An Efficacy Study of MORAb-009 in Subjects With Pancreatic Cancer

This study has been completed.

Sponsor:
Morphotek

Information provided by (Responsible Party):
Morphotek

ClinicalTrials.gov Identifier:
NCT00570713

First received: December 7, 2007
Last updated: September 4, 2015
Last verified: September 2015
History of Changes

Results First Received: December 8, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Pancreatic Cancer
Interventions:	Drug: MORAb-009 Drug: Placebo Drug: Gemcitabine

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Participants were recruited from a population of pancreatic cancer patients treated at investigational centers.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity

	necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Participant Flow: Overall Study

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
STARTED	78	77
COMPLETED	0	0
NOT COMPLETED	78	77
Adverse Event	16	9
Death	7	7
Lack of Efficacy	40	49
Physician Decision	2	2
Withdrawal by Subject	3	3
Discontinuation of Study by the Sponsor	10	7

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Total	Total of all reporting groups

Baseline Measures

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')	Total
Overall Participants Analyzed	78	77	155

[Units: Participants]			
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**78**	**77**	**155**
>=65 years	**0**	**0**	**0**
Age [Units: Years] Mean (Standard Deviation)	**64.3 (12.7)**	**65.8 (10.3)**	**65.0 (11.5)**
Gender [Units: Participants]			
Female	**39**	**38**	**77**
Male	**39**	**39**	**78**
Race/Ethnicity, Customized [Units: Participants]			
African American	**2**	**2**	**4**
Asian	**0**	**3**	**3**
Hispanic	**6**	**4**	**10**
White - White/Caucasian/European Heritage	**69**	**67**	**136**
Other	**1**	**1**	**2**
Region of Enrollment [Units: Participants]			
North America	**57**	**57**	**114**
Europe	**21**	**20**	**41**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Survival (OS) [Time Frame: 1-21 Months]

Measure Type	Primary
Measure Title	Overall Survival (OS)
Measure Description	This measure was defined as the time (in months) from the date of randomization to the date of death, whatever the cause. The primary endpoint was analyzed when 110 events (deaths) were observed. In the absence of death confirmation or for subjects alive at the time of analysis, the survival time will be censored at the date of the last study follow-up.
Time Frame	1-21 Months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Measured Values

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
Participants Analyzed [Units: Participants]	**78**	**77**
Overall Survival (OS) [Units: Months] Median (95% Confidence Interval)	**6.5** **(4.5 to 8.10)**	**6.9** **(5.4 to 8.8)**

No statistical analysis provided for Overall Survival (OS)

2. Secondary: Progression-free Survival [Time Frame: 1-21 Months]

Measure Type	Secondary
Measure Title	Progression-free Survival
Measure Description	Progression-free Survival (PFS) is defined as the time from the date of randomization to the date of the first observation of disease progression (clinical or radiological) or death due to any cause. Progression is defined, using RECIST, as a measurable increase in the smallest dimension of any target or non-target lesion, or the appearance of new lesions, since baseline. If progression or death is not observed, the PFS time will be censored at the date of the last tumor assessment without evidence of progression prior to the date of initiation of further anticancer treatment.
Time Frame	1-21 Months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Measured Values

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
Participants Analyzed [Units: Participants]	**78**	**77**
Progression-free Survival [Units: Months] Median (95% Confidence Interval)	**3.4** **(1.9 to 4.7)**	**3.5** **(2.8 to 4.9)**

No statistical analysis provided for Progression-free Survival

3. Secondary: Best Overall Response Rate [Time Frame: Baseline to response up to 21 months]

Measure Type	Secondary
Measure Title	Best Overall Response Rate
Measure Description	Best overall response is the number of participants with a Complete Response (CR) or Partial Response (PR), as classified by independent blinded review of the CT or MRI images, based on RECIST 1.0. A CR is the disappearance of all target lesions. PR is at least a 30% decrease in the sum of the longest diameters of target lesions, taking as a reference the baseline sum longest diameter. Progressive Disease (PD) is at least a 20% increase in the sum of the longest diameters of target lesions or the appearance of one or more new lesions. Stable disease (SD) is neither CR, PR or PD.
Time Frame	Baseline to response up to 21 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Measured Values

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
Participants Analyzed [Units: Participants]	78	77
Best Overall Response Rate [Units: Percentage of participants]		
Complete or Partial Response	6.4	7.8
Complete Response	0	0
Partial Response	6.4	7.8
Stable Disease	47.4	55.8
Progressive Disease	19.2	23.4
Not Evaluable	26.9	13.0

No statistical analysis provided for Best Overall Response Rate

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From Baseline up to 21 months.
Additional Description	73 participants received MORAB-009 plus gemcitabine and 75 participants received Placebo plus gemcitabine.

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Serious Adverse Events

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
Total, serious adverse events		
# participants affected / at risk	49/73 (67.12%)	54/75 (72.00%)
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	3/73 (4.11%)	5/75 (6.67%)
Neutropenia † 1		
# participants affected / at risk	4/73 (5.48%)	3/75 (4.00%)
Thrombocytopenia † 1		
# participants affected / at risk	3/73 (4.11%)	3/75 (4.00%)

Bone marrow failure † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Coagulopathy † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Febrile neutropenia † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Haemolytic uraemic syndrome † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Leukopenia † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Cardiac disorders		
Cardiac arrest † 1		
# participants affected / at risk	0/73 (0.00%)	2/75 (2.67%)
Cardio-respiratory arrest † 1		
# participants affected / at risk	0/73 (0.00%)	2/75 (2.67%)
Gastrointestinal disorders		
Vomiting † 1		
# participants affected / at risk	6/73 (8.22%)	6/75 (8.00%)
Nausea † 1		
# participants affected / at risk	4/73 (5.48%)	3/75 (4.00%)
Abdominal Pain † 1		
# participants affected / at risk	3/73 (4.11%)	3/75 (4.00%)
Obstruction gastric † 1		
# participants affected / at risk	2/73 (2.74%)	3/75 (4.00%)
Constipation † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	2/73 (2.74%)	0/75 (0.00%)
Ileus † 1		
# participants affected / at risk	2/73 (2.74%)	0/75 (0.00%)
Abdominal pain upper † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Colitis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Diarrhoea † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Duodenal perforation † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Duodenal ulcer † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Duodenal ulcer haemorrhage † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Faecaloma † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Gastrointestinal motility disorder † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)

Intestinal obstruction † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Oesophageal perforation † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Pancreatitis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Pneumoperitoneum † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Small intestinal obstruction † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
General disorders		
Asthenia † 1		
# participants affected / at risk	4/73 (5.48%)	1/75 (1.33%)
General physical health deterioration † 1		
# participants affected / at risk	1/73 (1.37%)	4/75 (5.33%)
Pyrexia † 1		
# participants affected / at risk	2/73 (2.74%)	3/75 (4.00%)
Chest pain † 1		
# participants affected / at risk	0/73 (0.00%)	2/75 (2.67%)
Generalized oedema † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Chills † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Multi-organ failure † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Performance status decreased † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Hepatobiliary disorders		
Cholangitis † 1		
# participants affected / at risk	2/73 (2.74%)	3/75 (4.00%)
Hyperbilirubinaemia † 1		
# participants affected / at risk	1/73 (1.37%)	3/75 (4.00%)
Jaundice cholestatic † 1		
# participants affected / at risk	2/73 (2.74%)	2/75 (2.67%)
Bile duct obstruction † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Hepatic failure † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Bile duct stenosis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Bile duct stone † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Cholecystitis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Cholestasis † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)

Hepatorenal syndrome † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Jaundice † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Immune system disorders		
Drug hypersensitivity † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Hypersensitivity † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Infections and infestations		
Pneumonia † 1		
# participants affected / at risk	2/73 (2.74%)	4/75 (5.33%)
Cellulitis † 1		
# participants affected / at risk	1/73 (1.37%)	4/75 (5.33%)
Bacteremia † 1		
# participants affected / at risk	0/73 (0.00%)	4/75 (5.33%)
Sepsis † 1		
# participants affected / at risk	2/73 (2.74%)	1/75 (1.33%)
Abdominal Abscess † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Biliary Sepsis † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Catheter related infection † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Clostridium difficile colitis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Gastroenteritis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Herpes zoster † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Lobar pneumonia † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Septic shock † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Staphylococcal sepsis † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Urinary tract infection † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Viral infection † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Radiation pneumonitis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
† 1		

Spinal fracture		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Investigations		
Blood bilirubin increased † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
International normalized ratio increased † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	5/73 (6.85%)	7/75 (9.33%)
Hyperglycaemia † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Hyponatraemia † 1		
# participants affected / at risk	0/73 (0.00%)	2/75 (2.67%)
Anorexia † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Diabetes mellitus † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Hypoalbuminaemia † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Hypovolaemia † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Lactic acidosis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Musculoskeletal and connective tissue disorders		
Muscular weakness † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Musculoskeletal discomfort † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Malignant neoplasm progression † 1		
# participants affected / at risk	13/73 (17.81%)	11/75 (14.67%)
Cancer pain † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Pancreatic carcinoma † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Pancreatic carcinoma metastatic † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Convulsion † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Ischaemic stroke † 1		

# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Loss of consciousness † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Transient ischaemic attack † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Tremor † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Psychiatric disorders		
Confusional state † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Mental status changes † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Renal failure acute † 1		
# participants affected / at risk	1/73 (1.37%)	1/75 (1.33%)
Nephritis † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Renal disorder † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism † 1		
# participants affected / at risk	7/73 (9.59%)	6/75 (8.00%)
Dyspnoea † 1		
# participants affected / at risk	2/73 (2.74%)	1/75 (1.33%)
Hypoxia † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Interstitial lung disease † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Pleural effusion † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Pneumonia aspiration † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Pulmonary hypertension † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Respiratory failure † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Surgical and medical procedures		
Parenteral nutrition † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	1/73 (1.37%)	7/75 (9.33%)
Arterial thrombosis limb † 1		

# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Hypovolaemic shock † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Peripheral ischaemia † 1		
# participants affected / at risk	0/73 (0.00%)	1/75 (1.33%)
Poor venous access † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Thromboangiitis obliterans † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)
Venous thrombosis † 1		
# participants affected / at risk	1/73 (1.37%)	0/75 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	From Baseline up to 21 months.
Additional Description	73 participants received MORAB-009 plus gemcitabine and 75 participants received Placebo plus gemcitabine.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
MORAb-009 Plus Gemcitabine ('MORAb-009')	MORAb-009 was administered at 5 mg/kg on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.
Placebo Plus Gemcitabine ('Placebo')	Placebo was administered on Day 1 of Weeks 1 through 7 during the first cycle and on Day 1 of Weeks 1 through 3 of subsequent cycles. Gemcitabine was administered by i.v. infusion at an initial dose of 1000 mg/m2 once weekly for up to 7 weeks (or until toxicity necessitated reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles consisted of infusions once weekly for 3 consecutive weeks, followed by a week of rest from treatment.

Other Adverse Events

	MORAb-009 Plus Gemcitabine ('MORAb-009')	Placebo Plus Gemcitabine ('Placebo')
Total, other (not including serious) adverse events		
# participants affected / at risk	**73/73 (100.00%)**	**75/75 (100.00%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**32/73 (43.84%)**	**36/75 (48.00%)**
Thrombocytopenia † 1		
# participants affected / at risk	**25/73 (34.25%)**	**25/75 (33.33%)**

Neutropenia † 1		
# participants affected / at risk	16/73 (21.92%)	20/75 (26.67%)
Leukopenia † 1		
# participants affected / at risk	11/73 (15.07%)	16/75 (21.33%)
Cardiac disorders		
Palpitations † 1		
# participants affected / at risk	4/73 (5.48%)	2/75 (2.67%)
Tachycardia † 1		
# participants affected / at risk	1/73 (1.37%)	4/75 (5.33%)
Gastrointestinal disorders		
Nausea † 1		
# participants affected / at risk	35/73 (47.95%)	38/75 (50.67%)
Constipation † 1		
# participants affected / at risk	34/73 (46.58%)	27/75 (36.00%)
Abdominal pain † 1		
# participants affected / at risk	27/73 (36.99%)	20/75 (26.67%)
Vomiting † 1		
# participants affected / at risk	23/73 (31.51%)	24/75 (32.00%)
Diarrhoea † 1		
# participants affected / at risk	22/73 (30.14%)	23/75 (30.67%)
Abdominal distention † 1		
# participants affected / at risk	12/73 (16.44%)	10/75 (13.33%)
Abdominal pain upper † 1		
# participants affected / at risk	3/73 (4.11%)	11/75 (14.67%)
Ascites † 1		
# participants affected / at risk	8/73 (10.96%)	5/75 (6.67%)
Flatulence † 1		
# participants affected / at risk	9/73 (12.33%)	4/75 (5.33%)
Dyspepsia † 1		
# participants affected / at risk	7/73 (9.59%)	2/75 (2.67%)
Stomatitis † 1		
# participants affected / at risk	3/73 (4.11%)	5/75 (6.67%)
General disorders		
Fatigue † 1		
# participants affected / at risk	32/73 (43.84%)	32/75 (42.67%)
Oedema peripheral † 1		
# participants affected / at risk	27/73 (36.99%)	23/75 (30.67%)
Pyrexia † 1		
# participants affected / at risk	13/73 (17.81%)	26/75 (34.67%)
Asthenia † 1		
# participants affected / at risk	15/73 (20.55%)	18/75 (24.00%)
Chills † 1		
# participants affected / at risk	13/73 (17.81%)	14/75 (18.67%)
Oedema † 1		
# participants affected / at risk	6/73 (8.22%)	4/75 (5.33%)
† 1		

Pain		
# participants affected / at risk	2/73 (2.74%)	7/75 (9.33%)
Chest pain † 1		
# participants affected / at risk	4/73 (5.48%)	3/75 (4.00%)
General physical health deterioration † 1		
# participants affected / at risk	2/73 (2.74%)	4/75 (5.33%)
Hepatobiliary disorders		
Hyperbilirubinaemia † 1		
# participants affected / at risk	5/73 (6.85%)	8/75 (10.67%)
Cholangitis † 1		
# participants affected / at risk	2/73 (2.74%)	4/75 (5.33%)
Jaundice † 1		
# participants affected / at risk	2/73 (2.74%)	4/75 (5.33%)
Infections and infestations		
Urinary tract infection † 1		
# participants affected / at risk	12/73 (16.44%)	10/75 (13.33%)
Cellulitis † 1		
# participants affected / at risk	5/73 (6.85%)	8/75 (10.67%)
Pneumonia † 1		
# participants affected / at risk	4/73 (5.48%)	5/75 (6.67%)
Candidiasis † 1		
# participants affected / at risk	3/73 (4.11%)	4/75 (5.33%)
Rhinitis † 1		
# participants affected / at risk	2/73 (2.74%)	4/75 (5.33%)
Bacteraemia † 1		
# participants affected / at risk	1/73 (1.37%)	4/75 (5.33%)
Investigations		
Weight decreased † 1		
# participants affected / at risk	10/73 (13.70%)	9/75 (12.00%)
Blood alkaline Phosphatase increased † 1		
# participants affected / at risk	9/73 (12.33%)	8/75 (10.67%)
Alanine aminotransferase increased † 1		
# participants affected / at risk	8/73 (10.96%)	6/75 (8.00%)
Aspartate aminotransferase increased † 1		
# participants affected / at risk	8/73 (10.96%)	5/75 (6.67%)
Neutrophil count decreased † 1		
# participants affected / at risk	5/73 (6.85%)	6/75 (8.00%)
Haemoglobin decreased † 1		
# participants affected / at risk	7/73 (9.59%)	3/75 (4.00%)
Blood bilirubin increased † 1		
# participants affected / at risk	4/73 (5.48%)	5/75 (6.67%)
Platelet count decreased † 1		
# participants affected / at risk	3/73 (4.11%)	6/75 (8.00%)
International normalised ratio increased † 1		
# participants affected / at risk	6/73 (8.22%)	2/75 (2.67%)
Metabolism and nutrition disorders		

Anorexia † 1		
# participants affected / at risk	26/73 (35.62%)	25/75 (33.33%)
Dehydration † 1		
# participants affected / at risk	13/73 (17.81%)	15/75 (20.00%)
Hypokalemia † 1		
# participants affected / at risk	12/73 (16.44%)	13/75 (17.33%)
Hyponatremia † 1		
# participants affected / at risk	7/73 (9.59%)	6/75 (8.00%)
Decreased appetite † 1		
# participants affected / at risk	3/73 (4.11%)	7/75 (9.33%)
Hypoalbuminaemia † 1		
# participants affected / at risk	3/73 (4.11%)	6/75 (8.00%)
Hyperglycaemia † 1		
# participants affected / at risk	6/73 (8.22%)	2/75 (2.67%)
Hypomagnesaemia † 1		
# participants affected / at risk	6/73 (8.22%)	2/75 (2.67%)
Hyperkalaemia † 1		
# participants affected / at risk	5/73 (6.85%)	2/75 (2.67%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	10/73 (13.70%)	14/75 (18.67%)
Pain in extremity † 1		
# participants affected / at risk	5/73 (6.85%)	11/75 (14.67%)
Musculoskeletal chest pain † 1		
# participants affected / at risk	4/73 (5.48%)	5/75 (6.67%)
Flank pain † 1		
# participants affected / at risk	4/73 (5.48%)	2/75 (2.67%)
Myalgia † 1		
# participants affected / at risk	0/73 (0.00%)	4/75 (5.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Malignant neoplasm progression † 1		
# participants affected / at risk	13/73 (17.81%)	11/75 (14.67%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	12/73 (16.44%)	12/75 (16.00%)
Headache † 1		
# participants affected / at risk	7/73 (9.59%)	9/75 (12.00%)
Dysgeusia † 1		
# participants affected / at risk	6/73 (8.22%)	5/75 (6.67%)
Hypoaesthesia † 1		
# participants affected / at risk	0/73 (0.00%)	5/75 (6.67%)
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	13/73 (17.81%)	10/75 (13.33%)

Anxiety † 1		
# participants affected / at risk	8/73 (10.96%)	6/75 (8.00%)
Depression † 1		
# participants affected / at risk	4/73 (5.48%)	5/75 (6.67%)
Sleep disorder † 1		
# participants affected / at risk	2/73 (2.74%)	5/75 (6.67%)
Confusional state † 1		
# participants affected / at risk	5/73 (6.85%)	1/75 (1.33%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	18/73 (24.66%)	11/75 (14.67%)
Cough † 1		
# participants affected / at risk	7/73 (9.59%)	9/75 (12.00%)
Pulmonary embolism † 1		
# participants affected / at risk	7/73 (9.59%)	8/75 (10.67%)
Dyspnoea exertional † 1		
# participants affected / at risk	4/73 (5.48%)	5/75 (6.67%)
Pleural effusion † 1		
# participants affected / at risk	4/73 (5.48%)	3/75 (4.00%)
Productive cough † 1		
# participants affected / at risk	5/73 (6.85%)	0/75 (0.00%)
Skin and subcutaneous tissue disorders		
Rash † 1		
# participants affected / at risk	11/73 (15.07%)	16/75 (21.33%)
Alopecia † 1		
# participants affected / at risk	11/73 (15.07%)	6/75 (8.00%)
Night sweats † 1		
# participants affected / at risk	6/73 (8.22%)	5/75 (6.67%)
Pruritus † 1		
# participants affected / at risk	4/73 (5.48%)	6/75 (8.00%)
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	7/73 (9.59%)	11/75 (14.67%)
Hypertension † 1		
# participants affected / at risk	5/73 (6.85%)	10/75 (13.33%)
Hypotension † 1		
# participants affected / at risk	5/73 (6.85%)	6/75 (8.00%)
Pallor † 1		
# participants affected / at risk	4/73 (5.48%)	0/75 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

- [x] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Susan Weil, MD
Organization: Morphotek, Inc.
phone: 610-423-6182
e-mail: sweil@morphotek.com

Responsible Party:	Morphotek
ClinicalTrials.gov Identifier:	NCT00570713 History of Changes
Other Study ID Numbers:	MORAb-009-002
Study First Received:	December 7, 2007
Results First Received:	December 8, 2011
Last Updated:	September 4, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK