Protocol Resilient

A Randomized, Open Label Phase 3 Study of Irinotecan Liposome Injection (ONIVYDE®) versus Topotecan in Patients with Small Cell Lung Cancer Who Have Progressed on or after Platinum-based First-Line Therapy

This is the trial summary as assessed on clinicaltrials.gov on 23/06/2020.

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

https://clinicaltrials.gov/ct2/show/NCT03088813?term=Irinotecan&cond=Lung+Cancer&cntry=BE&draw=2&rank=1

Trial Design:

The study will be conducted in two parts:

Part 1: Open-label dose-finding study of irinotecan liposome injection. 30 patients were enrolled.

Part 2: A randomized, efficacy study of irinotecan liposome injection versus IV topotecan.

Approximately 450 patients will be enrolled in part 2.

Inclusion Criteria:

- At least 18 years of age
- Able to understand and provide an informed consent
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy >12 weeks
- Histopathologically or cytologically confirmed small cell lung cancer
- Evaluable disease as defined by RECIST Version 1.1 guidelines (patients with non-measurable lesions only are eligible)
- Radiologically confirmed progression on or after first-line platinum based chemotherapy (carboplatin or cisplatin), immunotherapy, or chemo-radiation including platinum-based chemotherapy for treatment of limited or extensive stage Small Cell Lung Cancer (SCLC)
- Recovered from the effects of any prior chemotherapy, surgery, radiotherapy or other anti-neoplastic therapy (recovered to Grade 1 or better, with the exception of alopecia)
- Adequate bone marrow reserves
- Adequate hepatic function Adequate renal function
- Electrocardiogram during the screening period without any clinically significant findings, per investigator's assessment

Exclusion Criteria:

- Any medical or social condition deemed by the investigator to be likely to interfere with a patient's ability to sign informed consent, cooperate and participate in the study, or interfere with the interpretation of the results
- Pregnant or breast feeding
- Patients with large cell neuroendocrine lung carcinoma
- Patients who have received prior topoisomerase I inhibitor treatment, retreatment with e platinum-based regimen, antibody-drug conjugates or molecular targeted agents, more than one line of immunotherapy, or any other additional regimen of prior cytotoxic chemotherapy
- Patients with the symptomatic Central Nervous System (CNS) metastasis and/or who have developed new or progressive brain metastasis following prophylactic and/or therapeutic cranial radiation (whole brain stereotactic radiation).
- Patients with carcinomatous meningitis
- Unable to discontinue the use of strong CYP3A4 or UGT1A1 inhibitors at least 1 week or strong CYP3A4 inducers at least 2 weeks prior to receiving the first dose of irinotecan liposome injection
- Have a previous or concurrent cancer that is distinct in primary (non-pulmonary) site or SCLC histology
- Investigational therapy administered within 4 weeks, or within a time interval less than at least 5 half-lives of the investigational agent, whichever is less, prior to the first scheduled day of dosing in this study
- Severe cardiovascular and pulmonary diseases
- New York Heart Association Class III or IV congestive heart failure, ventricular arrhythmias, or uncontrolled blood pressure
- Active infection
- Known hypersensitivity to any of the components of irinotecan liposome injection, other liposomal products, or topotecan
- Clinically significant gastrointestinal disorder including hepatic disorders, bleeding, inflammation, occlusion, or diarrhea > grade 1