

PRESS RELEASE

Memo Therapeutics AG Starts U.S. Pivotal Phase II/III Clinical Trial with AntiBKV for Treatment of BKV Infection in Renal Transplant Patients

- AntiBKV has potential to be first- and best-in-class treatment representing the sole option for large and growing number of patients
- Interim data expected by the end of 2023; on track to reach patients in 2025

Schlieren / Zurich, Switzerland – June 22, 2023 – [Memo Therapeutics AG](#) (“MTx”), a late-stage biotech company developing best-in-class therapeutic antibodies, announced today that the first patient has been enrolled in a pivotal, multicenter U.S. Phase II/III trial of AntiBKV, MTx’s antibody therapeutic that targets BK polyomavirus (“BKV”) infection in renal transplant patients. MTx recently received Fast Track designation for AntiBKV from the U.S. Food and Drug Administration (“FDA”).

“The start of this U.S. pivotal Phase II/III clinical trial with AntiBKV is a significant milestone for us. We believe that AntiBKV, with its 100x more potent neutralization capacity than benchmark antibodies, has great potential to help renal transplant patients. Currently, these patients have no treatment options available to them to fight this dangerous infection. We are very grateful to the clinical teams that have already contributed so substantially and look forward to reporting interim results later in 2023,” said Dr. Jürgen Beck, Chief Medical Officer of Memo Therapeutics AG.

The Phase II part is a randomized, placebo-controlled trial designed to evaluate the therapeutic efficacy of AntiBKV in 60 renal transplant patients with BK viremia. The primary endpoint is the proportion of participants without detectable BKV in the blood at Day 92. Secondary endpoints include the number of participants with at least a reduction of 1 log₁₀ copies/mL change from baseline BK viral load on Day 8, as well as treatment-emergent adverse events (“TEAEs”) up to Day 92. Participants will be randomized to receive either four doses of AntiBKV (1,000 mg) or four doses of placebo (every 4 weeks). An interim analysis will be performed following the Day 92 visit of the last participant. Additional information on the trial can be found by ClinicalTrials.gov Identifier: [NCT05769582](#).

“This is the first time that a pivotal trial treating this devastating infection has been started. Therefore, AntiBKV could be a first- and best-in-class therapeutic addressing the desperate need of kidney transplant patients affected by BKV,” said Dr. Karsten Fischer, Chief Executive Officer of Memo Therapeutics AG. “Based on current development

timelines, we hope to be able to help this large and growing number of patients as soon as 2025.”

BKV infection occurs mostly in childhood and remains dormant in healthy individuals. However, BKV infection poses a significant threat following kidney transplantation, with serious adverse effects on graft function and ultimately patient survival. Due to the immunosuppressive drug regimen transplant patients receive, reactivation of BKV is triggered in 40 to 50% of kidney transplant recipients. Up to 10% then progress to BKV associated nephropathy, which is the leading cause of graft loss. There is currently no disease modifying therapy available to treat BKV infection; it can only be treated by lowering immunosuppression. However, this significantly increases the risk of a graft rejection reaction, leading to impaired functionality and longevity, or graft failure.

MTx is supported by [Vakzine Project Management](#) (“VPM”) based in Hannover, Germany, responsible for translational project management and clinical trial oversight, and by [TFS HealthScience](#) (“TFS”) headquartered in Lund, Sweden, with subsidiaries in Europe and North America, which is responsible for clinical trial management.

About Memo Therapeutics AG

Memo Therapeutics AG (“MTx”) is a late-stage biotech company developing best-in-class therapeutic antibodies to transform the lives of patients with virus infections and cancer. MTx’s lead program, AntiBKV, is a highly effective and safe neutralizing antibody to treat BK virus infection in kidney transplant recipients. This infection can lead to loss of kidney function, as well as organ failure and rejection. MTx’s pipeline consists of additional therapeutic antibodies focusing on infectious diseases, such as cytomegalovirus (“CMV”), undisclosed immuno-oncology targets as well as a partnership with Ono Pharmaceutical.

The product pipeline derives from MTx’s industry-leading throughput and functional screening capabilities, which can cover the entire antibody repertoire. Using its immortal cell libraries and unique nano droplet technology, MTx identifies and isolates the most potent antibodies based on functionality at an unprecedented rate, including discovering ultra-rare antibodies that competing technologies fail to identify. MTx is a private company located in Schlieren / Zurich, Switzerland.

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