Study Description

Brief Summary:
Twenty to forty patients will receive DeltaRex-G intravenously at a dose of $3 \times 10^{11}$ colony forming units (cfu) or equivalent $1.6 \times 10^{10}$ Neo Units (60 ml) per dose three times a week for 3 weeks followed by one week rest. Based on previous Phase 1/2 US based clinical studies, DeltaRex-G does not suppress the bone marrow or cause serious organ dysfunction, and enhanced immune cell trafficking in tumors may cause the tumors to appear larger or new lesions to
appear on CT, PET or MRI. Further, tumor stabilization/regression/remission may occur later during the treatment period. Therefore, DeltaRex-G will be continued regardless of CT, PET or MRI results if the patient has clinical benefit and does not have symptomatic disease progression.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic Cancer</td>
<td>Drug: DeltaRex-G</td>
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<tr>
<td>Osteosarcoma</td>
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<tr>
<td>MPNST (Malignant Peripheral Nerve Sheath Tumor)</td>
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<tr>
<td>Chondrosarcoma</td>
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<tr>
<td>Soft Tissue Sarcoma</td>
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<tr>
<td>Chordoma</td>
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<tr>
<td>Sarcoma</td>
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</tbody>
</table>

Detailed Description:

Twenty to forty patients with advanced pancreatic cancer and sarcoma will receive DeltaRex-G intravenously at a dose of 3 x 10e11 colony forming units (cfu) or equivalent 1.6 x 10e10 Neo Units (60 ml) per dose three times a week for 3 weeks followed by one week rest. Based on previous Phase 1/2 US based clinical studies, DeltaRex-G does not suppress the bone marrow or cause serious organ dysfunction, and enhanced immune cell trafficking in tumors may cause the tumors to appear larger or new lesions to appear on CT, PET or MRI. Further, tumor stabilization/regression/remission may occur later during the treatment period. Therefore, DeltaRex-G will be continued regardless of CT, PET or MRI results if the patient has clinical benefit and does not have symptomatic disease progression.

If the patient develops a treatment-related >Grade 3 adverse event, the DeltaRex-G infusions will be held and the patient will be monitored until the toxicity has resolved to <Grade 1, and the patient is stable, after which treatment may be resumed. If the adverse event does not resolve to <Grade 1 within 3 weeks, the DeltaRex-G treatment will be held until the data are discussed with the Food and Drug Administration and a decision is made whether to continue or terminate the study.

Study Design

Study Type: Expanded Access

Expanded Access Type: Intermediate-size Population

Official Title:

BLESSED: Expanded Access for DeltaRex-G for Advanced Pancreatic Cancer and Sarcoma
Intervention Details:

- **Drug:** DeltaRex-G

  Intravenous infusions of **DeltaRex-G** for treatment of advanced pancreatic cancer and sarcoma that have failed standard therapies

  Other Name: **DeltaRex-G** Retroviral Vector Encoding a Cyclin G1 Inhibitor

Eligibility Criteria

**Ages Eligible for Study:**

10 Years to 100 Years (Child, Adult, Older Adult)

**Sexes Eligible for Study:**

All

**Accepts Healthy Volunteers:**

No

**Criteria**
Inclusion Criteria:

- Patient is ≥10 years of age, either male or female.
- Patient has advanced metastatic pancreatic cancer or advanced metastatic sarcoma confirmed by pathologic examination at diagnosis.
- Patients with advanced metastatic pancreatic cancer who have received systemic therapies such as FOLFIRINOX and gemcitabine + albumin-bound paclitaxel; patients with metastatic sarcoma who have disease progression after two or more lines of systemic treatments and not amenable to surgical resection or radiotherapy; specifically for osteosarcoma: have disease progression after high dose methotrexate, cisplatinum, doxorubicin and ifosfamide; for soft tissue sarcoma: have disease progression after doxorubicin + ifosfamide/mesna, gemcitabine, docetaxel, dacarbazine, trabectedin, pazopanib, eribulin; patient who is intolerant to or declines available therapeutic options after documentation that patient has been informed of the available therapeutic options.
- Patient is able to understand or is willing to sign a written informed consent.
- Patient agrees to use barrier contraception during vector infusion period and for 6 weeks after infusion

Exclusion Criteria:

- Patient is unwilling to provide formal informed consent.
- Patient is unwilling to use barrier contraception during vector infusion period and for 6 weeks after infusion

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT04091295

Contacts

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Sub-Investigator: Doris Quon, MD
Sub-Investigator: Ania M Moradkhani, NP

Sponsors and Collaborators
Aveni Foundation

Investigators
Principal Investigator:    ERLINDA M GORDON, MD    Sarcoma Oncology Research Center, LLC

More Information
Go to

Publications of Results:


Other Publications:


**Responsible Party:**
Erlinda M Gordon, Chief Medical Officer, Aveni Foundation

**ClinicalTrials.gov Identifier:**
- NCT04091295
- History of Changes

**Other Study ID Numbers:**
- AF19-200

**First Posted:**
September 16, 2019

**Last Update Posted:**
February 14, 2020

**Last Verified:**
February 2020

**Keywords provided by Erlinda M Gordon, Aveni Foundation:**
- tumor targeted gene therapy
- human cyclin G1 inhibitor
- cell cycle control
- CCNG1 inhibitor

**Additional relevant MeSH terms:**
Pancreatic Neoplasms
Sarcoma
Osteosarcoma
Chondrosarcoma
Chordoma
Nerve Sheath Neoplasms
Neurofibrosarcoma
Digestive System Neoplasms
Neoplasms by Site
Neoplasms
Endocrine Gland Neoplasms
Digestive System Diseases
Pancreatic Diseases
Endocrine System Diseases
Neoplasms, Connective and Soft Tissue
Neoplasms by Histologic Type
Neoplasms, Bone Tissue
Neoplasms, Connective Tissue
Neoplasms, Germ Cell and Embryonal
Neoplasms, Nerve Tissue
Peripheral Nervous System Neoplasms
Nervous System Neoplasms
Nervous System Diseases
Peripheral Nervous System Diseases
Neuromuscular Diseases
Fibrosarcoma
Neoplasms, Fibrous Tissue
Neurofibroma