PRESS RELEASE

Memo Therapeutics AG's Potravitug Granted Orphan Designation in the European Union

- *Orphan designation confers market exclusivity, regulatory and financial benefits for medicines intended to treat rare diseases*
- *Recognizes both medical plausibility of the initial clinical data and that potravitug targets a life-threatening or chronically debilitating condition, BKPyV infection, which affects fewer than 5 in 10,000 people*

Schlieren / Zurich, Switzerland, 7 November, 2025 – Memo Therapeutics AG, a late-stage biotech company translating unique immune responses into superior medicines to treat viral infections and cancer, today announces that the European Commission has granted orphan designation in the European Union (EU) for potravitug, a highly potent human BK polyomavirus ("BKPyV")-neutralizing antibody for the treatment of BKPyV infection in kidney transplant recipients.

Orphan designation in the EU is a status granted to medicines intended to treat rare diseases (affecting fewer than 5 in 10,000 people). To qualify, the disease must be life-threatening or chronically debilitating, and there must be no satisfactory method of diagnosis, prevention, or treatment authorised, or if such a method exists, the new medicine must offer a significant benefit to those affected by the condition. The designation conveys several benefits, including the potential for 10 years of market exclusivity in the EU after approval, reduced or waived European Medicines Agency fees and access to protocol assistance. The granted designation was based on the medical plausibility of the initial clinical data providing support that potravitug might be efficacious in the targeted indication.

"This welcome news highlights the high unmet needs of kidney transplant recipients with BKPyV infection, for which there is currently no approved treatment, and the potential for potravitug to transform outcomes," **said Erik van den Berg, CEO of MTx.** "We will continue our discussions with regulatory authorities and planning for the initiation of a registrational trial next year."

In November 2025, MTx presented data from its Phase II SAFE KIDNEY trial of potravitug, demonstrating a sustained benefit of potravitug in kidney transplant recipients with a significant reduction in viral load and resolution of biopsy-proven BKPyV-associated nephropathy, supporting the role of potravitug as the first targeted therapy in kidney transplant recipients to improve viral clearance and kidney allograft outcome. Memo plans to advance potravitug into Phase III clinical development in 2026.

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

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