A Study of MM-121 in Combination With Chemotherapy Versus Chemotherapy Alone in Heregulin Positive NSCLC

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2016 by Merrimack Pharmaceuticals

Sponsor:
Merrimack Pharmaceuticals

Information provided by (Responsible Party):
Merrimack Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT02387216

First received: February 12, 2015
Last updated: August 4, 2016
Last verified: August 2016
History of Changes

Purpose

The purpose of this study is to determine whether the combination of MM-121 plus docetaxel or pemetrexed is more effective than docetaxel or pemetrexed alone in regards to OS in patients with heregulin-positive NSCLC.

Condition	Intervention	Phase
Non-Small Cell Lung Cancer NSCLC Adenocarcinoma Squamous Cell Carcinoma Heregulin Large Cell Carcinoma	Drug: MM-121 Drug: Docetaxel Drug: Pemetrexed	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase 2 Study of MM-121 in Combination With Docetaxel or Pemetrexed Versus Docetaxel or Pemetrexed Alone in Patients With Heregulin Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Lung Cancer

Drug Information available for: Docetaxel Pemetrexed Pemetrexed disodium

U.S. FDA Resources

Further study details as provided by Merrimack Pharmaceuticals:

Primary Outcome Measures:

- Overall Survival [Time Frame: Time from randomization to death, approximately 3 years] [Designated as safety issue: No]

Secondary Outcome Measures:

- Progression-free survival [Time Frame: Time from randomization to progression, approximately 3 years] [Designated as safety issue: No]
  Disease status will be assessed according to RECIST v 1.1
- Independent Central Review - PFS [Time Frame: Approximately 3 years] [Designated as safety issue: No]
- Objective Response Rate [Time Frame: Approximately 3 years] [Designated as safety issue: No]

Based on RECIST v1.1

- Time to Progression [Time Frame: Approximately 3 years] [Designated as safety issue: No]
- Rate of adverse events reported with the combination of MM-121 with docetaxel or pemetrexed [Time Frame: Approximately 3 years] [Designated as safety issue: Yes]
- Assess health-related quality of life (HRQOL) in NSCLC [Time Frame: Approximately 3 years] [Designated as safety issue: No]
- Pharmacokinetic (PK) parameters of MM-121 in combination with docetaxel or pemetrexed and of docetaxel and pemetrexed when given in combination with MM-121. [Time Frame: Approximately 3 years] [Designated as safety issue: Yes]

Estimated Enrollment: 280
Study Start Date: February 2015
Estimated Study Completion Date: December 2018
Estimated Primary Completion Date: December 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm A: Experimental Arm MM-121 in combination with either Docetaxel or Pemetrexed (Investigator's choice)	Drug: MM-121 Investigational, fully human antibody targeting and inhibiting ErbB3 Drug: Docetaxel approved chemotherapy treatment for NSCLC Other Name: Taxotere Drug: Pemetrexed approved chemotherapy treatment for NSCLC Other Name: ALIMTA
Active Comparator: Arm B: Comparator Arm Docetaxel or Pemetrexed (Investigator's choice) alone	Drug: Docetaxel approved chemotherapy treatment for NSCLC Other Name: Taxotere Drug: Pemetrexed approved chemotherapy treatment for NSCLC Other Name: ALIMTA

Detailed Description:
This study is a randomized, open-label, international, multi-center, phase 2 study in patients with Heregulin-positive NSCLC that have progressed following no more than three systemic therapies for locally advanced or metastatic disease, of which one must have been an anti-PD-1 or anti-PD-L1 therapy. All patients will initially be screened for heregulin status. Eligible patients will be randomized to receive MM-121 in combination with investigator's choice of either docetaxel or pemetrexed versus docetaxel or pemetrexed alone.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients with a diagnosis of cytologically or histologically confirmed NSCLC with either metastatic disease (stage IV) or Stage IIIB disease not amenable to surgery with curative intent
- Failed an anti-PD-1 or anti-PD-L1 therapy and has not received more than 3 prior systemic therapies for primary or recurrent disease
- Tissue submitted for HRG-biomarker testing
- ECOG performance status (PS) of 0 or 1

Exclusion Criteria:

- Known ALK mutation
- Presence of exon 19 deletion or exon 21 (L858R) substitution of the EGFR gene
- Received >3 prior systemic anti-cancer drug regimen for locally advanced disease
- Prior treatment with an anti-ErbB3 antibody
- CTCAE grade 3 or higher peripheral neuropathy
- Symptomatic CNS metastases or CNS metastases requiring steroids
- Any other active malignancy requiring systemic therapy
- Clinically significant cardiac disease

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02387216

Show 34 Study Locations

Sponsors and Collaborators

Merrimack Pharmaceuticals

Investigators

Study Director: MM-121 Program Medical Director, MD Merrimack Pharmaceuticals

More Information

Responsible Party:	Merrimack Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT02387216 History of Changes
Other Study ID Numbers:	**MM-121-01-02-09**
Study First Received:	February 12, 2015
Last Updated:	August 4, 2016
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merrimack Pharmaceuticals:

NSCLC	ErbB3
Non-Small Cell Lung Cancer	docetaxel
heregulin	pemetrexed

Additional relevant MeSH terms:

Lung Neoplasms	Neoplasms, Glandular and Epithelial
Carcinoma, Non-Small-Cell Lung	Neoplasms by Histologic Type
Carcinoma, Squamous Cell	Neoplasms, Squamous Cell
Adenocarcinoma	Docetaxel
Carcinoma	Pemetrexed
Carcinoma, Large Cell	Antineoplastic Agents
Respiratory Tract Neoplasms	Tubulin Modulators
Thoracic Neoplasms	Antimitotic Agents
Neoplasms by Site	Mitosis Modulators
Neoplasms	Molecular Mechanisms of Pharmacological Action
Lung Diseases	Enzyme Inhibitors
Respiratory Tract Diseases	Folic Acid Antagonists
Carcinoma, Bronchogenic	Nucleic Acid Synthesis Inhibitors
Bronchial Neoplasms	

ClinicalTrials.gov processed this record on September 23, 2016