Trial record **1 of 3** for: pisarro

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p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin Combination Chemotherapy With or Without APR-246

This study is currently recruiting participants.

See **Contacts and Locations**

Verified October 2017 *by Aprea Therapeutics AB*

Sponsor:
Aprea Therapeutics AB

ClinicalTrials.gov Identifier:
NCT02098343

First Posted: March 28, 2014
Last Update Posted: October 11, 2017

Information provided by (Responsible Party):
Aprea Therapeutics AB

Full Text View | Tabular View | No Study Results Posted | Disclaimer
How to Read a Study Record

Purpose

The purpose of this study is to make a preliminary assessment of the efficacy of a combined APR-246 and carboplatin/PLD chemotherapy regimen, compared with carboplatin/PLD chemotherapy regimen

alone, in patients with platinum sensitive recurrent high grade serous ovarian cancer (HGSOC) with mutated p53. In addition, the study aims to assess the safety profile of the combined APR-246 and carboplatin/PLD chemotherapy regimen compared with carboplatin/PLD chemotherapy regimen alone, to evaluate potential biomarkers, and to assess the biological activity in tumor and surrogate tissues. The trial will enroll up to a maximum of 400 patients.

Condition	Intervention	Phase
Platinum Sensitive Recurrent High-grade Serous Ovarian Cancer With Mutated p53	Drug: APR-246 Drug: Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD)	Phase 1 Phase 2

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: **PiSARRO**: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin Combination Chemotherapy With or Without APR-246

Resource links provided by NLM:

Genetics Home Reference related topics: ovarian cancer

MedlinePlus related topics: Ovarian Cancer

Drug Information available for: Carboplatin

Genetic and Rare Diseases Information Center resources: Ovarian Cancer
Ovarian Epithelial Cancer

U.S. FDA Resources

Further study details as provided by Aprea Therapeutics AB:

Primary Outcome Measures:

- Phase Ib: Dose-limiting toxicities (DLT) (see Description) of combined APR-246 and carboplatin/PLD regimen [Time Frame: Until the end of the first treatment cycle, i.e., Day 28]

DLT: Hematological and non-hematological toxicities according to grade/days stated in the protocol.

- Phase Ib: Safety Profile (see Description) of combined APR-246 and carboplatin/PLD regimen [Time Frame: Until 30 days after the last administration of study treatment to the patient]

  Safety Analysis: Adverse events (AEs) will be summarized by body system, preferred term, severity, and relationship to treatment. Serious adverse events, deaths, and AEs leading to early discontinuation of study drug will be summarized. Laboratory parameters will be summarized.

- Phase Ib: Maximum observed plasma concentration (Cmax) of APR-246 [Time Frame: Until Day 5 in cycle 1]
- Phase Ib: Area under the plasma concentration-time curve (AUC) of APR-246 [Time Frame: Until Day 5 in cycle 1]
- Phase II: Progression Free Survival (PFS) [Time Frame: Up to 24 months]

Secondary Outcome Measures:

- Phase II: Overall Survival (OS) [Time Frame: Up to 24 months]

  Time frame from registration to the date of death from any cause.

- Phase II: Overall Response Rate (RR) [Time Frame: Up to 24 months]
- Phase II: Safety Profile (see Description) of combined APR-246 and carboplatin/PLD regimen or the carboplatin/PLD regimen alone [Time Frame: Until 30 days after the last administration of study treatment to the patient.]

  Safety Analysis: Adverse events will be summarized by body system, preferred term, severity, and relationship to treatment. Serious adverse events, deaths, and AEs leading to early discontinuation of study drug will be summarized. Laboratory parameters will be summarized.

Estimated Enrollment:	400
Study Start Date:	March 2014
Estimated Primary Completion Date:	September 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions

Experimental: Phase Ib. APR-246 + Carboplatin/PLD. Dose escalation of APR-246.	Drug: APR-246 Intravenous infusion. Drug: Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD) Intravenous infusion.
Experimental: Phase II: Arm A. APR-246 + Carboplatin/PLD. Experimental	Drug: APR-246 Intravenous infusion. Drug: Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD) Intravenous infusion.
Active Comparator: Phase II: Arm B. Carboplatin/PLD. Active Comparator	Drug: Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD) Intravenous infusion.

Eligibility

Information from the National Library of Medicine NIH NLM

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:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Confirmed High Grade Serous Ovarian Cancer, and positive nuclear immunohistochemical (IHC) staining for p53
- Disease Progression between 6-24 months after a first or second platinum based regimen
- At least a single measurable lesion. Phase II patients only
- Adequate organ function prior to registration

- Toxicities from previous cancer therapies must have recovered to grade 1 (defined by Common Terminology Criteria for Adverse Events [CTCAE] 4.0) Chronic stable grade 2 peripheral neuropathy secondary to neurotoxicity from prior therapies may be considered on a case by case basis
- ECOG performance status of 0 to 1

Exclusion Criteria:

- Prior exposure to cumulative doses of doxorubicin >400 mg/m2 or epirubicin >720 mg/m2
- History of allergic reactions to carboplatin, platinum containing compounds or mannitol and/or hypersensitivity to PLD or to any of the excipients
- Unable to undergo imaging by either CT scan or MRI
- Evidence of any other medical conditions (such as psychiatric illness, infectious diseases, neurological conditions, physical examination or laboratory findings) that may interfere with the planned treatment, affect patient compliance or place the patient at high risk from treatment related complications
- Concurrent malignancy requiring therapy (excluding non-invasive carcinoma or carcinoma in situ)
- Is taking concurrent (or within 4 week prior to registration) chemotherapy, immunotherapy, radiotherapy, or any ancillary therapy that is considered to be investigational (i.e., used for non-approved indications(s) and in the context of a research investigation). Supportive care measures are allowed

Contacts and Locations

Information from the National Library of Medicine NIH NLM

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): ***NCT02098343***

Contacts

Contact: Roger Tell, MD PhD +46 8 508 845 04 Roger.Tell@aprea.com

Show 52 Study Locations

Sponsors and Collaborators

Aprea Therapeutics AB

Investigators

Principal Investigator: John A Green, Dr Coordinating Investigator. Clatterbridge Centre for Or

More Information

Additional Information:

Aprea Therapeutics AB's website (Sponsor)

Publications:

Lehmann S, Bykov VJ, Ali D, Andrén O, Cherif H, Tidefelt U, Uggla B, Yachnin J, Juliusson G, Moshfegh A, Paul C, Wiman KG, Andersson PO. Targeting p53 in vivo: a first-in-human study with p53-targeting compound APR-246 in refractory hematologic malignancies and prostate cancer. J Clin Oncol. 2012 Oct 10;30(29):3633-9. doi: 10.1200/JCO.2011.40.7783. Epub 2012 Sep 10.

Deneberg S, Cherif H, Lazarevic V, Andersson PO, von Euler M, Juliusson G, Lehmann S. An open-label phase I dose-finding study of APR-246 in hematological malignancies. Blood Cancer J. 2016 Jul 15;6(7):e447. doi: 10.1038/bcj.2016.60.

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Keywords provided by Aprea Therapeutics AB:
Ovarian cancer
Ovarian carcinoma
High Grade Serous Ovarian Cancer
Recurrent Cancer
Resistant Cancer

Additional relevant MeSH terms:

Ovarian Neoplasms
Endocrine Gland Neoplasms
Neoplasms by Site
Neoplasms
Ovarian Diseases
Adnexal Diseases
Genital Diseases, Female
Genital Neoplasms, Female
Urogenital Neoplasms
Endocrine System Diseases
Gonadal Disorders
Liposomal doxorubicin
Carboplatin
Doxorubicin
Antineoplastic Agents
Antibiotics, Antineoplastic
Topoisomerase II Inhibitors
Topoisomerase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action