LUNG005 (Merck)

Multicenter, Double Blind, Randomized, Controlled Study of M7824 with Concurrent Chemoradiation Followed by M7824 versus Concurrent Chemoradiation Plus Placebo Followed by Durvalumab in Participants with Unresectable Stage III Non-small Cell Lung Cancer

This is the trial summary as assessed on clinicaltrials.gov on 15/11/2019.

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

https://clinicaltrials.gov/ct2/show/NCT03840902?term=M7824+with+cCRT+in+Unresectable+Stage+III+NSCLC&draw=1&rank=1

Trial Design:

The main purpose of this study is to evaluate safety and efficacy in participants treated with concomitant chemoradiation therapy (cCRT) plus M7824 followed by M7824 compared to cCRT plus placebo followed by durvalumab.

Key Inclusion Criteria:

Participants must have histologically documented NSCLC who present with Stage III locally advanced, unresectable disease (International Association for the Study of Lung Cancer Staging Manual in Thoracic Oncology

Participants with tumor harboring an Epidermal growth factor receptor (EGFR) sensitizing (activating) mutation, Anaplastic lymphoma kinase (ALK) translocation, ROS-1 rearrangement are eligible.

Participants must have adequate pulmonary function defined as a forced expiratory volume in 1 second (FEV1) greater than equals to (>=) 1.2 liters or >= 50% of predicted normal volume measured within 3 weeks prior to randomization.

Adequate hematological, hepatic and renal function as defined in the protocol

Contraceptive use by males or females will be consistent with local regulations on contraception methods for those participating in clinical studies

Key Exclusion Criteria:

Participants with Mixed small cell with non-small cell lung cancer histology

Recent major surgery within 4 weeks prior to entry into the study

Significant acute or chronic infections including human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome, Active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection and active tuberculosis

Chronic Obstructive Pulmonary Disease exacerbation or other respiratory illness requiring hospitalization

Active autoimmune disease that has required systemic treatment in past 1 year (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs)

Any prior systemic cytotoxic chemotherapy for their NSCLC or any antibody or drug targeting T-cell coregulatory proteins