Thoracic Oncology Translational Research At UCLA & TRIO-US

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In This Issue:

Heart Monitoring Trial for Small Cell Lung Cancer Patients Open to Enrollment

The phase 1/2, open-label, single arm, SCRX001-007 study is now open to enrollment at UCLA Main Campus. This study investigates the effects of rovalpituzumab tesirine (Rova-T) on cardiac ventricular repolarization in patients with small cell lung cancer.

Rova-T is an antibody drug conjugate against DLL-3, a protein present at high levels in small cell lung cancer. In an ongoing phase 1 study, Rova-T has demonstrated an objective response rate of 44% and clinical benefit rate of 78% in patients with SCLC and high DLL3 expression. Toxicities of Rova-T include low platelet count as well as excess fluid build-up around the lungs.

Patients will receive 0.3mg/kg rovalpituzumab tesirine by infusion. Patients will receive treatment on Day 1 for two cycles, followed by a third cycle in which treatment is omitted. Each cycle is 6 weeks and treatment will continue in this pattern until progression. During Cycles 1 and 2, intensive ECG monitoring will be conducted. Blood samples will also be collected. Tumor response will be assessed every 6 weeks with CT scans during active treatment.

This trial is open to enrollment at UCLA Main Campus and numerous slots are anticipated to be available at least for the next 3 to 6 months.

Pre-surgical Immunotherapy Trial to Open at UCLA Main Campus

We are excited to announce the upcoming opening of a pre-surgical immunotherapy trial for patients with Stage IB, II, or IIIA non-small cell lung cancer. The Genentech ML39236 study will open in early April.

The Genentech ML395236 study is a phase II, open-label trial that will investigate atezolizumab as therapy before and after surgery in patients with resectable and untreated non-small cell lung cancer. Patients will receive treatment before surgery with atezolizumab 1200 mg every three weeks for a maximum of two 21 day cycles. Following induction therapy, patients will undergo surgical resection of their tumor. After surgery, interested patients can receive treatment with atezolizumab 1200 mg every three weeks up to 12 months.

Eligible patients must have untreated Stage IB, II, or IIIA non-small cell lung cancer and be eligible for surgical resection with curative intent. Interested patients must also be able to provide tissue for biomarker analysis prior to the start of treatment. The trial will open to enrollment at UCLA Main Campus.

Journal of Hematology and Oncology Publication

An article discussing the use of hepcidin monoclonal antibody, LY2787106, in cancer-associated anemia was recently published in the *Journal of Hematology and Oncology.*

Hepcidin is a small protein that regulates iron levels by causing decreased iron absorption and reduced iron export from cells. High hepcidin levels, as are generally found in cancer patients, have been shown to lead to anemia. Thirty-three patients with hepcidin levels ≥ 5 ng/mL received LY2787106 every three weeks in part A and weekly in part B. The effects of LY2787106 and its distribution throughout the body were studied and markers of iron and hematology biology were measured.

Results indicated that neutralizing hepcidin led to transient iron mobilization. This supports the role of hepcidin in iron regulation. In addition, LY2787106 was well tolerated in cancer patients with anemia.

Vadhan-Raj S, Abonour R, Goldman JW, Smith DA, Slapak CA, Ilaria RL Jr, tiu RV, Wang X, Callies S, Cox J, Tuttle JL, Lau YK, Roeland EJ. A first-in-human phase 1 study of a hepcidin monocloncal antibody, LY2787106, in cancer-associated anemia. J Hematol Oncol. 2017 Mar 21; 10(1):73.

Lung Cancer Publication

An article discussing the impact of a planned dose interruption of dacomitinib in the treatment of advanced non-small cell lung cancer was recently published in *Lung Cancer*. Dacomitinib is an EGFR inhibitor.

Results were based on the Archer 1042 study which enrolled at UCLA and in the TRIO-US network. To be eligible, patients needed to be untreated for advanced NSCLC and have an EGFR mutation. Patients received dacomitinib by mouth 45mg once a day with a planned dose interruption occurring in Cycle 1 through Day 11 through 14. The goal was to study the distribution and absorption of dacomitinib throughout the body in Cycle 1 Day 10 and during dose interruption.

Investigators found that at 45mg daily dosing, levels of dacomitinib in plasma in Cycle 1 Day 10 were comparable to that obtained in Cycle 1 Day 14 in other studies. During the dose interruption, the average dacomitinib concentration was about half of value obtained just before the dose interruption. The toxicity profile was consistent with other studies of dacomitinib. The researchers suggest that this may be a beneficial treatment schedule for dacomitinib.

Kim DW, Garon EB, Jatoi A, Keefe DM, Lacouture ME, Sonis S, Gernhardt D, Wang T, Giri N, Doherty JP, Nadanaciva S, O'Connell J, Sbar E, Cho BC. Impact of a planned dose interruption of dacomitinib in the treatment of advanced non-small cell lung cancer (ARCHER 1042). Lung Cancer. 2017 Apr;106:76-82.

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