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GL-ONC1 Oncolytic Immunotherapy in Patients With Platinum-resistant Ovarian Cancer

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified April 2016 by Genelux Corporation

Sponsor:
Genelux Corporation

Information provided by (Responsible Party):
Genelux Corporation

ClinicalTrials.gov Identifier:
NCT02759588

First received: April 25, 2016
Last updated: April 29, 2016
Last verified: April 2016
History of Changes

Purpose

The purpose of this study is to determine if GL-ONC1 oncolytic immunotherapy is well tolerated with anti-tumor activity in patients diagnosed with platinum-resistant or refractory ovarian cancer and peritoneal carcinomatosis.

Condition	Intervention	Phase
Ovarian Cancer Peritoneal Carcinomatosis Fallopian Tube Cancer	Biological: GL-ONC1	Phase 1

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase 1b Study With GL-ONC1 Oncolytic Immunotherapy in Patients With Platinum-resistant or Refractory Ovarian Cancer

Resource links provided by NLM:

Genetics Home Reference related topics: ovarian cancer

MedlinePlus related topics: Cancer Ovarian Cancer

Genetic and Rare Diseases Information Center resources: Fallopian Tube Cancer Ovarian Cancer

U.S. FDA Resources

Further study details as provided by Genelux Corporation:

Primary Outcome Measures:

- Incidence of Treatment-emergent Adverse Events [Safety and Tolerability] [Time Frame: Change from baseline during Treatment and for 30 days following last dose.] [Designated as safety issue: Yes]

  Determine safety and tolerability of administering multiple doses of GL-ONC1 via intraperitoneal catheter by the evaluation of the number of participants with treatment-emergent adverse events (type, frequency, and severity) as assessed by CTCAE 4.03.

Secondary Outcome Measures:

- Evaluation of Tumor Response to Treatment [Time Frame: Assessed post-treatment at 9 to 12 week intervals or until disease progression or death from any cause, whichever comes first, assessed up to 24 months.] [Designated as safety issue: No]

  Evaluate participant's best overall response to treatment with therapeutic intent assessed by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. (i.e., complete response, partial response, stable disease, or progressive disease).

- Evaluation of Tumor Response to Treatment with Oncolytic Immunotherapy [Time Frame: Assessed post-treatment at 9 to 12 week intervals or until disease progression or death from any cause, whichever comes first, assessed up to 24 months.] [Designated as safety issue: No]

  Evaluate participants' best overall response to treatment with oncolytic immunotherapy assessed by Immune-related Response Criteria (immune-related complete response, immune-related partial response, immune-related stable disease, or immune-related progressive disease).

- Tumor Marker Cancer Antigen-125 Response to Treatment with Oncolytic Immunotherapy [Time Frame: Assessed pre-treatment, during treatment and post-treatment at 9 to 12 week intervals, assessed up to 24 months.] [Designated as safety issue: No]

  Cancer Antigen (CA)-125 response to treatment according to the Gynecologic Cancer Intergroup (GCIG) is measured by at least a 50% reduction in CA-125 levels from pre-treatment sample which is confirmed and maintained for at least 28 days. Pre-treatment CA-125 sample must be at least twice the upper limit of normal and obtained within 2 weeks prior to starting treatment.

- Determine Progression-free Survival following Treatment [Time Frame: From date of randomization until the date of first documented disease progression or date of death from any cause, whichever comes first, assessed up to 24 months.] [Designated as safety issue: No]

  To assess progression-free survival (PFS) from time of randomization until disease progression or death in participant population.

- Overall Survival [Time Frame: By medical chart review until death or 3 years from the date of last treatment which ever comes first.] [Designated as safety issue: No]

  To determine overall survival (OS) with the treatment regimen in the participant population.

Estimated Enrollment:	12
Study Start Date:	May 2016
Estimated Study Completion Date:	April 2017
Estimated Primary Completion Date:	April 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: GL-ONC1	Biological: GL-ONC1 A genetically-engineered oncolytic vaccinia virus administered via intraperitoneal infusion as multiple doses.

Detailed Description:

Ovarian cancer (OC) remains the most lethal gynecologic malignancy owing to late detection, intrinsic and acquired chemo-resistance and remarkable heterogeneity. There is an unmet medical need to develop new therapy modalities. In preclinical studies, GL-ONC1, has shown the ability to preferentially locate, colonize and destroy tumor cells in more than 30 different human tumors, including ovarian cancer. GL-ONC1 has been investigated in early stage clinical trials in the United States and Europe via systemic delivery as monotherapy and in combination with other therapies, and via regional delivery as monotherapy. GL-ONC1 treatment was well tolerated across different malignancies, routes of administration, and monotherapy as well as combination therapy protocols. The ability of GL-ONC1 to infect tumor tissue and kill tumor cells was demonstrated. In addition, virus-induced immune activation and favorable anti-tumor immune response have been observed. Evidences of anti-tumor efficacy and clinical benefits have also been documented.

Eligibility

Ages Eligible for Study:	21 Years and older
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Signed, written informed consent.
- High-grade serous, endometrioid, or clear-cell ovarian cancer that is platinum-resistant (progressive disease within 6 months of platinum therapy) or platinum-refractory (progressive disease while on platinum therapy).
- Performance status ECOG is at 0 or 1, and life expectancy of 6 months
- Failed two consecutive therapies or are not eligible for additional cytotoxic therapies.
- Has either measurable disease in the peritoneal cavity as defined by RECIST 1.1 or has non-measurable disease in the peritoneal cavity and can be confirmed by laparoscopy and/or elevated CA-125.
- Able to undergo IP injection.
- Adequate renal, hepatic and bone marrow functions.

Exclusion Criteria:

- Tumors of malignant mixed mesodermal (MMMT) or mucinous subtypes, or non-epithelial ovarian cancers (e.g., Brenner tumors, Sex-cord tumors).
- **Unresolved bowel obstruction.**
- Known central nervous system (CNS) metastasis.
- Known seropositivity for HIV, hepatitis.
- History of thromboembolic event within the last 3 months.
- Pregnant or breast-feeding women.
- Smallpox vaccination within 1 year of study treatment.
- Clinically significant cardiac disease.
- Received prior gene therapy or therapy with cytolytic virus of any type.
- Receiving concurrent antiviral agent active against vaccinia virus.
- Have known allergy to ovalbumin or other egg products.
- Have clinically significant dermatological disorders (e.g., eczema, psoriasis, or unhealed skin wounds or ulcers) as assessed by the Investigator.

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02759588

Contacts

Contact: Deborah Sams 407-303-2090 deborah.sams@flhosp.org

Locations

United States, Florida

Florida Hospital Cancer Institute **Not yet recruiting**
Orlando, Florida, United States, 32804
Contact: Deborah Sams 407-303-2090 deborah.sams@flhosp.org
Principal Investigator: Robert W. Holloway, MD, FACOG, FACS

Sponsors and Collaborators

Genelux Corporation

Investigators

Principal Investigator: Robert W. Holloway, MD, FACOG, FACS Florida Hospital Cancer Institute

More Information

Additional Information:

Sponsor's company website

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ClinicalTrials.gov Identifier:	NCT02759588 History of Changes
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Keywords provided by Genelux Corporation:

GL-ONC1
oncolytic virus
virotherapy
Viral therapy
immunotherapy
immune therapy
peritoneal carcinomatosis
fallopian cancer
cancer
abdominal cancer
imaging
carcinoma

vaccinia
vaccinia virus
Genelux
ovarian cancer
platinum resistant
platinum refractory
DNA virus
neoplasms
neoplasms by histological type
neoplasms, Glandular and Epithelial
Poxviridae infections
Virus diseases

Additional relevant MeSH terms:
Ovarian Neoplasms
Adnexal Diseases
Endocrine Gland Neoplasms
Endocrine System Diseases
Genital Diseases, Female
Genital Neoplasms, Female
Gonadal Disorders
Neoplasms
Neoplasms by Site
Ovarian Diseases
Urogenital Neoplasms

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