Dual-Target Nectin-4/HER2 CAR-NK Cells in Advanced Urothelial Carcinoma

NCT07492628

Status	RECRUITING
Phase	Phase 1
Sponsor	Beijing Biotech
Enrollment	42 participants

Key Eligibility Criteria

Inclusion (10)

- Age 18-75 years at consent.
- Histologically confirmed urothelial carcinoma of the bladder, ureter, renal pelvis, or urethra that is unresectable locally advanced or metastatic.
- Disease progression after, intolerance to, or ineligibility for standard therapy, including platinum-based chemotherapy and PD-1/PD-L1 blockade when appropriate for the patient and region. Prior enfortumab vedotin and prior HER2-directed therapy are allowed, but a fresh biopsy is strongly preferred after the latest systemic regimen.
- At least one measurable lesion per RECIST v1.1.
- Tumor tissue available for central review demonstrating Nectin-4 positivity (for example, IHC e1+ in e10% tumor cells) and HER2 status assessed by IHC/ISH. At least one of the selected therapeutic targets must be present; dose expansion preferentially enrolls Nectin-4-positive disease.

... and 5 more (see full listing online)

Exclusion (10)

- Active or untreated central nervous system metastases or leptomeningeal disease. Previously treated CNS disease is allowed if clinically stable and off escalating corticosteroids.
- Prior allogeneic hematopoietic stem cell transplant, prior solid-organ transplant, or active graft-versus-host disease.
- Clinically significant autoimmune disease requiring systemic immunosuppression within the defined washout window.
- Uncontrolled infection, including uncontrolled hepatitis B, hepatitis C, HIV, sepsis, or active tuberculosis.
- Clinically significant cardiac disease, active myocarditis, unstable angina, recent myocardial infarction, uncontrolled arrhythmia, or clinically meaningful decline in left ventricular ejection fraction that would increase risk from HER2-directed cell therapy.

... and 5 more (see full listing online)

Locations (1 total)

Peking University Shenzhen Hospital, Shenzhen, Guangdong, China