

Protocol Registration Receipt

2007-09-13

IND Grantor: CBER IND Number: 11586 IND Serial Number: 0017

Safety and Efficacy Study Using Rexin-G for Sarcoma

This study is currently recruiting patients.

Verified by Epeius Biotechnologies 2007-07

Sponsors and Collaborators:	Epeius Biotechnologies
Information provided by:	Epeius Biotechnologies
ClinicalTrials.gov Identifier:	NCT00505713

► Purpose

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

Condition	Intervention	Phase
Sarcoma	Drug: Rexin-G	Phase 1 Phase 2

Study Type: Interventional

Study Design: Treatment, Open Label, Dose Comparison, Single Group Assignment

Number of arms in study: 1

Official Title: Evaluation of Safety and Efficacy of Rexin-G as Intervention for Recurrent or Metastatic Sarcoma

Further Study Details:

Primary Outcomes:

- Clinical toxicity (DLT and MTD) as defined by patient performance status, toxicity assessment score, hematologic, and metabolic profiles [Time Frame: 12 months]

Secondary Outcomes:

- To identify an objective tumor response to Rixin-G [Time Frame: 12 months]

Expected Total Enrollment: 24

Study Start: 2007-07; Expected Completion: 2008-07

The Phase I/II clinical trial incorporates a Phase II component that will evaluate the efficacy of Rixin-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 Rixin-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 Rixin-G and to determine the optimal dosing regimen for Rixin-G that would document the significant clinical benefits required to support a Phase II registration protocol.

Eligibility

Ages Eligible for Study: 10 Years and above , Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

1. Histologically or cytologically confirmed recurrent or metastatic sarcoma 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.

 Location and Contact Information

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 More Information

Study ID Numbers C07-103

NLM Identifier NCT00505713

Health Authority: United States: Food and Drug Administration