Protocol CPDR001C2101

Phase Ib, multicenter, open label study of PDR001 in combination with platinum-doublet chemotherapy in PD-L1 unselected, metastatic NSCLC patients.

This is the trial summary as assessed on clinicaltrials.gov on 17/05/2017.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/results?term=CPDR001C2101&Search=Search

Trial Design:

The primary purpose of this study is to establish the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE) of PDR001 when administered in combination with platinum-doublet chemotherapy in treatment naive patients with PD-L1 unselected, advanced NSCLC, and to estimate the preliminary anti-tumor activity of PDR001 in combination with platinum-doublet chemotherapy in this patient population.

Inclusion Criteria:

Patient has stage IIIB (and is not a candidate for definitive multimodality therapy) or has stage IV NSCLC or relapsed locally advanced or metastatic NSCLC as follows:

a. Group A, group B and group C only: Patients not previously treated with any systemic anti-cancer therapy (e.g. cytotoxic drugs, targeted therapy, monoclonal antibody therapy including immunotherapy (e.g. PD-1/PD-L1 inhibitors) or targeted therapies, either experimental or not), with exception of neo-adjuvant or adjuvant therapy as depicted in inclusion criterion 4.
b. Group D only: Patients who have received only one prior systemic therapy treatment consisting of a PD-1 and/or PD-L1 inhibitor with or without a CTLA4 inhibitor for NSCLC, with exception of neo-adjuvant or adjuvant therapy as depicted in inclusion criterion 4. The last dose of prior immunotherapy must have been administered at least 6 weeks prior to the start of study treatment (cycle 1 day 1).

Histologically or cytologically confirmed diagnosis of NSCLC that is EGFR Wild-type, ALK-negative rearrangement and ROS1-negative rearrangement

Eastern Cooperative Oncology Group (ECOG) performance status of 0-1

Patients with at least 1 measurable tumor lesion as assessed by Computed Tomography (CT) Scan or Magnetic Resonance Imaging (MRI) according to RECIST 1.1.

Exclusion Criteria:

Patient with a history of severe hypersensitivity reaction to the planned study treatment including gemcitabine, paclitaxel, cisplatin, carboplatin, pemetrexed or any known excipients of these drugs

History of severe hypersensitivity reactions to other monoclonal antibodies, which in the opinion of the investigator may pose an increased risk of serious infusion reaction.

Patient has history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis (i.e., affecting activities of daily living or requiring therapeutic intervention).

History of leptomeningeal metastases

Active, known or suspected autoimmune disease or a documented history of autoimmune disease, including ulcerative colitis and Crohn's disease (Patients with vitiligo, type I diabetes mellitus, residual hypothyroidism due to autoimmune condition only requiring hormone replacement, psoriasis not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger are permitted to enroll).

Use of any live vaccines against infectious diseases within 4 weeks of initiation of study treatment