ForPatients
by Roche

Muscle Invasive Urothelial Carcinoma

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)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	19 Countries	NCT06534983 2023-509023-40-00 BO45230

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized Phase II, Double-Blind, Multicenter Study Evaluating the Efficacy and Safety of Autogene Cevumeran Plus Nivolumab Versus Nivolumab as Adjuvant Therapy in Patients With High-Risk Muscle-Invasive Urothelial Carcinoma

Trial Summary:

The main purpose of the study is to evaluate the efficacy of adjuvant treatment with autogene cevumeran plus nivolumab compared with nivolumab in participants with high risk MIUC. In this study participants will be enrolled in a safety run-in phase to receive autogene cevumeran + nivolumab. This phase will be conducted to monitor and ensure the safety of study participants. After all participants in the safety run-in have been enrolled to receive autogene cevumeran + nivolumab, further participants will be randomization in either autogene cevumeran + nivolumab or the saline + nivolumab arm.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT06534983 2023-509023-40-00 BO45230
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Participants must have the capacity to participate/enroll in the study and to provide informed consent
- Histologically confirmed muscle-invasive UC (also termed TCC) of the bladder or upper urinary tract
- TNM classification (UICC/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 not received prior neoadjuvant cisplatin chemotherapy (NAC) must be ineligible to receive adjuvant cisplatin therapy due to participant refusal, cisplatin ineligibility or investigator decision
- Tumor tissue must be provided for biomarker analysis
- Absence of residual disease and absence of metastasis, as confirmed by a negative baseline Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scan of the pelvis, abdomen, and chest no more than 28 days prior to randomization.
- Full recovery from cystectomy or nephroureterectomy within 120 days following surgery
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Negative HIV test at screening
- Negative hepatitis B surface antigen (HbsAg) test at screening
- Positive hepatitis B surface antibody (HBsAb), or a negative HBsAb at screening accompanied by either of the following: negative total hepatitis B core antibody (HBcAb) or positive total HBcAb test followed by quantitative hepatitis B virus (HBV) DNA < 500 international units/milliliter (IU/mL)
- Negative hepatitis C virus (HCV) antibody test at screening, or a positive HCV antibody test followed by a negative HCV RNA test at screening

Exclusion Criteria:

- 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
- Any prior neoadjuvant immunotherapy
- Adjuvant chemotherapy or radiation therapy for UC following surgical resection
- Malignancies other than UC within 5 years prior to randomization
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment