

TAVI Forum #12

Potravitug as Treatment of BKV Infection in Kidney Transplant Recipients

Vienna, Austria, April 10th, 2025

Best and first-in-class mAb targeting BK viremia

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High unmet medical need

- **BK virus reactivation** may occur in immunosuppressed kidney transplant recipients and **can lead to significant post-transplantation complications**
- No disease modifying therapy available
- **Significant reduction of graft and patient survival** in kidney transplant patients with BK viremia
- **≈110k kidney transplantations worldwide p.a.** of which **≈24k target population** with risk to develop BK virus associated nephropathy ("BKVAN")

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Best and first-in-class mAb

- FDA **Fast Track Designation** obtained
- Blocking of crucial epitope supports high **functionality and high barrier to resistance**
- **Clinical POC exists** through mAb approach in Phase II ("MAU868")
- potravitug likely to outperform MAU868 given **up to 100x superior neutralization** potency in vitro

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Phase II (POC) data expected in mid-2025

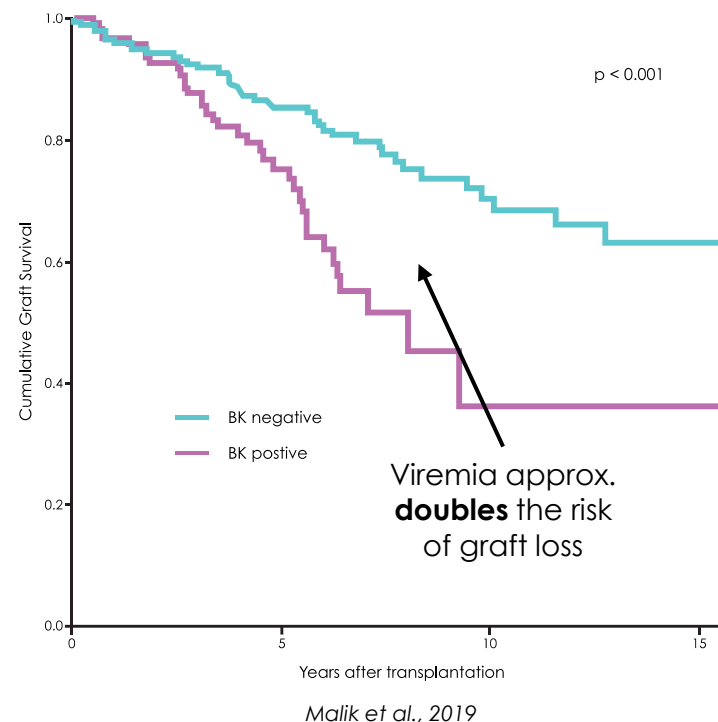
- Phase I successfully completed with **no safety concerns**
- **Phase II (POC) data** expected in **mid-2025**

1 BK viremia in kidney transplant recipients presents a high unmet medical need

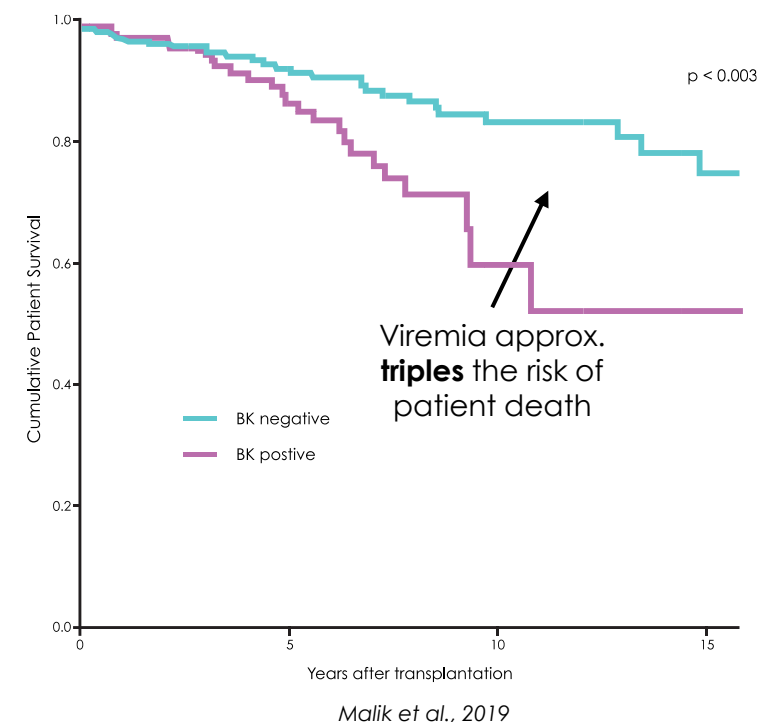
Introduction to BK virus

- Latent in **80-90%** of the **population**
- **Kidney transplant patients** receive immunosuppression leading to **increased risk of BK virus reactivation**
- Kidney transplant patients are routinely monitored for BK viremia
- Patients with BK viremia are at risk for **nephritis, nephropathy** and **graft loss**
- Current standard of care: Reduction of immunosuppression; no treatment available
- **Reconstitution of immunity is slow** resulting in prolonged kidney damaging exposure to viral replication
- Shortage of kidney donors and costly care

Graft survival

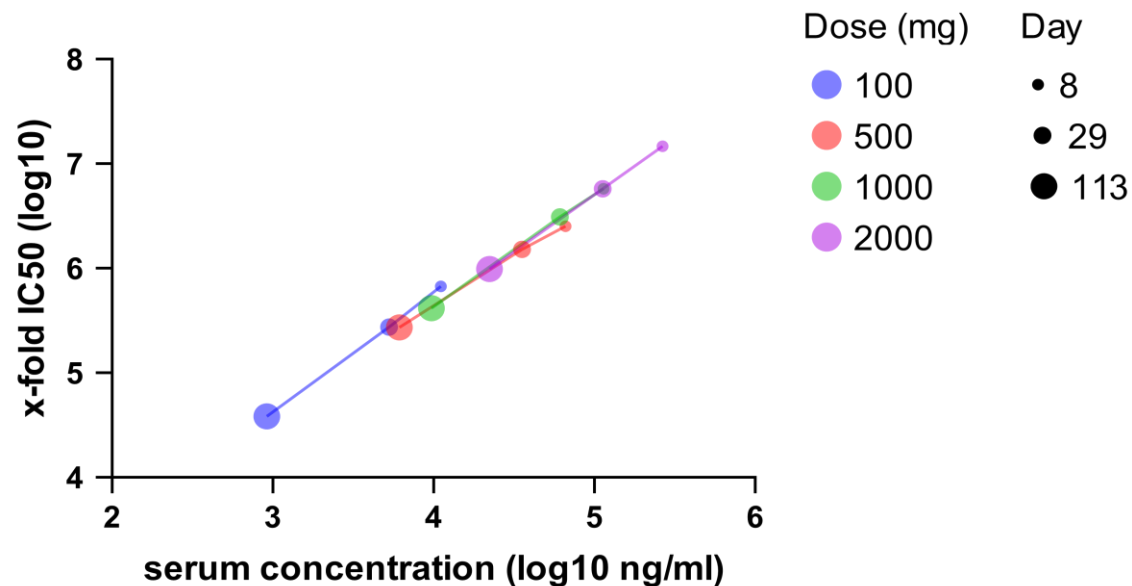


Patient survival



High unmet medical need: no disease modifying therapy available

Potravitug serum concentration correlates with viral neutralization potency in SAD Phase I study

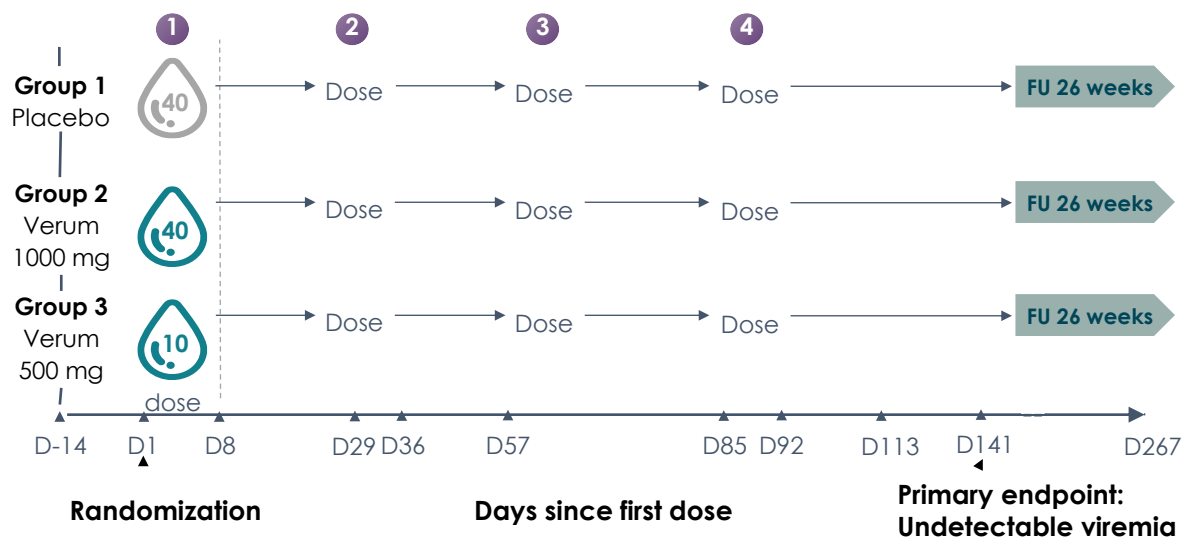


Phase I completed

- Placebo-controlled trial with **40 healthy volunteers**
- Single and multiple ascending doses, **no safety concerns** up to the highest dose of 2,000 mg
- **Pharmacokinetics normal and linear**
- **No ADAs**
- ≈28-day half-life
- High neutralization potency maintained over time

Potravitug is well tolerated with linear kinetics and superimposable concentration and activity

Phase II design



Phase II aligned with FDA

- Double-blind, randomized, placebo-controlled trial with 90 patients (40:40:10)
- 22 sites across the US, representing ≈25% of annual transplantation volume
- **Enrolment and dosing completed**
- Includes patients with **persistent** (>1k copies / ml measured twice) or **high viremia** (>10k copies / ml)
- Dose administration: 4 times a 30-minute infusion of study drug 4 weeks apart
- **Endpoints:** BK viral load below detection, reduction of BK viral load, progression to BKVAN
- **Phase II (POC) data** expected in **mid-2025**
- FDA **Fast Track Designation** obtained



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