

Protocol Registration Receipt
10/05/2008

Grantor: CBER IND/IDE Number: 11586 Serial Number: 0018

Safety and Efficacy Study Using Regin-G for Breast 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:	NCT00505271

► Purpose

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 registration protocol for recurrent or metastatic breast cancer.

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

Study Type: Interventional

Study Design: Treatment, Single Group Assignment, Open Label, N/A, Dose Comparison, Safety/Efficacy Study

Official Title: Phase I/II Evaluation of Safety and Efficacy of Pathotropic Nanoparticles Bearing a Dominant Negative Cyclin G1 Construct (Regin-G) as Intervention for Recurrent or Metastatic Breast 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 months] [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</p> <p>Escalating doses of Regin-G will be given two or three times a week for four weeks, with a 2 week rest period</p>	<p>Genetic: Regin-G</p> <p>Three patients will receive Regin-G at Dose Level I. If 1 of 3 patients at Dose Level I develops a grade 3 or 4 adverse event (CTCAE Version 3.0) which appears to be related or possibly related to Regin-G, then 3 additional patients will be enrolled at the same dose level. If at least 2 of the first 3, or 3 of 6 patients at Dose Level I develop a grade 3 to 4 adverse event which appears to be related or possibly related to Regin-G, accrual into the study will be held.</p> <p>At any dose level, up to six patients may be enrolled if there is evidence of biological activity in the first three patients. Dose escalation may stop if there is impressive evidence of biological activity. An amendment would be submitted to allow further expansion of dose level based on impressive biological activity.</p>

The clinical trial 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 nanomedicine 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 registration protocol for breast cancer.

 Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

1. Histologically or cytologically confirmed recurrent or metastatic breast cancer that is refractory to standard chemotherapy 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 > 18 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.

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Bruckner Oncology

More Information

Responsible Party: Epeius Biotechnologies Corporation (Erlinda M. Gordon, M.D.)

Study ID Numbers: C07-104

Health Authority: United States: Food and Drug Administration