Memo Therapeutics AG Announces Phase II Trial Results for Potravitug in Kidney Transplant Recipients with BKPyV Infection

- *Results show biopsy-proven resolution of BK polyomavirus nephropathy in kidney transplant recipients*
- *No safety or tolerability concerns were observed*
- *Supports progression into Phase III development with the potential to transform the treatment landscape for kidney transplant patients with BK polyomavirus infection*
- *Further results from the trial to be presented at the World Transplant Congress in San Francisco, 2-6 August*

Schlieren / Zurich, Switzerland, 25 July, 2025 – Memo Therapeutics AG ("MTx"), a late-stage biotech company translating unique immune responses into superior medicines to treat viral infections and cancer, today announced results from its Phase II clinical trial evaluating potravitug, a highly potent human BK polyomavirus ("BKPyV")-neutralizing monoclonal antibody, for the treatment of BKPyV infection in kidney transplant recipients ("KTR").

The randomized, double-blind, placebo-controlled SAFE KIDNEY II trial enrolled 95 patients across 22 U.S. sites (NCT05769582) to evaluate the clinical effectiveness of potravitug in reducing BKPyV infection in blood and kidney tissue.

While the primary endpoint – undetectable BKPyV DNAemia in blood – was not met with statistical significance, the treatment group demonstrated significantly higher viral response (defined as ≥1 $\log_{10}$ reduction in BK viral load) with resolution of biopsy-proven BK polyomavirus nephropathy ("BKPyVAN") by week 20.

This histological improvement in BKPyVAN indicated resolution of the underlying disease, decreasing from 51.2% at baseline to 31.6% at week 20 in the treatment group, while no change was observed in the placebo group (23.8% vs 24.4%).

The trial also demonstrated that potravitug dosed at 1,000mg achieved a greater reduction in BKPyV DNAemia compared to placebo, with 61.0% of patients receiving potravitug showing a ≥1-$\log_{10}$ reduction from baseline or achieving levels below the lower limit of quantification ("LLOQ") at week 20, compared to 40.5% in the placebo group.

Potravitug had a favorable safety profile with no treatment-related serious adverse events or withdrawals due to adverse events.

"These promising results mark a significant milestone in our mission to develop the first approved treatment for BKPyV infection in kidney transplant recipients," **said Erik van den Berg, CEO of MTx.** "The resolution of BKPyV infection and its associated damage, positions potravitug as a potentially transformative treatment for kidney transplant patients. This was the first placebo-controlled study with prospective kidney biopsies, evaluating the correlation between BKPyV viral load in blood and viral presence in kidney tissue. Based on the data we see a clear path to market for this serious condition, which affects thousands of transplant patients annually."

Nadiesda Costa, MD, MPH, Associate Professor of Medicine, Georgetown University School of Medicine, and Principal Investigator, added: "The results from this trial are exciting and represent a potential breakthrough in the treatment of BKPyV infection in kidney transplant patients, especially given that there are no specific antiviral therapies for BK viremia available. The data showed strong results in demonstrating pathologic improvement in BKPyVAN which, combined with a supportive safety profile, is highly encouraging for future clinical studies."

Based on these exciting results, MTx plans to advance potravitug into Phase III development and engage with regulatory authorities to discuss trial design later this year.

MTx received fast-track designation for potravitug from the FDA in May 2023 in recognition of the high unmet medical need.

Further results from the Phase II clinical trial will be presented at the World Transplant Congress in San Francisco taking place 2-6 August 2025, details below.

Session: LOA04 - Late Breaking Studies in Transplant Infectious Diseases

Title: Potravitug for the Treatment of BK Polyomavirus Infection in Kidney Transplant Recipients: A Phase II, Randomized, Double-Blind, Placebo-Controlled Clinical Trial

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