Protocol Abemaciclib – Pembrolizumab : I3Y-MC-JPCE

A Phase 2 Study of Abemaciclib in Combination With Pembrolizumab for Patients With Stage IV Non-Small Cell Lung Cancer or Hormone Receptor Positive, HER2 Negative Breast Cancer.

This is the trial summary as assessed on clinicaltrials.gov on 22/02/2017.

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

https://clinicaltrials.gov/ct2/results?term=I3Y-MC-JPCE&Search=Search

Trial Design :

The main purpose of this study is to evaluate the safety and efficacy of abemaciclib in combination with pembrolizumab in participants with advanced non-small cell lung cancer (NSCLC) or hormone receptor positive (HR+), human epidermal growth factor receptor negative (HER2-) breast cancer.

Inclusion Criteria:

Have a Stage IV diagnosis of 1 of the following: Part A: NSCLC (Kirsten rat sarcoma mutant [KRAS mt], PD-L1+); Part B: NSCLC (squamous histology); or Part C: metastatic breast cancer (HR+, HER2-).

Part A: must be chemotherapy naïve for metastatic NSCLC

Part B: must have received at least 1 prior therapy containing platinum-based chemotherapy for advanced/metastatic NSCLC

Part C: must have previously received prior treatment with at least 1 but no more than 2 chemotherapy regimens in the metastatic setting

Are amenable to provide tumor tissue prior to treatment and provide tumor tissue after treatment initiation (both mandatory).

Have presence of measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST 1.1).

Have a performance status (PS) ≤1 on the Eastern Cooperative Oncology Group (ECOG) scale.

Have discontinued all previous treatments for cancer and recovered from the acute effects of therapy.

Have an estimated life expectancy of ≥12 weeks.

Exclusion Criteria:

Have a personal history of any of the following conditions: syncope of either unexplained or cardiovascular etiology, ventricular arrhythmia (including but not limited to ventricular tachycardia

and ventricular fibrillation), or sudden cardiac arrest. Exception: subjects with controlled atrial fibrillation for >30 days prior to study treatment are eligible.

Have central nervous system (CNS) metastasis with development of associated neurological changes 14 days prior to receiving study drug.

Have corrected QT interval of >470 milliseconds on screening electrocardiogram (ECG).

Have history of interstitial lung disease or pneumonitis.

Have history of or active autoimmune disease, or other syndrome that requires systemic steroids or autoimmune agents for the past 2 years.

Have received a live vaccination within 30 days of study start.

Have received prior treatment with an anti PD-1, anti-programmed death ligand 1 (PD-L1), or anti cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) agent.