

# Safety, Tolerability and Effectiveness of ALVR105 in Kidney Transplant Recipients

**Status:** OPEN TO ACCRUAL

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

- Patients who had a kidney transplant performed greater than or equal to 28 days prior to enrollment
- At least 1 identified, suitably matched Posoleucel (ALVR105) cell line for infusion is available. (If a matching Posoleucel line is not available, the following patient data will be collected: demographic data and human leukocyte antigen [HLA] type.)
- Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in the protocol.
- Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.
- A female patient is eligible to participate if she is not pregnant or breastfeeding, and 1 of the following conditions applies:
- She is a woman of non-childbearing potential (WONCBP) as defined in the protocol
- She is a woman of childbearing potential (WOCBP) and using an acceptable contraceptive method as described in the protocol during the study treatment period and for at least 90 days after the last dose of study treatment. The Investigator should evaluate the potential for contraceptive method failure.

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### Exclusion Criteria:

- Undergone allogeneic hematopoietic cell transplantation
- Evidence or history of graft versus host disease (GVHD) or cytokine release syndrome (CRS).
- Uncontrolled or progressive bacterial or fungal infections
- Known or presumed pneumonia
- Ongoing therapy with high-dose systemic corticosteroids (ie, prednisone dose >0.5 mg/kg/day or equivalent).
- Pregnant or lactating or planning to become pregnant.
- Weight <40 kg.
- Patients who received, or planned to receive abatacept or belatacept, within 3 months of screening

## Conditions & Interventions

### Interventions:

Biological: Posoleucel (formerly known as ALVR105) cells, Biological: Placebo (visually identical to Posoleucel), drug: Viralym-m (alvr105)

### Conditions:

BK Virus Nephropathy, BK Virus Infection, Infectious and Parasitic Diseases (001-139)

## More Information

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**Phase:** II

**IRB**

**Number:** HM20020745

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