cancer that has progressed to a stage where a clinical review and treatment change is required.

We were very pleased that the strong interest in enrollment, which we also saw during the previous stages of the study from prostate cancer patients and their attending physicians remains strong. This reflects the high medical need in this indication and continues to encourage our confidence in the potential of a well-tolerated and effective treatment option for prostate cancer. Our approach could significantly change the way prostate cancer is treated, as it allows for a less invasive, less aggressive treatment modality that could cure the cancer or, at a minimum, reduce a patient's chances of needing a more definitive treatment in the future.



## Cosmin Filker: When can the first results be expected and do you still consider the timetable, according to which the completion of the study is expected for summer of 2022, to be up-to-date?

**Dr Ben Lipps:** Indeed, based on the current plan and conditions set out by the FDA, we target to finish patient treatments in late summer 2022. In parallel, we will submit interim data packages at 15 and 30 patients treated for FDA review, whilst treatments continue. These packages will be updated and submitted for approval after trial completion.

As studies such as ours require face to face interaction, the spread of the new COVID-19 virus variants and a surge in diagnosed cases over the winter months also had an effect on our recruitment. Fortunately, the structure we implemented in the U.S., where our centers for the focal treatment of prostate cancer are set-up as stand-alone units, independently from hospitals, enables us to conduct the clinical registration study despite COVID-19. Because cancer does not halt in the face of the pandemic - and neither do we.

To further mitigate any pandemic impacts and accelerate the process, we have contracted additional urological practices – so-called reference centers - in proximity to our study sites in Florida, Texas and Washington. Two of this practices are already actively screening patients with the onboarding process for the third practice currently underway. All reference centers run own Active Surveillance programs and will screen their respective patient base for eligible subjects, i.e. men diagnosed with low-intermediate risk and intermediate-high risk prostate cancer for which a clinical review and treatment change is required. Following screening, the patients will be referred to MagForce, and we will be handling the study recruitment and treatment process.

So, all in all, we are confident that we can proceed in a swift and timely manner with the patient treatments of Stage 2b.

### Cosmin Filker: Once FDA approval is granted, how soon could you start commercial treatments?

**Dr Ben Lipps:** We expect to start commercialization immediately upon FDA approval. This might seem ambitious at first glance, but the way we have set-up our study was specifically aimed at supporting a seamless transition. To avoid delays between approval and start of commercial treatments, we decided to conduct the clinical study at centers owned and operated by MagForce. This way the Focal Cancer Treatment Centers are already established and operational once the study concludes with staff well-versed in the therapy and treatment.

Our strategy is to continue to operate those stand-alone Focal Cancer Treatment Centers as this will allow MagForce USA to bill for the entire procedure, including the instillation of the nanoparticles. Operating proprietary treatment sites enables MagForce to more efficiently utilize its devices and significantly increase revenue per patient. This should enable us to generate up to threefold revenues compared to just selling the NanoTherm particles. In addition to our current locations in San Antonio, Texas; Seattle, Washington; and Sarasota, Florida, which will be our immediate commercial locations, we plan to have additional proprietary treatment centers in place still in 2022. In subsequent years, we will continue to open up Focal Cancer Treatment Centers in strategic locations in the U.S. in order to treat patients locally.

It is estimated that there were 209,500 new cases of prostate cancer in 2020 in the USA alone and despite advances in diagnosis and treatment options, an estimated 31,000 deaths occurred according to the American Society of Clinical Oncology. Our focal abla-



tion approach targets patients who have progressed to intermediate prostate cancer stages and are under active surveillance. By destroying smaller cancer lesions, it is anticipated that patients will be able to remain in Active Surveillance programs and avoid, for as long as possible, definitive therapies such as surgery or whole gland radiation with their well-known side effects. The addressable market in the USA alone is worth USD 4.1 billion per year considering the revenue from the entire procedure.

# Cosmin Filker: Last year you signed a cooperation agreement with a Spanish clinic, so the European roll-out for glioblastoma treatment could gain momentum. When will the market entry take place here and which countries are still in focus?

**Dr Ben Lipps:** The collaboration, you are referring to, is the partnership with Complejo Hospitalario Integral Privado – or CHIP - in Málaga, headed by the General Director Toni Serra together with the treating neurosurgeon Prof. Miguel Angel Arraez. We signed it in September last year. Spain is one of our initial target countries and the center's strategic location will allow access to our therapy for a large number of patients from Andalusia, further regions of Spain but also for patients from other countries abroad.

The private clinic CHIP will be equipped with MagForce's 'plug-and-treat' solution - a mobile container fully operational with a pre-installed NanoActivator device. As you may know, as of May 2021, all European-based medical device manufacturers must comply with the requirements of the new Medical Device Regulation ("MDR"), which will subsequently require new MDR certification for each of the devices that are part of our NanoTherm Therapy system. We expect to be among the first companies to deploy devices under the new MDR certificate in the first half of 2022. Subject to all inspections and permissions by local authorities being granted, we expect commercial treatments to start in the second half of 2022.

To add to Germany, Spain and our very active center in Poland, our next focus country will be Italy. There we also received high interest through clinics who would like to start with the NanoTherm Therapy system. Additionally, we saw a significant rise in patient inquiries from Italy, as a result of pursuit for further therapy options to treat glioblastoma.

However, we have to note that especially in Europe and the indication glioblastoma, the pandemic continues to have a negative impact on our work. The situation in hospitals remains tense and patients still avoid going to the clinics as long as they can for fear of a Covid-19 infection, unfortunately. We are, of course, continuing discussions with other potential locations. In Austria and Germany as well as Italy, advanced negotiations with potential partners are ongoing. However, the respective hospitals have more pressing problems at the moment. Nevertheless, I hope and believe it is quite realistic that we will be able to announce further cooperation agreements this year.

Beyond further partnerships we are always looking at utilizing existing capacities in the best possible way. This includes agreements with public and private clinics in the surrounding areas of our partner hospitals. The model could be, in a nutshell, that the local clinics instill patients with our NanoTherm particles and then transfer them to the next treatment center with a NanoTherm device. This way, with one device per region, considerably more patients can receive treatment, without the need to install additional devices.



### Cosmin Filker: Can you briefly outline the topic of reimbursement by insurance providers? Currently, so-called Investigator-Initiated Trials (IIT) are taking place.

**Dr Ben Lipps:** Reimbursement by healthcare systems of course is an important factor and remains a top priority for us. We are continuously working with experts on solutions for efficient reimbursement processes, both for patients treated in Germany and abroad.

In Germany for example, private patients are currently reimbursed, while public insurances usually cover the treatment costs on a case-by-case request. All patient data collected and filed with our European registry will be used to support budget negotiations with health insurance providers.

The Investigator Initiated Trials, or short IIT, you are referring to, are trials initiated and managed by the hospitals themselves, meaning they are responsible for the legal and regulatory aspects of the trial. While MagForce is not directly involved as a sponsor, we of course support our partners in every way and also benefit from the results.

Both in Poland and Spain, those IITs will support patient reimbursement. The trial at SPSK4 in Lublin is currently underway and has produced encouraging interim data that was presented at two prestigious conferences last year: the 45<sup>th</sup> Congress of Polish Neurosurgeons in Cracow, Poland and the Congress of Neurological Surgeons 2021 in Austin, Texas, USA.

The data will be used to apply to the Agency for Health Technology Assessment and Tariff System in Poland for the reimbursement of NanoTherm therapy as a supplementary treatment.

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

**Dr Ben Lipps:** In five years' time, MagForce will have a fully set-up commercial operation in the US for prostate cancer with full reimbursement. We envision to have a number of strategically positioned centers across the US to provide broad access to patients. By 2027 MagForce should have some 30 centers in the country. Depending on how many shifts are run at each center, they could generate 10m USD of revenues each on average. This would result in US revenues of approx. 300m USD at an EBITDA margin of approx. 60 percent.

In Europe the roll-out will have continued for the treatment of glioblastoma, also providing good geographical coverage with reimbursement set up in most relevant countries and patient treatments far exceeding the approximate break-even point. In addition, MagForce will likely have started to look at further cancer indications by then, including bringing the prostate cancer treatment over to Europe as well as the glioblastoma treatment to the US.

Cosmin Filker: Dr Lipps, thank you for the interview.



### ANNEX

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