Trial record **1 of 1** for: DeltaRex-G

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

ClinicalTrials.gov Identifier: NCT04091295

Expanded Access Status : Available
First Posted : September 16, 2019
Last Update Posted : February 14, 2020

Sponsor:
Aveni Foundation

Information provided by (Responsible Party):
Erlinda M Gordon, Aveni Foundation

Study Details | Tabular View | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
Twenty to forty patients 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.

Condition or disease	Intervention/treatment
Pancreatic Cancer Osteosarcoma MPNST (Malignant Peripheral Nerve Sheath Tumor) Chondrosarcoma Soft Tissue Sarcoma Chordoma Sarcoma	Drug: **DeltaRex-G**

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

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Study Type :

Expanded Access

Expanded Access Type :

Intermediate-size Population

Official Title:

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

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Pancreatic Cancer Soft Tissue Sarcoma

Genetic and Rare Diseases Information Center resources: Pancreatic Cancer Chondrosarcoma Soft Tissue Sarcoma Osteosarcoma Malignant Peripheral Nerve Sheath Tumor Neurofibrosarcoma Chordoma Fibrosarcoma Neurofibromatosis Neurofibroma

U.S. FDA: Expanded Access (Compassionate Use)

U.S. FDA Resources

Interventions

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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

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

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

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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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Locations

United States, California

Sarcoma Oncology Research Center, LLC **Available**

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Contact: ERLINDA M GORDON, MD 310-552-9999 egordon@sarcomaoncology.com
Contact: Victoria Chua-Alcala, MD 3105529999 ext Chawla santchawla@sarcomaoncology.com
Sub-Investigator: Sant P Chawla, MD
Sub-Investigator: Steven Wong, MD
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

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Publications of Results:

Kim S, Federman N, Gordon EM, Hall FL, Chawla SP. Rexin-G(®), a tumor-targeted retrovector for malignant peripheral nerve sheath tumor: A case report. Mol Clin Oncol. 2017 Jun;6(6):861-865. doi: 10.3892/mco.2017.1231. Epub 2017 Apr 28.

Other Publications:

Chawla SP, Chawla NS, Quon D, Chua-Alcala V, Blackwelder WC, Hall FL and Gordon EM: An advanced phase 1/2 study using an XC-targeted gene therapy vector for chemotherapy resistant sarcoma. Sarcoma Res Int 3: 1024, 2016

Gordon EM, Hall FL. Rexin-G, a targeted genetic medicine for cancer. Expert Opin Biol Ther. 2010 May;10(5):819-32. doi: 10.1517/14712598.2010.481666. Review.

Chawla SP, Chua VS, Fernandez L, Quon D, Saralou A, Blackwelder WC, Hall FL, Gordon EM. Phase I/II and phase II studies of targeted gene delivery in vivo: intravenous Rexin-G for chemotherapy-resistant sarcoma and osteosarcoma. Mol Ther. 2009 Sep;17(9):1651-7. doi: 10.1038/mt.2009.126. Epub 2009 Jun 16.

Chawla SP, Bruckner H, Morse MA, Assudani N, Hall FL, Gordon EM. A Phase I-II Study Using Rexin-G Tumor-Targeted Retrovector Encoding a Dominant-Negative Cyclin G1 Inhibitor for Advanced Pancreatic Cancer. Mol Ther Oncolytics. 2018 Dec 14;12:56-67. doi: 10.1016/j.omto.2018.12.005. eCollection 2019 Mar 29.

Al-Shihabi A, Chawla SP, Hall FL, Gordon EM. Exploiting Oncogenic Drivers along the CCNG1 Pathway for Cancer Therapy and Gene Therapy. Mol Ther Oncolytics. 2018 Dec 12;11:122-126. doi: 10.1016/j.omto.2018.11.002. eCollection 2018 Dec 21. Review.

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 Key Record Dates

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