TRIO-US L-06 IST (Tesaro) Now Open at UCLA Main Campus and satellite sites for accelerated Phase 1b part of trial for Small-cell lung cancer (SCLC) Patients.

Dr. Jonathan Goldman’s TRIO-US L-06 investigator-sponsored trial, or IST, (Tesaro) is now open at UCLA Main Campus as well as Alhambra, Burbank, Pasadena, and Porter Ranch. This is a Phase 1b/2 randomized, open-label study of niraparib plus temozolomide versus best supportive care as maintenance therapy in patients with extensive-stage small cell lung cancer (SCLC) that had a complete or partial response to platinum-based first-line chemotherapy. For the phase 1b portion of this trial, patients must have advanced and incurable cancer confirmed by cytology and histology. For the randomized phase 2 portion of the trial, SCLC confirmed through laboratory histology with extensive-stage disease is required (not yet open). To be eligible for this trial, patients must have an Eastern Cooperative Oncology Group Score of 0 or 1. In the meantime, TRIO-US L-07 is available for patients with SCLC progressing after one line of anti-cancer chemotherapy.

Those who are interested should contact Dr. Goldman Jonathan for more information.

BMS CA209-816 Neoadjuvant Study Now Open in TRIO-US for patients with stage Ib, IIa, and IIIa NSCLC.

Dr. John Glaspy’s BMS CA209-816 study is now open at the following TRIO sites: Ft. Wayne, Hollywood, Orlando, and Wichita. This is a randomized, open-label, phase 3 trial of nivolumab plus ipilimumab or nivolumab plus platinum-doublet chemotherapy versus platinum-doublet chemotherapy in early stage NSCLC. To be eligible, patients must have early stage NSCLC confirmed by histology. Patients must also have an Eastern Cooperative Oncology Group (ECOG) score of 0-1.

Those who are interested should contact Dr. John Glaspy for more information.

IOVANCE IOV-COM-202 Open for Patients with Solid Tumors at UCLA Main Campus.

Dr. Edward Garon’s IOVANCE IOV-COM-202 Study is now open at UCLA Main Campus. This is a Phase 2, multicenter study of autologous tumor infiltrating lymphocytes (LN-144/LN-145) in patients with solid tumors. This is for patients with stage 3/4 skin cancer, or melanoma, that cannot be treated by surgery or that has spread (study group 1), advanced head and neck squamous (originating from the skin’s outermost layer) cell carcinoma (study group 2) or non-small-cell lung carcinoma (study group 3). Patients in study groups 1 and 2 must not have received prior anti-PD-1 checkpoint inhibitors and patients receive TIL LN-144/LN-145 in combination with pembrolizumab. Study group 3 patients are those who have previously received systemic therapy as well as inhibitors that target certain immune checkpoints and these patients receive TIL LN-144/LN-145 as a single treatment.

Those who are interested should contact Dr. Edward Garon for more information.
Merck MK-3475-495 Open for Patients with Advanced NSCLC at UCLA Main Campus.

Dr. Edward Garon’s Merck MK-3475-495 Study is now open at UCLA Main Campus. This is a Phase 2 Study of biomarker-directed, pembrolizumab-based combination therapy for Advanced Non-small Cell Lung Cancer. This study is for patients with advanced non-small-cell lung cancer without prior systemic therapy. Patients will undergo assessment for tumor mutation burden and a gene expression panel. Patients will be randomized to pembrolizumab with either lenvatinib or a LAG-3 inhibitor.

Those who are interested should contact Dr. Edward Garon for more information.

Nektar 16-214-02 Now Open for patients with solid tumor cancers

Dr. Jonathan Goldman’s Nektar 16-214-02 trial is now open for enrollment at UCLA Main Campus. This is a Phase 1/2, Open-label, multicenter study of the combination of NKTR-214 and nivolumab or the combination of NKTR-214, nivolumab, and other anti-cancer therapies in patients with tumors that are restricted to the lungs or tumors that have spread to other parts. To be eligible for this trial, patients must have not received prior interleukin-2 (II-2) therapy, and must have an Eastern Cooperative Oncology Group (ECOG) performance score of 0 or 1.

Those who are interested should contact Dr. Goldman Jonathan for more information.

TOTR At ASCO 2019.

The ASCO Post featured the results of the Checkmate 384 trial at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium (Abstract 100) that Dr. Edward B. Garon and colleagues presented. In this study, 329 patients were randomly assigned to receive a 30-minute infusion of nivolumab at a dose regimen of either 480 mg every 4 weeks (n=166) or 240 mg every 2 weeks (n=163). All patients were previously treated with nivolumab at 3 mg/kg, or 240 mg, every 2 weeks for up to 12 months, and all patients responded to previous treatment (complete response, partial response, or stable disease). The primary endpoints of the study were progression-free survival at 6 months and 1 year. Safety was a secondary endpoint. At median follow-up of 9.5 and 10.2 months respectively, patients treated with 480 mg every 4 weeks (n=164) showed similar rates of progression-free survival compared to patients who received 240 mg of nivolumab every 2 weeks (n=161). Safety was found to be similar between both groups. Adverse events leading to drug discontinuation were reported in 6% of patients receiving treatment every 4 weeks vs 9% of those receiving treatment every 2 weeks. There were no reports of treatment-related deaths. The investigators concluded that nivolumab administered every 4 weeks at a dose of 480 mg showed similar efficacy and safety as the every-2-week schedule. They added that administering nivolumab every 4 weeks at 480 mg could offer a more convenient option in second-line treatment of patients with advanced NSCLC.


JCO Clinical Cancer Informatics Publication.

Dr. Edward Garon, Dr. Amy Cummings, James Carroll, and Krikor Bornazyan are among authors on a recent paper published in the JCO Clinical Cancer Informatics in collaboration with our colleagues in UCLA’s Department of Psychology. Timothy Williamson and Dr. Annelette Stanton conducted a study in which they used questionnaires on physical and psychological symptoms at up to three assessment points, Fares and colleagues evaluated the extent of data concordance from clinical trial adverse event (AE) logs, electronic medical records (EMR) and patient-reported outcomes (PROs). Patients enrolled in clinical trials or receiving standard treatment for lung cancer (n=62) completed validated questionnaires on physical and psychological symptoms at up to three assessment points. Temporary matched documentation was extracted from EMR notes and, for clinical trial participants (n=41), AE logs. Evaluated data included symptom assessment, vital signs, medication logs, and laboratory values. Agreement (positive, negative) and Cohen’s K coefficients were calculated to assess concordance of symptoms among sources, with PROs considered the gold standard. The authors found that patient-reported weight loss correlated significantly with clinical measurements (t=2.90; P=0.02), and average number of PROs correlated negatively with albumin concentration, supporting PROs as the gold standard. Comparisons of PROs versus EMR yielded poor concordance across 11 physical symptoms, anxiety, and depressive symptoms (all K<0.40). Providers under-reported the presence of each symptom in the electronic medical record (EMR) compared with PROs. AE logs showed similarly poor concordance with PROs (all K<0.40, except shortness of breath). Negative agreement among sources was higher than positive agreement for all symptoms except pain. The findings suggest that EMR notes and AE logs may not be reliable sources for capturing physical and psychological symptoms experienced by patients with lung cancer, supporting use of PRO assessments in oncology practices. Dr. Fares is now a fellow in Hematology and Oncology.

Open Clinical Trial Descriptions.

1st Line , Metastatic.

NSCLC
EGFR and ALK Wildtype
BMS CheckMate 817 (TRIO, UCLA): Phase IIIb/W Safety Trial of Flat Dose Nivolumab in Combination with Ipilimumab in Participants with Non-Small Cell Lung Cancer.

NEON NT-002 (UCLA): An open-label, phase 1B study of NED-PF-01 with pembrolizumab plus chemotherapy in patients with advanced or metastatic nonsquamous non-small cell lung carcinoma

Novartis CPD001C2101 (UCLA): Phase Ib, multicenter, open label study of PD0001 in combination with platinum-doublet chemotherapy in PD-L1 unselected, metastatic NSCLC patients

EGFR/HER2 Exon 20 Mutation
Spectrum Pharmaceuticals SPI-POZ – 202: A Phase 2 Study of Pozotinib in Patients with EGFR or HER2 Exon 20 Insertion Mutation-Positive Non-Small Cell Lung Cancer (POZITIVE20-1).

PD-1/PD-L1 c<50%

CIRM CCL-21 Lung (UCLA): A phase 1 trial of intratumoral administration of CCL21-gene modified dendritic combined with intravenous pembrolizumab for advanced NSCLC.

PD-1/PD-L1 c>50%

Merck 3475-495: A Phase 2 precision Oncology Study of Biomarker-Directed, Pembrolizumab-Based Combination therapy for advanced Non-small Cell Lung Cancer.

Exon 14 Skipping Mutant or High Level MET Amplification
Novartis CINC280A220 (UCLA): A phase II study of oral cMET inhibitor INC280 in adult patients with EGFR wild-type, advanced NSCLC who have received one or two prior lines of systemic therapy for advanced/metastatic disease.

Early Stage Disease.

RESECTABLE DISEASE
GNE ML39236 LCMC III (UCLA): A Phase II Open label, multicenter, single-arm study to investigate the efficacy and safety of atezolizumab as neoadjuvant and adjuvant therapy in patients with Stage Iib, II, or IIIA resectable and untreated non-small cell lung cancer.

BMS CA209-816: Randomized, Open-Label, Phase 3 Trial of Nivolumab plus Ipilimumab or Nivolumab plus Platinum-Doublet Chemotherapy versus Platinum-Doublet Chemotherapy in Early Stage NSCLC.

RESECTED DISEASE
Novartis CACE885T2301 (UCLA, TRIO): A Phase III, multicenter, randomized, double blind, placebo-controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UNCC v. 8 II-IIIA and IIIB (T<5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC).

Locally Advanced

iSABR (UCLA): RandomizedPhase II/I Study of Stereotactic Ablative Body Radiotherapy +/- Medi 4736 (Durvalumab) for Medically Inoperable Early-Stage Non-Small Cell Lung Cancer

SBRT-RFA (UCLA): Phase II study evaluating the safety and efficacy of stereotactic body radiotherapy and radiofrequency ablation for medically inoperable and recurrent lung tumors near central airways.

2nd-Line Therapy and Beyond.

EGFR Mutations/EGFR Amplification
PUMA-NER-5201: An open-label, phase 2 study of neratinib in patients with solid tumors with somatic EGFR, HER2, HER3 mutations or EGFR gene amplification.

HER2 Exon 20 Mutation
Spectrum Pharmaceuticals SPI-POZ – 202: A Phase 2 Study of Pozotinib in Patients with HER2 Exon 20 Insertion Mutation-Positive Non-Small Cell Lung Cancer (POZITIVE20-1).

HER2 Positive
Pfizer CO541001: A Phase 1 Dose Escalation Study Evaluating the Safety and Tolerability of PF-06804103 in Patients with Human Epidermal Growth Factor Receptor 2 (HER2) Positive Solid Tumors

EGFR Mutation
Molecular Partners MP0250-CP202: A Phase 1b/2, single-arm, open-label study of MP0250 ± osimertinib in patients with EGFR-mutated NSCLC

G1 Therapeutics G1T38-03: A Phase 1b/2 safety, pharmacokinetic and efficacy study of G1T38 in combination in patients with EGFR-mutation-positive metastatic NSCLC.

EGFR Negative
Mirati MRTX-500: A Phase 2 study of glesatinib, si-travatinib or mocetinostat in combination with nivolumab in advanced or metastatic NSCLC

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MET Positive
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Non-Interventional Studies
Solid Malignancy Tissue Bank—LCTB: A tissue bank for patients with solid malignancies, which allows for the collection of tissue and bodily fluid specimens. Contact Dr. Garon’s correlative research team for more information.

IOVANCE IOV-LUN-201: A Phase 2 study to assess the efficacy and safety of autologous tumor infiltrating lymphocytes (LN-145) in combination with anti-PD-L1 inhibitor durvalumab in patients with locally advanced NSCLC.

RGX-104-01: A Phase 1 study of RGX-104, a small molecule agonist, with or without nivolumab in patients with advanced solid malignancies and lymphoma with an expansion in select malignancies (Rgenx RGX-104-001 Advanced Solid Malignancies).

Dynavak DV9-NSC-01: Phase 1b Dose Escalation and Dose Expansion Trial of DV281 in Combination With an Approved Anti-D-1 Inhibitor in Subjects With Advanced Non-Small Cell Lung Cancer

Incyte INCB59872-101 (UCLA): Phase 1//2, open-label, dose-escalation/dose-expansion, safety and tolerability study of INCB05872 in subjects with advanced malignancies.

Infinity IPI-549-01: A Phase 1/1b First-In-Human, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of IPI-549 Monotherapy and in Combination with Nivolumab in Subjects with Advanced Solid Tumors (Infinity IPI-549-01 Advanced Solid Tumors).

Nektar 16-214-02 (UCLA): A phase 1//2, open-label, dose-escalation/dose-expansion, safety and tolerability study of INCB65872 in subjects with advanced malignancies.


Pfizer B9991004 Advanced Malignancies: A Phase 1//2 study to evaluate safety, clinical activity, pharmacokinetics and pharmacodynamics of Avelumab in combination with other cancer immunotherapies in patients with advanced malignancies.

Tesaro Bio 4020: A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-022, an anti-TIM-3 Monoclonal Antibody, in Patients with Advanced Solid Tumors


MESOTHERIUM
Polaris Group POLARIS2015-003 : Randomized, Double-Blind, Phase 2/3 Study in Subjects with Malignant Pleural Mesothelioma with Low Argininosuccinate Synthetase 1 Expression to Assess ADI-PEG 20 with Pemetrexed and Cisplatin (ATOMIC-Meso Phase 2/3 Study)

SCLC
MAINTENANCE
TRIO-US L-06 IST: A Phase 1b/2 randomized, open-label Study of Niraparib monotherapy or niraparib plus temozolomide versus best supportive care as maintenance therapy in patients with extensive stage SCLC had a complete or partial response to platinum-based first-line chemotherapy.

SALVAGE
TRIO-US L-07: A Phase 2 study of continuous talazopar plus intermittent low-dose temozolomide in patients with relapsed or refractory extensive stage small cell lung cancer.
Lung Cancer Rear Line Therapy / Maintenance / Non-Interventional

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This newsletter was prepared by Wisdom Akingbemi. Please contact me at wakingbemi@mednet.ucla.edu with any questions, comments, or concerns.

Lung Cancer Second Line Therapy and Beyond

Non-Small Cell Lung Cancer

Small Cell Lung Cancer

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