

**S0720: PHASE II ERCC1 AND RRM1-BASED ADJUVANT THERAPY TRIAL IN PATIENTS WITH STAGE I NON-SMALL CELL LUNG CANCER (NSCLC)**

*Fast Facts*

**Conditions for Patient Eligibility**

1. Patients must have histologically confirmed, surgically resected Stage IA (with longest tumor diameter  $\geq 2$  cm), or Stage IB non-small-cell lung cancer, which must have been confirmed (diagnosed) at the time of surgery.
2. Patients must have tumor tissue from the surgical resection specimen available and must agree to have treatment assignment determined by a gene expression analysis performed on that tissue. Shipment of specimens should be planned to occur within 7 days after registration.
3. Patients must have had all disease completely resected (RO). Surgery to completely resect disease must be performed within 35 days prior to registration. The total time from surgery to initiation of chemotherapy should not exceed 84 days. Resection must have been performed by open thoracotomy or video assisted thoracoscopic surgery (VATS). Surgery must consist of a lobectomy, bilobectomy, or pneumonectomy as determined by the attending surgeon based on the operative findings. The type of resection chosen must provide complete removal of the primary lesion with negative gross and microscopic margins (RO).  
Documentation of margins by paraffin embedded sections at surgery is strongly recommended. A complete mediastinal sampling is encouraged and at least two lymph node stations must be sampled. For right sided lesions, this includes stations 4R, 7, 8, 9 and 10R. On the left side, this includes stations 4L, 5, 6, 7, 8, 9 and 10L.
4. A whole body PET scan or a combined PET/CT must be performed within 84 days prior to patient registration (a repeat will be required if more than 84 days have passed since last scan). Any finding on PET scan that clinically suggests N1, N2, N3, or M1 disease must have been cleared by further evaluation. This evaluation must include an appropriate imaging study, such as, but not limited to, ultrasonography, X-ray radiology, magnetic resonance imaging, and nuclear medicine imaging.
5. Patients must not have had any prior systemic chemotherapy or biologic therapy for lung cancer.
6. Patients must not have received prior thoracic radiation therapy (including RT to the chest wall).
7. Patients must have a Zubrod Performance Status of 0 - 1 (see Section 10.1).
8. Patients must have adequate hematologic function as documented by an ANC  $\geq 1,500/\text{mcl}$ , a platelet count  $\geq 100,000/\text{mcl}$ , and a hemoglobin  $\geq 10$  mg/dl obtained within 28 days prior to registration.
9. Patients must have adequate hepatic function, as determined by the following tests measured within 28 days prior to registration: serum bilirubin  $\leq 1.5 \times \text{IULN}$ ; SGOT (AST) or SGPT (ALT)  $\leq 1.5 \times \text{the IULN}$ .
10. Patients must have adequate renal function, as determined by the following tests measured within 28 days prior to registration: serum creatinine  $\leq 1.5 \times \text{IULN}$  OR a measured creatinine clearance or calculated creatinine clearance  $\geq 60$  mL/min using the following formula:  

$$\text{Calculated Creatinine Clearance} = \frac{(140 - \text{age}) \times \text{wt (kg)} \times 0.85 \text{ (if female)}}{72 \times \text{serum creatinine (mg/dl)}}$$
11. Patients must not be planning to receive other investigational agents, other chemotherapeutic agents, radiation therapy, or hormonal therapy while on treatment or active monitoring on this study except for steroids administered for antiemesis, adrenal failure, or septic shock or hormones administered for non-disease-related conditions (e.g., insulin for diabetes).
12. No other prior malignancy is allowed except for the following: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease-free for 5 years.
13. Patients must be willing to provide prior smoking history.
14. Patients must be offered participation in the banking of tissue, buffy coat, and plasma specimens for future unspecified research.
15. Pregnant or nursing women must not participate in this trial because of the increased risk of fetal harm including fetal death from the chemotherapeutic agents. Women/men of reproductive potential must not participate unless they have agreed to use an effective contraceptive method.
16. All patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

17. At the time of patient registration, the treating institution's name and ID number must be provided to the Data Operations Center in Seattle in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered into the data base.

**Pre-study requirements:**

1. History and physical including weight, performance status, disease assessment
  2. Required labs: CBC/Diff./Platelets, Bilirubin, SGOT/SGPT, Creatinine clearance/Serum Creatinine, Alk Phos., total protein, Na, K, Ca, glucose, Chloride, CO<sub>2</sub>, Albumin, BUN, Mg, LDH
  3. Scans: Whole body PET or combined PET/CT
- See study calendars section 9.1 and 9.2 for complete details*

**Treatment**

