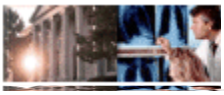

Mesothelioma Articles

A Study of MORAb-009 in Subjects With Pancreatic Cancer, Mesothelioma, or Certain Types of Ovarian or Lung Cancer

This study is currently recruiting patients.
Verified by Morphotek July 2006

Sponsored by:	Morphotek
Information provided by:	Morphotek
ClinicalTrials.gov Identifier:	NCT00325494

Purpose

The purpose of this study is to establish the safest doses of an investigational drug called MORAb-009 in subjects with pancreatic cancer, mesothelioma, or certain types of ovarian or lung cancer. MORAb-009 is a monoclonal antibody that is directed to an antigen on the surface of these cancers.

Condition	Intervention	Phase
Pancreatic Cancer Mesothelioma Ovarian Cancer Non-Small Cell Lung Cancer	Drug: MORAb-009	Phase I

MedlinePlus related topics: Lung Cancer; Mesothelioma; Ovarian Cancer; Pancreatic Cancer

Study Type: Interventional
Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study

Official Title: A Study of the Safety, Tolerability, and Pharmacokinetics of MORAb-009, a Chimeric Monoclonal Antibody, in Subjects With Advanced Mesothelin-Expressing Tumors

Further study details as provided by Morphotek:

Primary Outcomes: Safety; Tolerability
Secondary Outcomes: Pharmacokinetics; Human Anti-Chimeric Antibody formation; Objective Tumor Measurement (CT; MRI; RECIST criteria; biomarkers)
Expected Total Enrollment: 21

Study start: May 2006; Expected completion: January 2007
Last follow-up: January 2007; Data entry closure: January 2007

MORAb-009 is a high-affinity monoclonal antibody raised against human mesothelin, a membrane glycoprotein thought to be involved in cell adhesion and tightly associated with a range of cancers. It has been shown that mesothelin is over-expressed in pancreatic cancers, mesotheliomas, and ovarian or mesothelin-expressing ovarian or non-small cell lung cancers, while showing little expression in normal tissues. Preclinical experiments indicate that MORAb-009 is a potentially useful anti-cancer agent. This clinical trial is being performed to determine the safety of MORAb-009 in subjects with mesothelin-expressing tumors, as well as to establish serum pharmacokinetics of the antibody, and to assess tumor antigens that may serve as predictors of a response to MORAb-009.

Eligibility

Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

- Female or male subjects, ≥ 18 years of age, with a histologically confirmed diagnosis of pancreatic adenocarcinoma, mesothelioma, or mesothelin-positive ovarian or non-small cell lung cancer. As nearly 100% of pancreatic adenocarcinoma and mesotheliomas express mesothelin, immunohistochemical confirmation of mesothelin-positivity is not necessary.
- Subject must have disease, as defined by Response Evaluation Criteria in Solid Tumors (RECIST) or evaluable by clinical signs/symptoms (e.g., ascites, pleural effusion, or lesions of less than 2 cm) supported by biomarker, radiologic, or pathologic studies conducted within 4 weeks prior to study entry.
- Subject must have failed at least one standard chemotherapy regimen. Patients with pancreatic cancer must have received gemcitabine as part of prior therapy and be considered refractory, or in the case of ovarian cancer be considered platinum refractory or resistant.
- Life expectancy ≥ 3 months, as estimated by the investigator.
- Eastern Cooperative Oncology Group performance status or 0, 1 or 2.
- Female subjects of childbearing potential and all male subjects must consent to use a medically acceptable method of contraception throughout the study period and for 28 days after MORAb-009 administration. A barrier method of contraception must be included.
- Other significant medical conditions must be well controlled and stable in the opinion of the investigator for at least 30 days prior to Study Day 1.
- Laboratory and clinical results within the 2 weeks prior to Study Day 1 as follows:

Absolute neutrophil count (ANC) ≥ 1.5 x 109/L; Platelet count ≥ 100 x 109/L; Hemoglobin ≥ 9 g/dL; Serum bilirubin ≤ 2.0 mg/dL; Aspartate transaminase (AST) ≤ 5 x upper limit of normal (ULN); Alanine transaminase (ALT) ≤ 5 x ULN; Alkaline Phosphatase ≤ 5 x ULN; Serum creatinine ≤ 2.0 mg/dL. If the elevations of liver functions are due to obstruction of the common bile duct extrinsic to the liver, the subject may be enrolled at the discretion of the investigator even if the elevations are greater than the limits above. Stenting to reduce liver functions to qualifying levels is permitted.

- Subject must be willing and able to provide written informed consent.

Exclusion Criteria:

- Known central nervous system (CNS) tumor involvement.
- Evidence of other active malignancy requiring treatment.
- Clinically significant heart disease (e.g., congestive heart failure of New York Heart Association Class III or IV, angina not well controlled by medication, or myocardial infarction within 6 months).
- ECG demonstrating clinically significant arrhythmias (Note: Subjects with chronic atrial arrhythmia, i.e., atrial fibrillation or paroxysmal SVT, are eligible).
- Active serious systemic disease, including active bacterial or fungal infection.
- Active hepatitis or HIV infection.
- Treatment within three months with immunomodulatory therapy (e.g. interferons, immunoglobulin therapy, IL-1RA or systemic corticosteroids). Short term systemic corticosteroids or topical or intra-articular steroids are acceptable, subject to the judgment of the investigator.
- Chemotherapy, biologic therapy, or immunotherapy within 3 weeks prior to dosing with MORAb-009.
- Breast-feeding, pregnant, or likely to become pregnant during the study.

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00325494

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More Information

Study ID Numbers: MORAb-009-001
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Record first received: May 11, 2006
ClinicalTrials.gov Identifier: NCT00325494
Health Authority: United States: Food and Drug Administration
ClinicalTrials.gov processed this record on 2006-07-19

Source: www.ClinicalTrials.gov

www.MIRG.org