

Protocol Registration Receipt

10/05/2008

Grantor: CBER IND/IDE Number: 11586 Serial Number: 0023

Safety/Efficacy Study of Regin-G to Treat Pancreatic Cancer

This study is currently recruiting participants.

Verified by Epeius Biotechnologies, October 2008

Sponsored by:	Epeius Biotechnologies
Information provided by:	Epeius Biotechnologies
ClinicalTrials.gov Identifier:	NCT00504998

 Purpose

The goal of the adaptive trial design is to determine the over-all safety of escalating doses of Regin-G and to determine the optimal dosing regimen for Regin-G that would document the significant clinical benefits required to support a Phase II registration protocol.

Condition	Intervention	Phase
Pancreatic Cancer	Genetic: Regin-G	Phase 1/Phase 2

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Open Label, Non-Randomized, Uncontrolled, Safety/Efficacy Study

Official Title: Phase I/II Evaluation of Safety and Efficacy of Regin-G for Recurrent or Metastatic Pancreatic Cancer

Further study details as provided by Epeius Biotechnologies:

Primary Outcome Measure:

- Clinical toxicity (DLT and MTD) as defined by patient performance status, toxicity assessment score, hematologic, and metabolic profiles. [Time Frame: 24] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- To identify an objective tumor response to Regin-G [Time Frame: 24 months] [Designated as safety issue: No]

Estimated Enrollment: 24

Study Start Date: July 2007

Estimated Study Completion Date: July 2009

Estimated Primary Completion Date: December 2008

Arms	Assigned Interventions
<p>Experimental: 1 Dose Level 1 of escalating doses of Regin-G i.v.</p>	<p>Genetic: Regin-G Dosing Schedule: 1 x 10¹¹ cfu 2 times a week for 4 weeks, followed by a 2-week rest period. Treatment cycle may be repeated if patient has Grade 1 or less toxicity.</p>
<p>Experimental: 2 Dose Level 2 of escalating doses of Regin-G i.v.</p>	<p>Genetic: Regin-G Dosing Schedule: 1 x 10¹¹ cfu three times a week for 4 weeks, followed by a 2-week rest period. Treatment cycle may be repeated if patient has Grade 1 or less toxicity.</p>
<p>Experimental: 3 Dose Level 3 of escalating doses of Regin-G i.v.</p>	<p>Genetic: Regin-G Dosing Schedule: 2 x 10¹¹ cfu three times a week for 4 weeks, followed by a 2-week rest period. Treatment cycle may be repeated if patient has Grade 1 or less toxicity.</p>
<p>Experimental: 4 Dose Level 4 of escalating doses of Regin-G i.v.</p>	<p>Genetic: Regin-G Dose Schedule: 3 x 10¹¹ cfu i.v. three times a week for 4 weeks, followed by a 2-week rest period. Treatment cycle may be repeated if patient has less than Grade 1 or less toxicity.</p>
<p>Experimental: 5 Dose Level 5 of escalating doses of Regin-G i.v.</p>	<p>Genetic: Regin-G Dosing Schedule: 4 x 10¹¹ cfu i.v. three times a week for 4 weeks, followed by a 2-week rest period. Treatment cycle may be repeated if patient has Grade 1 or less toxicity.</p>

The clinical trial is a safety and efficacy study using escalating doses of Regin-G that incorporates a Phase II component that will evaluate the efficacy of Regin-G using an adaptive trial design. Each treatment cycle will be six weeks: four weeks of treatment and two weeks of rest. Unlike a standard Phase I protocol, eligible patients

may have repeat cycles after the safety data and objective tumor response/s are recorded. Continued Regin-G treatment will enable the targeted genetic medicine to catch up with tumor growth, halt disease progression, and reduce tumor burden. The treatment strategy is to achieve tumor control as quickly as safely possible. The goal of the adaptive trial design is to confirm the over-all safety of Regin-G and to determine the optimal dosing regimen for Regin-G that would document the significant clinical benefits required to support a Phase II/III pivotal trial.

Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

1. Histologically or cytologically confirmed recurrent or metastatic pancreatic cancer that has failed gemcitabine and that is measurable.
2. Adequate hepatic function: Total bilirubin < 2.0 mg/dL (upper limit included); AST/ALT < 2x institutional norm; alkaline phosphatase < 2.5x upper limit of institutional norm unless the patient has extensive bone metastases. Patients with elevated alkaline phosphatase due to extensive liver disease will be excluded from study; albumin > 3.0 mg/dL. There must be no substantial ascites. PT and PTT must be within normal limits.
3. Performance status must be < 1 (ECOG 0-1) with a life expectancy of at least 3 months.
4. Hemoglobin > 9 gms%
5. Absolute granulocyte count > 1000/uL, and platelet count > 100,000/uL.
6. Serum creatinine of less than 1.5 mg%.
7. There must be no plans for the patient to receive further cancer therapy from the date of enrollment until the completion of the 6-week follow-up visit.
8. Accessibility of peripheral or central IV line
9. Age > 10 years
10. Patients will be off chemotherapy for a minimum of 4 weeks prior to initiation of therapy and should have recovered to Grade 1 or less toxicity.
11. The ability to understand and the willingness to sign a written informed consent document.

Exclusion Criteria:

1. Prior malignancy, except for non-melanoma skin cancer, stage 1 breast cancer, CIS of cervix from which the patient has been disease-free for 5 years.
2. Woman who are pregnant or nursing
3. Fertile patients unless they agree to use barrier contraception (condoms and spermicide jelly) during the vector infusion period and for six weeks after infusion. Male patients must agree to use barrier contraception.
4. Patients who are transfusion dependent (more than one transfusion per month)
5. Patients with medical, psychiatric, or social conditions that would compromise successful adherence to this protocol.
6. Patient who do not meet the inclusion criteria.

Contacts and Locations

Contacts

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Locations

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Investigators

Principal Investigator:	Sant P Chawla, M.D.	Epeius Clinical Research Unit/Sarcoma Oncology Center
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More Information

Responsible Party: Epeius Biotechnologies Corporation (Erlinda M. Gordon, M.D.)
Study ID Numbers: C07-105, FDA-OOPD R01 FD003071-01
Health Authority: United States: Food and Drug Administration