



Thoracic Oncology Translational Research

At UCLA and TRIO-US

Phase 3 Trial for EGFRm Positive NSCLC Now Open

We are excited to announce the opening of CheckMate 722, a phase 3 trial for patients with stage IV or recurrent NSCLC, who test positive for EGFR mutations and who have progressed on prior EGFR-targeted (TKI) therapies. Patients must also test negative for T790M mutation. PD-L1 expression will be assessed, but will not be used as a criterion for study participation. Enrolled patients will be randomized to receive either: nivolumab with platinum-doublet chemotherapy; nivolumab with ipilimumab; or platinum-doublet chemotherapy alone. CheckMate 722 is now open to enrollment at UCLA Main Campus.

Please contact Dr. Edward Garon for more information.

Lilly JVCY Study Expands to Select TRIO-US Sites

The Lilly 14T-MC-JVCY-NSCLC study will now be open at select sites in the TRIO-US Network. This is a randomized, double-blind study of EGFR inhibitor erlotinib in combination with anti-VEGF antibody ramucirumab or placebo in previously untreated patients with metastatic NSCLC that is positive for EGFR mutation.

The trial will now be available at the following sites (site PIs in parentheses):

Bakersfield, CA (Dr. Ravi Patel); Fort Wayne, IN (Dr. Ahad Sadiq); Paducah, KY (Dr. Winston Chua); Santa Maria, CA (Dr. Robert Dichmann); Wichita, KS (Dr. Shaker Dakhil)

Clinical Lung Cancer Publication

A recent article in *Clinical Lung Cancer* by lead author Dr. Daria Gaut discusses the relationship between T790M mutation and response to EGFR tyrosine kinase inhibitor (TKI) therapy. Dr. Gaut completed the initial research for this project with our team during the summer of her first year of medical school, and was able to build off of that in this publication. As Gaut et al. note, EGFR TKIs have been shown to be superior to chemotherapy as first-line treatment for patients with EGFR-mutated NSCLC, but these patients' cancer often develops resistance to therapy 9-14 months into treatment. The T790M mutation is often responsible for this resistance to TKI therapy, accounting for 50% of resistance cases. Using patient records from previous studies of the TKI drug rociletinib, the authors evaluate the relationship between T790M status and treatment response following progression on first-line EGFR-targeted therapy. Gaut et al. find that on both first-line TKI therapy and chemotherapy, patients with T790M mutations showed the same overall response rate as, but significantly longer progression-free survival than did their counterparts who did not have T790M mutations. Conversely, T790M⁺ and T790M⁻ patients exhibited similar progression free survival upon additional TKI treatment following progression on first-line TKI therapy. Essentially, Gaut et al. find that the presence or absence of the T790M mutation has implications for treatment. Patients with T790M mutations can be expected to show slower progression on first-line TKI therapy, but do not show slower progression when treated with second- and third-line EGFR TKIs.

Gaut D, Sim MS, Yue Y, Wolf BR, Abarca PA, Carroll JM, Goldman JW, Garon EB. Clinical implications of the T790M mutation in disease characteristics and treatment response in patients with epidermal growth factor receptor (EGFR)-mutated NSCLC. *Clin Lung Cancer* 2017. doi: 10.1016/j.clc.2017.06.004.

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Phase 1b NSCLC Study of Anti-PD-1 Antibody with Chemotherapy Now Open

The Novartis CPDR001C2101 study is now open to enrollment at UCLA Main Campus, UCLA Burbank, UCLA Pasadena, UCLA Torrance, UCLA Valencia, UCLA Ventura, and UCLA Westlake Village sites. This trial will investigate the anti-PD-1 antibody PDR001 in combination with platinum-doublet chemotherapy in PD-L1 unselected, metastatic NSCLC patients.

Patients must have locally advanced or metastatic NSCLC, which can be either squamous or non-squamous. They must also be negative for EGFR mutations, ALK rearrangement, and ROS1 rearrangement. There are cohorts for both patients who have not received systemic cancer therapy and patients who have received only one prior systemic therapy for NSCLC consisting of a PD-1/PD-L1 inhibitor with or without a CLTA4 inhibitor.

Please contact Dr. Edward Garon for more information.

KEYNOTE 407 Trial for Metastatic, Squamous NSCLC Expected to Complete Enrollment Soon

The KEYNOTE 407 trial is expected to have filled all open spots for patients in the near future. This double-blinded phase 3 trial is for patients with metastatic, squamous NSCLC, who have not previously received systemic therapy. Patients receive either pembrolizumab or saline placebo with chemotherapy (carboplatin + paclitaxel OR nab-paclitaxel). KEYNOTE 407 is currently open to enrollment at the UCLA Main Campus, UCLA Pasadena, and UCLA Westlake Village sites.

Please contact Dr. Edward Garon for more information.

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