



Thoracic
Oncology
Translational
Research At
UCLA & TRIO-US

DECEMBER 2016

Multimillion Dollar Grant Awarded from the National Cancer Institute for Translational Research at UCLA and in TRIO-US

We are excited to announce that the National Cancer Institute has awarded funding to study determinants of benefit from PD-1 inhibitors in patients at UCLA (including satellite sites) and the TRIO US Network for the proposal, “A model for predicting response to PD-(L)1 inhibitors in Non-Small Cell Lung Cancer.” The goal is to identify predictors of benefit to single agent inhibitors of the PD-1 immune checkpoint in a broad population of non-small cell lung cancer patients.

The FDA has now approved immune checkpoint inhibitors, pembrolizumab, nivolumab, and atezolizumab for use in certain patients with non-small cell lung cancer after research has shown durable responses. The potential of these immunotherapies has caused tremendous enthusiasm in the lung cancer research community and there is much to learn about which patients can benefit from these treatments.

We have generated a large specimen bank, and we plan to add to it substantially. With this tissue bank, we will evaluate clinical characteristics and properties of tumors and the immune microenvironment that predict benefit from immune checkpoint inhibition. From this data, we will create a model to identify patients with non-small cell lung cancer that are likely to benefit from PD-1/ PD-L1 inhibition. Lastly, we will validate that model in a set of independent samples.

Lancet Oncology Immunotherapy Publication

An article discussing nivolumab plus ipilimumab as first-line treatment for advanced non-small cell lung cancer was recently published in *The Lancet Oncology*.

Results were based on Checkmate 012, an open-label, phase 1, multicohort study. Patients were randomly assigned to receive nivolumab 1 mg/kg every 2 weeks plus ipilimumab 1 mg/kg every 6 weeks, nivolumab 3 mg/kg every 2 weeks plus ipilimumab 1 mg/kg every 12 weeks, or nivolumab 3 mg/kg every 2 weeks plus ipilimumab 1 mg/kg every 6 weeks until disease progression, unacceptable toxicities, or withdrawal.

Findings from the study indicate that first-line nivolumab plus ipilimumab has a tolerable safety profile as well as a high response rate and durable response. This study was conducted at UCLA Main Campus.

UCLA and the TRIO-US Network are continuing to investigate the use of combination therapies and immunotherapies with multiple studies and studies of this specific combination will be coming to UCLA and the TRIO-US network in the coming months.

Hellmann MD, Rizvi NA, Goldman JW, Gettinger SN, Borghaei H, Brahmer JR, Ready NE, Gerber DE, Chow LQ, Juergens RA, Shepherd FA, Laurie SA, Geese WJ, Agrawal S, Young TC, Li X, Antonia SJ. Nivolumab plus ipilimumab first-line in advanced non-small cell lung cancer: results of an open-label, phase 1, multicohort study (CheckMate 012). *Lancet Oncology*, 2016 Dec5.

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Clinical Cancer Research Publication

An article discussing the dose escalation results of the first-in-human study of MET antibody, emibetuzumab, was recently published in *Clinical Cancer Research*.

The results were based on the phase I study, JTBA. Emibetuzumab is an antibody that inhibits hepatocyte growth factor (HGF)-dependent and HGF-independent MET signaling. This was comprised of a 3+3 dose escalation for emibetuzumab monotherapy and in combination with erlotinib.

Patients received emibetuzumab every two weeks by infusion. 23 patients with solid tumors received emibetuzumab monotherapy at 20, 70, 210, 700, 1400, and 2000 mg and 14 non-small cell lung cancer patients received emibetuzumab at 700, 1400, 2000mg in combination with erlotinib 150 mg daily. Based on tolerability, PK/PD analysis and clinical activity, the recommended Phase II dose range was found to be 700-2000 mg for emibetuzumab monotherapy and in combination with erlotinib.

Rosen LS, Goldman JW, Algazi AP, Turner PK, Moser B, Hu T, Wang XA, Tuttle J, Wacheck V, Wooldridge JE, Banck B. A first-in-human phase I study of bivalent MET antibody emibetuzumab (LY2875358), as monotherapy and in combination with erlotinib in advanced cancer. *Clinical Cancer Research*. 2016 Oct 10. pii: clincanres.1418.2016. [Epub ahead of print]

Juniper Trial Closing to Accrual

The Juniper trial is now closed to accrual. The Juniper trial is a phase III study of abemaciclib plus best supportive care versus erlotinib in patients with previously treated KRAS mutated Stage IV non-small cell lung cancer.

Patients participating in the Juniper trial were randomized into Arms A and B. In the E Arm A, patients received 200 mg abemaciclib administered orally every 12 hours plus best supportive care on Day 1 to 28. Patients in Arm B received 150 mg erlotinib administered orally every 24 hours plus best supportive care on Days 1 to 28. Primary outcome measures were progression free survival and overall survival.

The Juniper was conducted at UCLA Main Campus, Pasadena, Valencia, Westlake Village, Porter Ranch, and at several sites in the TRIO-US network including Santa Maria, Bakersfield, Las Vegas, Fullerton, San Luis Obispo, and Ft. Wayne. Dr. Jonathan Goldman is leading the North American portion of this trial at UCLA.

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TOTR 2016 Research Year in Review

Presentations

18e Nationale Longkanker Symposium. *The rapidly shifting landscape of inhibition of the PD-1 checkpoint in non-small cell lung cancer.* Amsterdam, Netherlands. 1/16. Audience: Physicians, Scientists.

Goldman JW. "Rociletinib," "Evofofosamide" In 14th Annual Targeted Therapies of Lung Cancer. Santa Monica, CA February, 2016.

Young PA, Marquz-Garban DC, Strunck J, Li AH, Adame C, Wells C, Spiegel M, Carroll J, Tucker DA, Famenini S, Callahan RD, Wong DJ, Goldman JW, Pietras RJ, Garon EB. Phase I dose escalation study of carboplatin, pemetrexed, and exemestane in postmenopausal women with metastatic non-squamous, non-small cell lung cancer (NSCLC). International Association for the Study of Lung Cancer (IASLC) Annual Targeted Therapies of Lung Cancer Meeting. 2016, February 17-20. Santa Monica, California.

Smit EF, Garon EB, Reck M, Cappuzzo F, Bidoli P, Cohen R, Gao L, Ernest II CS, Lee P, Zimmerman A, Ferry D, Treat J, Melemed A, Perol M. Exposure-response relationship for ramucirumab (RAM) from the randomized, double-blind, phase III REVEL trial (docetaxel [DOC] vs DOC plus RAM in second-line treatment of metastatic non-small cell lung cancer (NSCLC)). 32nd Deustcher Krebskongress (DKK). 2016, February 24-27. Berlin, Germany. Abstract nr.01910.

Reck M, Kimmich M, Schuette W, Schumann C, Paz-Ares L, Garon E, Perol M, Zimmermann A, Lee P. Exploratory analysis of efficacy by histology and frontline therapies in a non-squamous non-small cell lung cancer (NSCLC) subgroup in REVEL: A randomized phase III study of ramucirumab (RAM) plus docetaxel (DOC) vs DOC + Placebo (PC) for second-line treatment of stage IV NSCLC. 32nd German Cancer Congress (DKK). 2016 Februarv 24-27. Berlin. Germanv.

Rao J, Dhar M, Pao E, Renier C, Go DE, Che J, Montoya R, Conrad R, Matsumoto M, Heirich K, Triboulet M, Jeffrey SS, Garon E, Goldman J, Rao NR, Kulkarni R, Sollier E, Di Carlo D. Label-free enumeration, collection and downstream cytological and cytogenetic analysis of circulating tumor cells. Presented at the United States and Canadian Academy of Pathology Annual Meeting. 2016 March 12-18. Seattle, Washington. Board nr. 87.

Dhar M, Che J, Garon EB, Hu-Lieskovan S, Matsumoto M, Wolf B, Han M, Carroll J, Strunck J, Crabtree M, Kulkarni R, Sollier E, Di Carlo D, Goldman JW. Serial evaluation of PD-L1 expression on CTCs and comparison to pembrolizumab treatment response in advanced lung cancer. Hamburg-International Symposium on Minimal Residual Cancer (ISMRC) 2016, March 19-21. Hamburg, Germany.

Goldman JW. "Review of Phase I Research: Strategies, Ethics, and Recent Developments," Hematology/Oncology Fellows Journal Club. 3/29 and 3/31/2016.

Reck M, Paz-Ares L, Pérol M, Ciuleanu TE, Kowalyszyn RD, Lewanski CR, Syrigos K, Arrieta O, Prabhaskar K, Park K, Pikiel J, Gökseel T, Lee P, Zimmerman A, Treat J, Ferry D, Melemed A, Carter GC, Alexandris E, Garon E. Efficacy and safety of the combination of ramucirumab (RAM) plus Docetaxel (DOC) versus placebo (PL) plus DOC in patients with pre-treated non-squamous non-small-cell lung cancer (NSCLC): exploratory analysis of the REVEL study (RAM plus DOC versus PL plus DOC in second-line treatment of stage IV NSCLC). Annual Congress of German Pulmonologists (DGP). 2016, March 2-5. Leipzig, Germany. Pneumologie 2016; 70 - V556.

Teng AE, Share M, Hsu JJ, Garon E, Goldman J, Yang EH, Tung R. Torsades de pointes with pseudo-T wave alternans during rociletinib therapy: novel manifestation of a rare side effect. American College of Cardiology 65th Annual Scientific Session 2016.

Lee MH, Yanagawa J, Walser TC, Goldman JW, Garon EB, Zeng G, Sharma S, Gao B, Minna JD, Dubinett SM, Lee JM. FRA1 contributes to ERK-mediated increased PD-L1 expression in KRAS mutated premalignant human bronchial epithelial cells. In: Proceedings of American Association for Cancer Research Annual Meeting. 2016 April 16-20. New Orleans, Louisiana. Abstract nr.2324.

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Goldman JW. "Review of Cancer and Transplant Immunology" Transplant Nephrology Journal Club. 5/20/2016.

Cummings A, Mendenhall M, Goldman JW. Phase I-II targeted therapy and immunotherapy non-small cell lung cancer clinical trials: no age limit to benefit. UCLA Research Conference on Aging, 2016.

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Hall R, Gadgeel S, Garon EB, Bria E, Reck M, Vida J, Zhou H, Raftopoulos H, Gandhi L. Phase III study of platinum-based chemotherapy with or without pembrolizumab for first-line metastatic, non-squamous non-small cell lung carcinoma (NSCLC): KEYNOTE-189. American Society of Clinical Oncology (ASCO) Annual Meeting. 2016 June 3-7. Chicago, Illinois. J Clin Oncol 34, 2016 (suppl; abstr TPS9104).

Garon EB, Herbst RS, Kim DW, Felip E, Perez-Gracia J, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, Gubens M, de Castro Jr G, Garrido M, Shentu Y, Im E, Lubiniecki GM, Baas P. Pembrolizumab vs docetaxel for previously treated advanced non-small cell lung cancer (aNSCLC) with PD-L1 tumor proportion score (TPS) 1%-49%: results from KEYNOTE-010. American Society of Clinical Oncology (ASCO) Annual Meeting. 2016 June 3-7. Chicago, Illinois. J Clin Oncol 34, 2016 (suppl; abstr 9024).

Hui R, Gandhi L, Carcereny E, Felip E, Ahn MJ, Eder JP, Balmanoukian AS, Leigh N, Aggarwal C, Horn L, Patnaik A, Middleton G, Gubens M, Hellman M, Soria JC, Ramalingam SS, Lubiniecki GM, Zhang J, Piperdi B, Garon EB. Long-term survival for patients with advanced non-small cell lung cancer (aNSCLC) enrolled in the KEYNOTE-001 study of pembrolizumab. American Society of Clinical Oncology (ASCO) Annual Meeting. 2016 June 3-7. Chicago, Illinois. J Clin Oncol 34, 2016 (suppl; abstr 9024).

A Tolcher, M. Sznol, S. Hu-Lieskovan, K. Papadopoulos, A. Patnaik, D. Rasco, D. DiGravio, B. Huang, D. Gambhire, Y.Chen, N. Pathan, K. Wang, E. Schmidt, L. Chow. Phase 1b study of Pf05082566 in combination with pembrolizumab in patients with advanced solid tumors. 2016 ASCO Annual Meeting.

A.Patnaik, P. Eisenberg, J. Sachdev, A. Weise, A.N.Tse, M. Hutchingsons, I.Aromin, B.L. West, S. Tong, A.Ribas, S. Hu-Lieskovan. Phase 1/2a study of double immune suppression blockade by combining a CSF1R inhibitor (pexidartinib/PLX3397) with an anti PD-1 antibody (pembrolizumab) to treat advanced solid tumors. 2016 ASCO Annual Meeting.

Herbst RS, Baas P, Perez-Gracia JL, Felip E, Kim DW, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, Surmont V, de Castro Jr G, Garrido M, Shentu Y, Dolled-Fillhart M, Im E, Garon EB. Archival vs new tumor samples for assessing PD-L1 expression in the KEYNOTE-010 study of pembrolizumab (pembro) vs docetaxel (doce) for previously treated advanced non-small cell lung cancer (NSCLC). American Society of Clinical Oncology (ASCO) Annual Meeting. 2016 June 3-7. Chicago, Illinois. J Clin Oncol 34, 2016 (suppl; abstr 3030).

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Scott Joseph Antonia, Sang-We Kim, Alexander I. Spira, Myung-Ju Ahn, Sai-Hong Ignatius Ou, Neda Stjepanovic, Angela Fasolo, Dirk Jäger, Patrick Alexander Ott, Zev A. Wainberg, Heather A. Wakelee, Jonathan Wade Goldman, John Kurland, Marlon C. Rebelatto, Wenliang Yao, Ashok Kumar Gupta, John A. Blake-Haskins, Neil Howard Segal. Safety and Clinical Activity of Durvalumab (MEDI4736), an Anti-PD-L1 Antibody, in Treatment-naïve Patients with Advanced Non-small Cell Lung Cancer. ASCO Annual Conference. Chicago, 2016.

D. Ross Camidge, Teresa Moran, Ingel Demedts, Heidrum Grosch, Jean-Pierre Di Mercurio, Kathrin Finch Mileham, Julian R. Molina, Oscar Juan Vidal, gerold Bepler, Jonathan Wade Goldman, Conrad Lewanski, Keunchil Park, Johan Wallin, Sameera R. Wijayawardana, Xuejing Aimee Wang, Volker Wacheck, Egbert F. Smit. A randomized, open-label, phase 2 study of emibetuzumab plus erlotinib (LY+E) and emibetuzumab monotherapy (LY) in patients with acquired resistance to erlotinib and MET diagnostic positive (MET Dx+) metastatic NSCLC. ASCO Annual Conference, Chicago, 2016.

Sai-Hong Ignatius Ou, Garrett Michael Frampton, James Suh, Zachary Rockow Chalmers, Mark Rosenweig, Jonathan Wade Goldman, Patrick M. Forde, Kurt Leuenberger, Nir Peled, Gregory Kalemkerian, Jeffrey S. Ross, Philip J. Stephens, Vincent A. Miller, Siraj Majamed Ali, Alexa Betzig Schrock. Comprehensive genomic profiling of 298 lung cancers of varying histologies harboring MET exon 14 alterations. Poster Discussion Session. ASCO Annual Conference, Chicago, 2016.

Matthew David Hellmann, Scott N. Gettinger, Jonathan Wade Goldman, Julie R. Brahmer, Hossein borghaei, Laura Q. Chow, Neal Ready, David E. Gerber, Rosalyn A. Juergens, Frances A. Shepherd, Scott Andrew Laurie, Ye Zhou, William J. Geese, Shruti Agrawal, Xuemei Li, Scott Joseph Antonia. Checkmate 012: Safety and efficacy of first-line nivolumab and ipilimumab in advanced NSCLC. Oral Abstract. ASCO Annual Conference, Chicago, 2016.

Heather A. Wakelee, Shirish M. Gadgeel, Jonathan Wade Goldman, Karen L. Reckamp, Chris Alan Karlovich, Vladislava Melnikova, Jean-Charles Soria, Helena Alexandra Yu, Benjamin J. Solomon, Maurice Perol, Joel W. Neal, Stephen V. Liu, Mitch Raponi, Darrin Despain, Mark G. Erlander, Shannon L. Matheny, Sergey Yurasov, D. Ross Camidge., Lecia V Sequist. Epidermal growth factor receptor genotyping of matched urine, plasma, and tumor tissue from non-small cell lung cancer patients treated with rociletinib. Oral Abstract. ASCO Annual Conference, Chicago, 2016.

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D'Ambruoso S, Walling AM, Hurvitz SA, Drakaki A, Goldman JW, Pietras C, Watts F, Coscarelli A, Wenger N. Use of the Edmonton Symptom Assessment Scale in patients with advanced cancer referred to an embedded palliative care clinician.. ASCO Palliative Care Symposium, 2016.

Wainberg ZA, Geroge B, Goldman JW, Hochster HS, Kelly K, Ko A, O'Dwyer PJ, Trunova N, Waterhouse D, Soliman HH. P139 interim results from the phase I study of nivolumab + nab-paclitaxel in pancreatic cancer, non-small cell lung cancer, and metastatic breast cancer. EORTC-NCI-AACR, Munich 2016.

Garon EB. Immune checkpoint inhibitors in lung cancer. China Cancer Immunotherapy Workshop. 2016, June 25-26. Beijing, China. Abstract nr. A4.

Hui R, Gandhi L, Carcereny E, Felip E, Ahn MJ, Eder JP, Balmanoukian AS, Leigh N, Aggarwal C, Horn L, Patnaik A, Middleton G, Gubens M, Hellmann MD, Soria JC, Ramalingam SS, Lubiniecki GM, Zhang J, Piperdi B, Garon EB. Long-term overall survival for patients with advanced non-small cell lung cancer enrolled in the KEYNOTE-001 study of pembrolizumab. Australian Lung Cancer Conference (ALCC). 2016 August 18-20. Melbourne, Australia. Abstract nr 046-O16.

Herbst RS, Baas P, Perez-Gracia JL, Felip E, Kim DW, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, Surmont V, de Castro Jr G, Garrido M, Shentu Y, Dolled-Filhart M, Im E, Garon EB. Archival vs new tumor samples for assessing PD-L1 expression in the KEYNOTE-010 study of pembrolizumab vs docetaxel for previously treated advanced NSCLC. Australian Lung Cancer Conference (ALCC) 2016 August 18-20. Melbourne, Australia. Abstract nr. 047-O16.

Blumenschein G, Chandler J, Garon E, Waterhouse D, Goldman J, Gunuganti V, Boccia R, Spigel D, Glaspy J, Berry D, Korytowsky B, Zhu J, Lin W, Bennet K, Renolds C. Checkmate 370: A master protocol of phase ½ studies of nivolumab as maintenance or first-line ± standard-of-care therapies in advanced NSCLC. IASLC Chicago Multidisciplinary Symposium in Thoracic Oncology. 2016, September 22-24. Chicago, Illinois. Abstract nr. 55.

Goldman JW. "The UCLA Phase I Program in 2016" UCLA/TRIO-US Lake Arrowhead Conference. 9/23/2016.

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Schuetz W, Reck M, Kimmich M, Schumann C, Paz-Ares L, Garon E, Perol M, Zimmermann A, Lee P. Exploratory analysis of efficacy by histology and frontline therapies in a non-squamous non-small cell lung cancer (NSCLC) subgroup in REVEL: A randomized phase III study of ramucirumab (RAM) plus docetaxel (DOC) vs DOC plus placebo (PBO) for second-line treatment of stage IV NSCLC. German Hematology and Oncology Congress (DGHO) Congress. 2016 October 14-18. Berlin, Germany. Abstract nr. P293-32.

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Goldman JW. "Implications of NGS Testing on Therapy Selection" Personalized Therapies and Best Clinical Practices for Lung Cancer. 10/15/2016.

Goldman JW. "Systemic Thereapy for Brain Metastases: Immunotherapy and Targeted Therapy" UCLA Conference on Novel Therapeutic Approaches for Brain Metastasis. 10/22/2016.

Barlesi. F. Garon, EB, Kim DW, Felip E, Han JY, Kim JH, Ahn, MJ, Fidler MJ, Gubens MA, Castro G, Surmont V, Li Q, Deitz AC, Lubiniecki GM, Herbst RS. Assessment of health-related quality of life (HRQoL) in KEYNOTE-010: a phase 2/3 study of pembrolizumab (pembro) vs docetaxel in patients (pts) with previously treated advanced NSCLC. ESMO 2016 Congress. 2016 October 7-11.

Garon EB, Halmos B, Hui R, Leighl N, Lee S, Walsh W, Dragnev K, Shinwari N, Wei Z, Piperdi B, Rodriguez LPA. Phase III study of carboplatin-paclitaxel/nab-paclitaxel chemotherapy with or without pembrolizumab for first-line metastatic, squamous non-small cell lung carcinoma: KEYNOTE 407. Society for Immunotherapy of Cancer (SITC) Annual Meeting. 2016 November 9-13. National Harbor, Maryland. Abstract nr 143.

Lee JM, Lee MH, Garon EB, Goldman JW, Baratelli FE, Schae D, Wang G, Rosen F, Yanagawa J, Walser TC, Lin Y, Adams S, Marincola FM, Tumeh PC, Abtin F, Suh R, Reckamp K, Wallace WD, Zeng G, Elashoff DA, Sharma S, Dubinett SM. Augmentation of tumor infiltrating CD8⁺ T cells and specific response to autologous tumor antigens in a phase I trial of *in situ* vaccination with CCL21 gene-modified dendritic cells. Society for Immunotherapy of Cancer (SITC) Annual Meeting. 2016 November 9-13. National Harbor, Maryland. Abstract nr. 170.

Wolf B, Garon EB, Lisberg A, Kim KY, Davidovics H, Horton JM, Kamranpour N, Chau K, Abarca P, Spiegel ML, Han M, Sago W, Hu-Lieskovan S, Das K, Wallace WD, Slamon DJ, Dubinett SM, Goldman JW. Prior TKI in EGFR mutant non-small cell lung cancer (NSCLC) patients associates with lack of response to anti PD-1 treatment. Sackler Medical School Student Research Meeting 2016. New York City, New York.

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