Protocol Title: EA5162: Phase II Study of AZD9291 (Osimertinib) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR

Target Population: Recurrent or Stage IIB / IV Non-Small Cell Lung Cancer

Summary: This phase II trial studies how well Osimertinib works in treating patients with Non-Small Cell Lung Cancer with EGFR Exon 20 insertion mutation that is recurrent or Stage IIB - IV.

Key Eligibility Criteria:
- Must have a pathologically-confirmed diagnosis of Non-Small Cell Lung Cancer (NSCLC)
- Must have advanced disease
  - Stage IV disease
  - Stage IIB disease not amenable to definitive multi-modality therapy or
  - Recurrent disease after a prior diagnosis of Stage I-III disease
- An EGFR exon 20 insertion mutation must be detected in the tumor tissue
  - May be enrolled based on exon 20 insertion EGFR mutation detected by CLIA-certified tissue assay
- Must have measurable disease
- Must have previously received at least 1 line of therapy for their advanced lung cancer
  - There are no restrictions on the maximum number of prior therapies allowed
- May not have received any prior treatment with therapies targeting PDL1, PD1 or CTLA4
- ECOG Performance Status ≤ 1
- Adequate bone marrow, renal, and liver function
- May not have clinically active or symptomatic interstitial lung disease or interstitial pneumonitis, or a history of clinically significant interstitial lung disease or radiation pneumonitis
- May not have had radiation to the lung fields within 4 Weeks (28 Days) of starting treatment
- May not have clinically symptomatic brain metastases or leptomeningeal disease
  - May be on a stable dose of corticosteroids to control brain metastases if on a stable dose for 2 Weeks (14 Days) prior to study treatment and are clinically asymptomatic
- Must have an ECHO or a nuclear study (MUGA or first pass) within 4 Weeks prior to registration to treatment and must not have a LVEF < institutional LLN or > 50% for the patient to be eligible
- May not have a second, clinically active, cancer
  - Second cancers which have been treated with curative intent and/or are currently inactive are allowed
- May not be receiving any other investigational agents
  - Patients previously treated with investigational agents must complete a washout period of at least 2 Weeks or 5 half-lives, whichever is longer, before starting treatment
- May not have uncontrolled intercurrent illness or psychiatric illness/social situations that would limit compliance with study requirements
- No history of hypersensitivity to active or inactive excipients of Osimertinib or drugs with a similar chemical structure or class to Osimertinib
- No unresolved toxicities from prior therapy greater than CTCAE grade 1 at the time of starting study treatment, with the exception of alopecia and grade 2, prior platinum-therapy-related neuropathy
- Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the formulated product or previous significant bowel resection that would preclude adequate absorption of Osimertinib
- Women must not be pregnant or breast-feeding

Contacts:
Principal Investigator: Suma Satti, MD
Research Nurses (RN): Nicole Duffaut (nicole.duffaut@ochsner.org, ext. 23683)
Amanda Woolery (amanda.woolley@ochsner.org, ext. 20275)

For additional information: https://clinicaltrials.gov/ct2/show/NCT03191149