ForPatients
by Roche

Pancreatic CancerPancreatic Adenocarcinoma

A Study of Multiple Immunotherapy-Based Treatment Combinations in Participants With Metastatic Pancreatic Ductal Adenocarcinoma (Morpheus-Pancreatic Cancer)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT03193190 2016-004126-42 WO39608

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 Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Metastatic Pancreatic Ductal Adenocarcinoma (Morpheus-Pancreatic Cancer)

Trial Summary:

A Phase Ib/II, open-label, multicenter, randomized study designed to assess the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of immunotherapy-based treatment combinations in participants with metastatic Pancreatic Ductal Adenocarcinoma (PDAC). Two cohorts will be enrolled in parallel in this study: Cohort 1 will consist of patients who have received no prior systemic therapy for metastatic PDAC, and Cohort 2 will consist of patients who have received one line of prior systemic therapy for PDAC. In each cohort, eligible patients will be assigned to one of several treatment arms.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT03193190 2016-004126-42 WO39608
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

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- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Histologically or cytologically confirmed metastatic pancreatic ductal adenocarcinoma
- For patients in Cohort 1: no prior systemic treatment for PDAC
- For patients in Cohort 2: disease progression during administration of either 5-FU- or gemcitabine-based first-line chemotherapy
- Life expectancy greater than or equal to 3 months
- Availability of a representative tumor specimen that is suitable for determination of programmed death-ligand 1 (PD-L1) and/or additional biomarker status via central testing
- Measurable disease (at least one target lesion) according to RECIST v1.1
- Adequate hematologic and end-organ function test results
- Tumor accessible for biopsy
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating eggs, as outlined for each specific treatment arm
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm, as outlined for each specific treatment arm

Exclusion Criteria:

- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring drainage procedure (i.e., more than one time per month)
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- History of leptomeningeal disease
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Positive human immunodeficiency (HIV) test at screening or at any time prior to screening
- Active hepatitis B or C virus infection or active tuberculosis
- Severe infection within 4 weeks prior to initiation of study treatment
- Prior allogeneic stem cell or solid organ transplantation
- History of malignancy other than pancreatic carcinoma within 2 years prior to screening, with the exception of those with a negligible risk of metastasis or death

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