A Phase 2 Study of MM-141 Plus Nab-paclitaxel and Gemcitabine in Front-line Metastatic Pancreatic Cancer (CARRIE)

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

Verified July 2016 by Merrimack Pharmaceuticals

Sponsor:
Merrimack Pharmaceuticals

Information provided by (Responsible Party):
Merrimack Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT02399137

First received: March 19, 2015
Last updated: July 29, 2016
Last verified: July 2016
History of Changes

Purpose

The purpose of this study is to determine whether the combination of MM-141 plus nab-paclitaxel and gemcitabine is more effective than nab-paclitaxel and gemcitabine alone based on Progression Free Survival (PFS) in front-line metastatic pancreatic cancer patients with high serum levels of free IGF-1.

Condition	Intervention	Phase
Pancreatic Cancer	Drug: MM-141 Drug: Placebo Drug: Gemcitabine Drug: Nab-Paclitaxel	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized, Double-blind, Placebo-controlled Phase 2 Study of MM-141 Plus Nab-paclitaxel and Gemcitabine Versus Nab-paclitaxel and Gemcitabine in Front-line Metastatic Pancreatic Cancer

Resource links provided by NLM:

MedlinePlus related topics: Cancer Pancreatic Cancer

Drug Information available for: Paclitaxel Gemcitabine Gemcitabine hydrochloride

U.S. FDA Resources

Further study details as provided by Merrimack Pharmaceuticals:

Primary Outcome Measures:

- Progression Free Survival [Time Frame: Approximately 2 years] [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall Survival [Time Frame: Approximately 2.5 years] [Designated as safety issue: No]
- Objective Response Rate according to RECIST v1.1 [Time Frame: Approximately 2 years] [Designated as safety issue: No]
- Duration of Response according to RECIST v1.1 [Time Frame: Approximately 2 years] [Designated as safety issue: No]
- Rate of adverse events reported with the combination of MM-141 with nab-paclitaxel and gemcitabine versus the comparator arm [Time Frame: Approximately 2 years] [Designated as safety issue: Yes]

Estimated Enrollment: 260
Study Start Date: May 2015
Estimated Study Completion Date: November 2017
Estimated Primary Completion Date: August 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm A (Experimental Arm) MM-141 in combination with nab-paclitaxel and gemcitabine	Drug: MM-141 Drug: Gemcitabine Other Name: Gemzar Drug: Nab-Paclitaxel Other Name: Abraxane
Active Comparator: Arm B (Comparator Arm) Placebo in combination with nab-paclitaxel and gemcitabine	Drug: Placebo Drug: Gemcitabine Other Name: Gemzar Drug: Nab-Paclitaxel Other Name: Abraxane
No Intervention: Observational Group	

Detailed Description:
This is a randomized, double-blind, placebo-controlled Phase 2 study of MM-141 plus nab-paclitaxel and gemcitabine or placebo plus nab-paclitaxel and gemcitabine in front-line metastatic pancreatic cancer. All patients will be initially screened for free IGF-1 status. Eligible patients with high free IGF-1 will be randomized to receive MM-141 plus nab-paclitaxel and gemcitabine or placebo plus nab-paclitaxel and gemcitabine and patients. Patients with low free IGF-1 or patients who have high free IGF-1 but are not otherwise eligible will be followed in an observational group.

Eligibility

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

Criteria

Inclusion Criteria:

- Metastatic adenocarcinoma of the pancreas. Patients with islet cell neoplasms are not eligible.
- Patient must have received no prior radiotherapy, surgery, chemotherapy, or investigational therapy for the treatment of metastatic disease.
- Blood sample sent for free IGF-1 testing
- ECOG performance status (PS) of 0 or 1

Exclusion Criteria:

- Patients who only present with localized disease
- Patients with CNS malignancies (primary or metastatic)
- 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: NCT02399137

Show 34 Study Locations

Sponsors and Collaborators

Merrimack Pharmaceuticals

Investigators

Study Director: MM-141 Medical Director, MD Merrimack Pharmaceuticals

More Information

Responsible Party: Merrimack Pharmaceuticals
ClinicalTrials.gov Identifier: NCT02399137 History of Changes
Other Study ID Numbers: **MM-141-07-02-02**
Study First Received: March 19, 2015
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Health Authority: United States: Food and Drug Administration

Keywords provided by Merrimack Pharmaceuticals:

Pancreatic Cancer
Front-line Pancreatic Cancer
Metastatic Pancreatic Cancer
Gemcitabine
Nab-paclitaxel
Abraxane
Free IGF-1
Heregulin

Additional relevant MeSH terms:

Pancreatic Neoplasms
Digestive System Neoplasms
Neoplasms by Site
Neoplasms
Endocrine Gland Neoplasms
Digestive System Diseases
Pancreatic Diseases
Endocrine System Diseases
Paclitaxel
Gemcitabine
Albumin-Bound Paclitaxel
Antineoplastic Agents, Phytogenic
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Antimetabolites, Antineoplastic
Antimetabolites
Antiviral Agents
Anti-Infective Agents
Enzyme Inhibitors
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs

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