

BATTLE-2 Program: A Biomarker-Integrated Targeted Therapy Study in Previously Treated Patients with Advanced Non-Small Cell Lung Cancer

Objectives:

- To determine the best individual treatment for patients with advanced refractory NSCLC based on the biomarker profile of the patient's cancer
- To identify the prognostic and predictive markers for the four proposed treatment regimens

Procedures:

- Patients with refractory NSCLC are assigned to one of four treatment regimens with oral targeted therapy drugs
- Physical exam and routine labs done at study entry and every four weeks
- Staging CT scan and/or MRI done at study entry and every eight weeks
- Biopsy of tumor for biomarker evaluation done prior to beginning treatment (mandatory) and after cycle 2 (optional)
- Eye exam done at baseline and after four weeks for patients on AZD6244 and/or MK-2206
- Echocardiogram or MUGA done at study entry (all patients) and every six weeks for patients on AZD6244

Benefits for Patients:

- May have access to novel oral targeted agents that might be otherwise unavailable
- Use biomarkers to guide individualized targeted therapy



Eligibility Criteria:

- Patients with stage IIIb or IV NSCLC that has failed ≥ 1 line of chemotherapy or EGFR TKI
- Measurable disease that is accessible for biopsy
- PS ≤ 2
- Adequate hematologic, renal, and hepatic function
- No uncontrolled cardiovascular conditions or other serious uncontrolled comorbid medical conditions
- If brain metastases are present, they must be asymptomatic or treated (off corticosteroids for ≥ 2 weeks) If a patient has had any prior malignancies, they must be disease-free for > 2 years
- No pre-existing neuropathy of \geq grade 2
- No prior hemoptysis or bleeding diathesis
- Patients whose tumors are EML 4-ALK fusion gene positive or EGFR-mutation positive are excluded

Protocol #2009-0360

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Schedule an appointment or make referral online at <https://my.mdanderson.org> or call 713- 745-5353

For more information about the study, contact Research Nurses, James Gil, Denise Casey, or Christine Alden in the Department of Thoracic/Head & Neck Medical Oncology, at 713-792-6363

For information on related articles or references for this study, visit <http://physicianrelations.org> or <http://www.clinicaltrial.gov/ct2/show/NCT01248247>

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