A Study of Safety and Efficacy of KFA115 Alone and in Combo With Pembrolizumab in Patients With Select Advanced Cancers

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A Phase I, Open-label, Multi-center Study of KFA115 as a Single Agent and in Combination With Pembrolizumab in Patients With Select Advanced Cancers
ClinicalTrials.gov Identifier:
NCT05544929
Novartis Reference Number:CKFA115A12101
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to characterize the safety and tolerability of KFA115 and KFA115 in combination with pembrolizumab in patients with select advanced cancers, and to identify the maximum tolerated dose and/or recommended dose. This is a phase I, open-label, multi-center study of KFA115 as a single agent and in combination with pembrolizumab. The study consists of a dose escalation part, followed by dose expansion part(s) for single-agent KFA115 and KFA115 in combination with pembrolizumab. The escalation parts will characterize safety and tolerability. After the determination of the maximum tolerated dose (MTD) / recommended dose (RD), the dose expansion parts will assess the preliminary anti-tumor activity in defined patient populations and further assess the safety and tolerability at MTD/RD.

Condition
Carcinoma, Non-Small-Cell Lung, Cutaneous Melanoma, Carcinoma, Renal Cell, Carcinoma, Ovarian Epithelial, Nasopharyngeal Carcinoma, Carcinoma, Thymic, Anal Cancer, Mesothelioma, Esophagogastric Cancer, High Microsatellite Instability Colorectal Carcinoma, Squamous Cell Carcinoma of Head and Neck, Triple Negative Breast Neoplasms
Phase
Phase1
Overall Status
Recruiting
Number of Participants
180
Start Date
Oct 26, 2022
Completion Date
Sep 01, 2027
Gender
All

Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

KFA115

Immunomodulatory agent
Drug

pembrolizumab

Anti-PD-1 antibody

Eligibility Criteria

Inclusion Criteria:

* Non-small cell lung cancer with historic PD-L1 ≥ 1%, as determined locally using a clinically accepted assay. Patients must have experienced benefit from previous anti-PD(L)1-containing therapy for at least 4 months based on investigator-assessed disease stability or response prior to developing documented disease progression. Patients must have also received prior platinum-based chemotherapy, either in combination or in sequence with anti-PD-(L)1, unless patient was ineligible to receive such treatment.
* Renal cell carcinoma, clear cell histology, previously treated with anti-PD(L)1-containing therapy and a VEGF targeted therapy as monotherapy or in combination. Patients should have documented disease progression following anti-PD(L)1-containing therapy.
* Cutaneous melanoma, previously treated with anti-PD(L)1-containing therapy. Patients should have documented disease progression following anti-PD(L)1-containing therapy. Patients with BRAF V600-mutant melanoma must have also received prior therapy with a BRAF V600 inhibitor, with or without a MEK inhibitor.
* Ovarian cancer, high-grade serous histology, naïve to anti-PD(L)1 therapy, must have received one prior systemic therapy in platinum-resistant setting.
* Nasopharyngeal carcinoma, non-keratinizing locally advanced recurrent or metastatic. Depending on the study arm, patients may be naïve to anti-PD(L)1 therapy, or previously treated with platinum-based chemotherapy with or without anti-PD-(L)1.
* Locally advanced unresectable or metastatic triple negative breast cancer, ovarian cancer (high-grade serous histology), anal cancer (squamous), MSI-H CRC, esophagogastric cancer, mesothelioma, and HNSCC.
* Locally advanced unresectable or metastatic anal cancer (squamous), thymic carcinoma, MSI-H CRC, esophagogastric cancer, mesothelioma, and HNSCC, all naïve to anti-PD(L)1 therapy and for whom anti PD(L)1 therapy is not available.
* Triple negative breast cancer with historic PD-L1 CPS ≥ 1%, must have received at least one line of chemotherapy. In addition, these patients must have previously received sacituzumab govitecan, and in the case of a BRCA mutation a PARP inhibitor, if these treatments are locally approved and accessible to the patient.

Exclusion Criteria:

* Impaired cardiac function or clinically significant cardiac disease.
* Use of agents known to prolong the QT interval unless they can be permanently discontinued for the duration of study.
* History of severe hypersensitivity reactions to any ingredient of study drug(s) and other mAbs and/or their excipients.
* Active, known or suspected autoimmune disease. Patients with vitiligo, type I diabetes, residual hypothyroidism only requiring hormone replacement, psoriasis not requiring systemic treatment or conditions not expected to recur may be considered. Patients previously exposed to anti-PD-1/PD-L1 treatment who are adequately treated for skin rash or with replacement therapy for endocrinopathies should not be excluded.
* Any evidence of interstitial lung disease (ILD) or pneumonitis, or a prior history of ILD or non-infectious pneumonitis requiring high-dose glucocorticoids.
* Patients who discontinued prior anti-PD-(L)1 therapy due to an anti-PD-(L)1-related toxicity (applicable to the KFA115 in combination with pembrolizumab treatment arms).
* Patients with symptomatic peripheral neuropathy limiting instrumental activities of daily living.

Other protocol-defined inclusion/exclusion criteria may apply

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