A Safety Study of Enfortumab Vedotin in Indian Adults With Urothelial Cancer

NCT06862219

Status	RECRUITING
Phase	Phase 4
Sponsor	Astellas Pharma Global Development, Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (15)

- Participant has histologically or cytologically confirmed urothelial carcinoma (i.e., cancer of the bladder, renal pelvis, ureter or urethra). Participants with urothelial carcinoma (transitional cell) with squamous differentiation or mixed cell types are eligible.
- Participant must have experienced radiographic progression or relapse during or after a checkpoint inhibitor (CPI) (anti-PD-1 or anti-PD-L1) for locally advanced (LA) or metastatic disease. Participants who discontinued CPI treatment due to toxicity are eligible provided that they have evidence of disease progression following discontinuation. The CPI need not be the most recent therapy. Participants for whom the most recent therapy has been a non-CPI based regimen are eligible if they have progressed / relapsed during or after their most recent therapy. LA disease must not be amenable to resection with curative intent.
- Participant must have received a platinum-containing regimen (cisplatin or carboplatin) in the metastatic / LA, neoadjuvant or adjuvant setting. If platinum was administered in the ajuvant/neoadjuvant setting, the participant must have progressed within 12 months of completion.
- Participant must have measurable metastatic or LA disease at baseline according to RECIST version 1.1.
- Participant has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

... and 10 more (see full listing online)

Exclusion (24)

- Participant has preexisting sensory or motor neuropathy grade e 2.
- Participant has active central nervous system (CNS) metastases. Participant with treated CNS metastases is permitted on study if all the following are true:
- CNS metastases have been clinically stable for at least 6 weeks prior to screening
- If requiring steroid treatment for CNS metastases, the participant is on a stable dose d 20 mg/day of prednisone or equivalent for at least 2 weeks
- Baseline scans show no evidence of new or enlarged brain metastasis

... and 19 more (see full listing online)

Locations (10 total)

Site IN91015, Kochi, Kerala, India
Site IN91004, Mumbai, Maharashtra, India
Site IN91016, New Delhi, National Capital Territory of Delhi, India
... and 7 more locations