

PRESS RELEASE

Memo Therapeutics AG Receives FDA Fast Track Designation for AntiBKV as Treatment of BKV Infection in Renal Transplant Patients

- Pivotal U.S. phase II/III clinical trial has started recruiting patients
- AntiBKV antibody therapeutic has potential to be first- and best-in-class treatment; scheduled to be launched in 2025

Schlieren / Zurich, Switzerland – May 2, 2023 – [Memo Therapeutics AG](#) (“MTx”), a biotech company developing best-in-class therapeutic antibodies, announced today that the U.S. Food and Drug Administration (“FDA”) has granted Fast Track designation to AntiBKV, MTx’s lead antibody therapeutic that targets BK polyomavirus (“BKV”) infection commonly seen in renal transplant patients. AntiBKV has successfully completed a phase I clinical study and following FDA clearance has started actively recruiting patients for a pivotal phase II/III clinical trial.

The FDA’s Fast Track process has been designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. This means important new drugs could potentially get to the patient earlier. There are currently no therapeutics to treat BKV infection.

“Receiving Fast Track designation from the FDA is a significant achievement for Memo, validating the potential of AntiBKV and expediting its development. We believe AntiBKV could be a first- and best-in-class treatment option for kidney transplant patients suffering from BKV infection,” said Dr. Karsten Fischer, Chief Executive Officer of Memo Therapeutics AG. “AntiBKV demonstrated very promising results in our phase I trial. We have recently started recruitment into a pivotal phase II/III clinical trial in the U.S. and plan for a subsequent BLA submission in 2024. We hope then to be able to offer patients a much needed therapeutic option by 2025 at the latest.”

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.

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.

Contacts

Memo Therapeutics AG
Karsten Fischer
media@memo-therapeutics.com

Halsin Partners
Mike Sinclair
+44 (0) 7968 022075
msinclair@halsin.com