

A Study to Evaluate the Efficacy and Safety of Autogene Cevumeran With Nivolumab Versus Nivolumab Alone in Participants With High-risk Muscle-invasive Urothelial Carcinoma (MIUC)

NCT06534983

Status	RECRUITING
Phase	Phase 2
Sponsor	Hoffmann-La Roche
Enrollment	362 participants

Key Eligibility Criteria

Inclusion (14)

- Participants must have the capacity to participate/enroll in the study and to provide informed consent
- Histologically confirmed muscle-invasive UC (also termed transitional cell carcinoma [TCC]) of the bladder or upper urinary tract
- Tumor-node-metastasis (TNM) classification (Union for International Cancer Control [UICC]/American Joint Committee on Cancer [AJCC] 7th edition) at pathological examination of surgical resection specimen of (y)pT3-4 or (y)pN+ and M0
- Surgical resection of MIUC of the bladder or upper tract
- Participants who have received neoadjuvant chemotherapy (NAC), including antibody drug-conjugate, either alone or in combination with a checkpoint inhibitor (CPI), are eligible

... and 9 more (see full listing online)

Exclusion (5)

- Partial cystectomy in the setting of bladder cancer primary tumor or partial nephroureterectomy in the setting of renal pelvis primary tumor
- Any approved anti-cancer therapy, including chemotherapy, or hormonal therapy within 3 weeks prior to initiation of study treatment
- Adjuvant chemotherapy, immunotherapy, or radiation therapy for UC following surgical resection
- Prior active malignancies within 3 years prior to randomization
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment

Locations (107 total)

Highlands Oncology Group., Springdale, Arkansas, United States
Kaiser Permanente - Baldwin Park, Baldwin Park, California, United States
City of Hope Cancer Center, Duarte, California, United States
... and 104 more locations

<https://clinicaltrials.gov/study/NCT06534983>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.