Clinical Trials at your Fingertips

The Jefferson Clinical Trials app allows you to quickly reference the TJU clinical trials database, including access to contact information for all trials. Download the app by searching Jefferson Clinical Trials.

For more information, please contact Anthony Roberts, BS 215-955-4235 or Anthony.Roberts@jefferson.edu

Introducing Thomas Jefferson University’s Quarterly Molecular Tumor Board

January 9, 2018 @ 5:30pm

Goals of Virtual Molecular Tumor Board

Clinical Care
- Providing real time interpretation of molecular profiling of patients to select treatment strategies

Education
- Refreshing and updating provider awareness of key genetic components of cancer and the methods used to detect them

Research
- Identifying patients for clinical trials
- Quantifying trends across hospitals
- Expanding personalized medicine through PMEC

Collaboration
- Enhancing conversations between providers and gaining wisdom through the experience of our colleagues

For more information please contact Joshua Schoppe:
Phone: 215.955.0448
Joshua.Schoppe@jefferson.edu

REFERRING A PATIENT?

The SKCN has launched a new referral email address to streamline the process for working together to provide our patients with personalized oncology treatment care.

Please email information to clinical-trial-referrals@jefferson.edu
Title: A Phase II, Single-Arm, Open-Label, Multicenter Study of Enfortumab Vedotin (ASG-22CE) for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer Who Previously Received Immune Checkpoint Inhibitor (CPI) Therapy

Sponsor: Seattle Genetics
PI: Jean Hoffman-Censits, MD

Primary Objective: To determine the antitumor activity of single-agent enfortumab vedotin as measured by confirmed objective response rate (ORR) in patients with locally advanced or metastatic urothelial cancer who have received systemic therapy with a CPI

Treatment: Enfortumab vedotin 1.25 mg/kg will be administered as an IV infusion over approximately 30 minutes on Day 1, 8, and 15 of each 28-day cycle.

Eligibility:
Inclusion Criteria
- Patients must have histologically or cytologically confirmed locally advanced or metastatic transitional cell carcinoma of the urothelium (TCCU) (i.e. cancer of the bladder, renal pelvis, ureter or urethra). Patients with squamous differentiation or mixed cell types are eligible. Patients with resectable locally advanced disease are ineligible. Patient must have received prior treatment with a CPI in the locally advanced or metastatic urothelial cancer setting
- Patients must either have prior treatment with platinum-containing chemotherapy or be ineligible for treatment with cisplatin at time of enrollment due to one of the following: impaired renal function (CrCl ≥ 30 and < 60 mL/min), or hearing loss of 25 decibels at two contiguous frequencies. If platinum was administered in the adjuvant/neoadjuvant setting the patient must have progressed within 12 months of completion
- Patients must have had progression or recurrence of urothelial cancer during or following receipt of most recent therapy
- Tumor tissue samples must be available for submission to the sponsor prior to study treatment

Exclusion Criteria
- Ongoing sensory or motor neuropathy grade ≥ 2
- Active CNS metastases. Patients with treated CNS metastases are permitted on study only if:
  - CNS metastases have been clinically stable for at least 6 weeks prior to screening and baseline scans show no evidence of new or enlarged metastasis
  - If requiring steroid treatment, the patient is on stable dose ≤ 20 mg/day of prednisone or equivalent for at least 2 weeks
  - Patient does not have leptomeningeal disease
- Ongoing clinically significant toxicity (Grade 2 or higher) associated with prior treatment
- Prior treatment with enfortumab vedotin or other MMAE-based ADCs

For more Information, Please contact Karah Williams
Clinical Research Coordinator
Karah.Williams@jefferson.edu
215-955-0017
**Title:** Nivolumab Plus Cisplatin/Pemetrexed or Cisplatin/Gemcitabine as Induction in Resectable Non-Small Cell Lung Cancer

**Sponsor:** Thomas Jefferson University/Bristol Myers Squibb

**PI:** Ralph Zinner, MD

**Primary Objective:**
The primary study aim is to estimate major pathologic response (mpCR) in patients with newly diagnosed and untreated non-small cell lung cancer stage I-IIIA that will be treated with three courses of induction Nivolumab added to either cisplatin/pemetrexed or cisplatin/gemcitabine prior to surgery.

**Secondary Objectives:**
- Incidence of adverse events according to CTCAE ver. 4.03 up to 6 months post-treatment
- Progression free survival (PFS) at 1 year
- Overall survival (OS) up to 6 months
- Overall clinical response up to 6 months

**Treatment:**
- Non-Squamous NSCLC
  - Nivolumab 360mg q 3weeks x 3
  - Cisplatin 75mg/m^2 q 3weeks x 3
  - Pemetrexed 500mg/m^2 q 3weeks x 3
- Squamous NSCLC
  - Nivolumab 360mg q 3weeks x 3
  - Cisplatin 75mg/m^2 q 3weeks x 3
  - Gemcitabine 1250mg/m^2 D1 + D8 x 3

**Eligibility:**
**Inclusion Criteria**
- Patients must have pathologically confirmed non-small cell lung cancer, not previously treated, with a plan to undergo surgery
- Stage I-IIIA disease (stage I tumors must be >= 4cm)
- Tumor sample must be available for PD-L1 testing. Archival tissue within 3 months of study enrollment will be used. If archival tissue is unavailable, a fresh biopsy will be taken
- Adequate organ function as defined by the following:
  - WBC >/= 2,000/ul
  - ANC >/= 1500/ul
  - Platelets >/= 100,000/ul
  - Hgb >/= 9g/dL
  - Bilirubin </= 1.5 times the ULN
  - AST and ALT </= 3 times the ULN
  - GFR </= 40ml/min using the Cockcroft-Gault formula or serum creatinine </= 1.5 times the ULN

**Exclusion Criteria**
- Patients who have participated in a study with an investigational agent or device within 2 weeks of enrollment
- Any prior radiotherapy to the lung
- Any prior treatment for NSCLC
- EGFR or ALK activating alteration
- Any prior therapy with anti-PD-1, anti-PD-L1, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways
- Any history of a severe hypersensitivity reaction to monoclonal antibody
- Any history of allergy to the study drug components
- Any diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 14 days of initiation of study therapy

For more Information,
Please contact
Linda Phan
Clinical Research Coordinator, CTO
Linda.Phan@jefferson.edu
215-490-6279
NCTN OPEN TO NETWORK PARTICIPATION:

SWOG 1609: DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors

NRG BN003: A Phase III Trial of Observation versus Irradiation for a Gross Totally Resected Grade II Meningioma

NRG GU003: A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) Versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)

NCTN PENDING FOR NETWORK PARTICIPATION:


SWOG 1602: A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer

Alliance A021501: Preoperative Extended Chemotherapy vs. Chemotherapy plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas

The Data Quality Portal (DQP) is available on the CTSU website in the “Data Management” tab, previously labeled “Rave/DQP”. The DQP should be utilized to manage delinquent forms, to manage queries, and to monitor performance for Rave studies.

The Registration and Credential Repository (RCR) was released on July 28, 2017. Information is available on the CTSU website.

Registration is now OPEN for the NRG Oncology Semiannual Meeting in Phoenix, AZ. Pre-registration deadline is January 3, 2018!

Please register online for this meeting by January 3, 2018 in order to avoid long lines at the onsite registration desk. Registering onsite will incur an additional $50 fee.

Registration and meeting information is available on the NRG Oncology Website.

VTOC Training

VTOC Webinar Series schedule and registration is available for NRG Oncology Research Associates working on RTOG 0924, RTOG 0920, NRG-HN001, HN002, CC003, and CC004. The next training will be held at the NRG meeting on January 25th, 2018 at 1pm.

EAY131 (MATCH) Updates

Subprotocol U Suspension – Suspension Date 11/9/17

Subprotocol Z1B Suspension – Suspension Date 11/14/17

NRG-BR003, “A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer”, continuing review CIRB approved

NRG-CC001, “A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance in Patients with Brain Metastases”, amendments #2 and #3 CIRB approved

Reminder: All TJU-IRB approved consents, consent addenda and approved patient materials will be sent to all participating study sites via email and are also available upon request to the TJU Protocol Support Unit (PSU) via the RNOregulatory@jefferson.edu email address. Urgent requests can be made suing the RNO cell phone @ 215-600-9151

Please continue to pull the consents from JeffTrial. If you have any questions, please email RNOregulatory@jefferson.edu
Save the Dates:

- **Clinical Research Fundamentals Course**: January 23, 2018 – Philadelphia, PA
- **NRG Oncology Semiannual Meeting**: January 25-27, 2018 - Phoenix, AZ
- **Jefferson’s Clinical Trial Roadmap**: February 21, 2018 – Philadelphia, PA
- **6th Annual Lung Cancer Symposium**: March 2, 2018 – Philadelphia, PA
- **CRA Research Update**: March 14, 2018 – Philadelphia, PA
- **SoCRA Oncology Clinical Trials Conference**: March 15-16, 2018 – Nashville, TN
- **ECOG-ACRIN Semiannual Meeting**: May 3-5, 2018 – Chicago, IL

On behalf of the Course Directors, Drs. Gregory Kane and Ralph Zinner, we are inviting all Sidney Kimmel Cancer Network Members to attend this CME Certified event at a DISCOUNTED RATE of only $60!

In order to attend this event, you must pre-register on the course webpage at [https://cme.jefferson.edu/content/lungcancer2018](https://cme.jefferson.edu/content/lungcancer2018)

**The Clinical Research E-News:**
Archive is now located on the Sidney Kimmel Cancer Center webpage under the SKCN Member Area: [http://isley.kcc.tju.edu/skcn/e-newsletters.html](http://isley.kcc.tju.edu/skcn/e-newsletters.html)

**Sidney Kimmel Cancer Network Homepage:**
### Contact Information:

<table>
<thead>
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For URGENT ISSUES, Please call the RNO cellphone at 215-600-9151