NCI National Clinical Trials Network

EA5162

ECOG-ACRIN cancer research group

Please Enroll Your Eligible Patients!

For Patients with Advanced NSCLC

EA5162 Available Through ECOG-ACRIN Cancer Research Group

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

Patient Population

See Section 3 for complete eligibility criteria

- Must have a pathologically-confirmed diagnosis of NSCLC; must have measurable disease per protocol
- Must have advanced disease– either stage IV disease, stage IIIB disease not amenable to definitive multi-modality therapy, or recurrent disease after a prior diagnosis of stage I-III disease (AJCC/IASLC 7th ed.)
- An EGFR exon 20 insertion mutation must be detected in the tumor tissue
- Must have previously received at least 1 line of therapy for advanced lung cancer (no restrictions on maximum number of prior therapies allowed)
- Must not have previously received osimertinib
- Must not have received therapies targeting PDL1, PD1, or CTLA4 within 180 days of registration
- Age ≥ 18 years, ECOG PS ≤ 1, and adequate lab values
- No clinically active or symptomatic interstitial lung disease/interstitial pneumonitis, or a history of clinically significant interstitial lung disease/radiation pneumonitis
- May not have had radiation to the lung fields within 28 days of starting treatment; for patients receiving palliative radiation to a site where the field includes the lungs, radiation must be completed at least 2 weeks before starting treatment; for palliative radiation to all other sites, at least 7 days must have elapsed prior to starting treatment; at least 180 days must have elapsed prior to starting treatment for radiation given with curative intent (see protocol for details)
- No clinically symptomatic brain metastases, leptomeningeal disease, or spinal cord compression
- Certain cardiac criteria are not permitted (see protocol)
- No second, clinically active, cancer
- No uncontrolled intercurrent illness (see protocol)
- No history of hypersensitivity to active/inactive excipients of AZD9291/drugs with a similar chemical structure/class
- Certain concomitant medications/treatments not permitted per protocol

Treatment Plan

See Section 5 for complete treatment details

- Osimertinib administered at a dose of 160 mg by mouth once daily on days 1-21 of a 21-day cycle
  - ◊ Osimertinib should be taken at the same time every day (+/- 4 hours; either in the AM or PM), with or without food
- Treatment will be given without interruption, unless interruptions are required to manage treatment-related side effects
- Missed doses will not be taken later
- Patients should continue on treatment with osimertinib until RECIST 1.1 defined progression or until treatment discontinuation criteria (per protocol) are met
- Patients may continue to receive osimertinib beyond RECIST 1.1 defined progression as long as they are continuing to show clinical benefit as judged by the investigator (i.e., there is no maximum duration of treatment)

Study Chair:
Zofia Piotrowska, MD, MHS

Co-Chair:
Lecia Sequist, MD, MPH

Patient Enrollment (Oncology Patient Enrollment Network [OPEN])

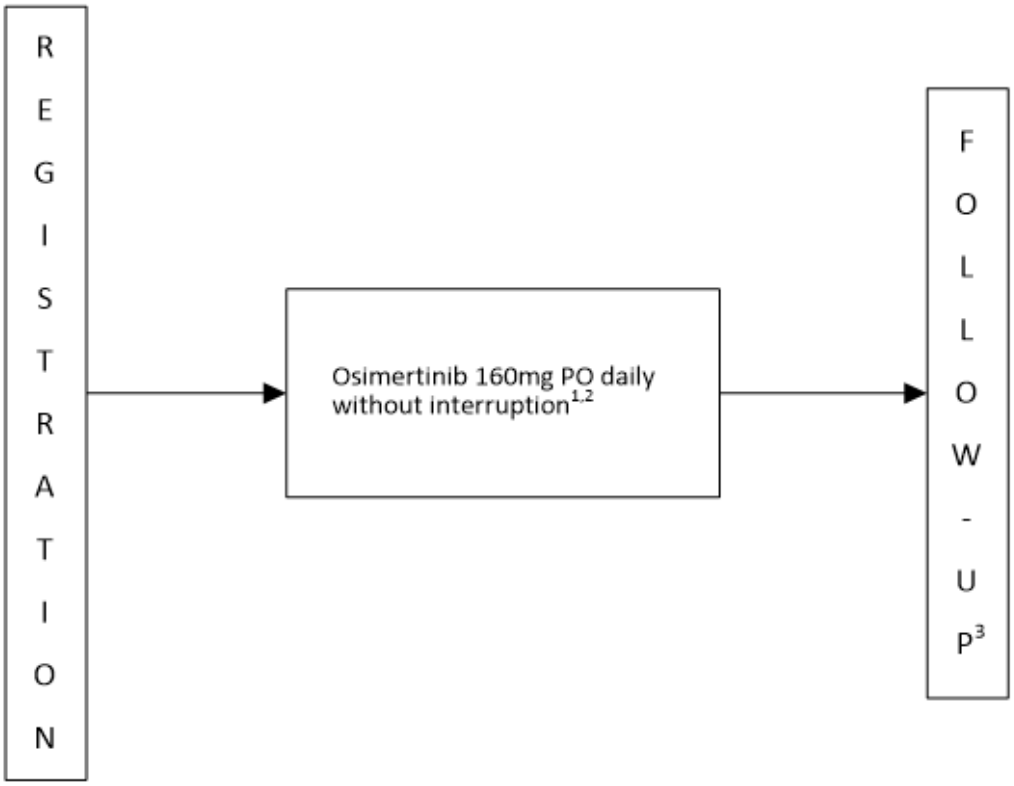
https://open.ctsu.org/open 1-888-823-5923

Protocol Information (ECOG-ACRIN Operations – Boston)

http://ecog-acrin.org (Member Login) 1-857-504-2900

EA5162

Schema



Cycle = 3 weeks (21 days)

1. Until disease progression or unacceptable toxicities.
2. Restaging scans every 2 cycles (6 weeks).
3. Patients will be followed for 5 years from registration.

The primary endpoint is best objective response per RECIST 1.1, with confirmation of response required.

Accrual = 46 patients