modality for their production in which pH gradient liposomes are encapsulated in alginate microspheres and subsequentially radiolabeled after production.

**Materials and Methods:** In brief, pH gradient liposomes were manufactured and microencapsulated in alginate microspheres via ultrasonication atomization. Microsphere diameter was measured via light microscopy. Microspheres were subsequently incubated with Re-186/Tc-99m-BMEDA complex and then washed to remove unencapsulated radionuclide. Re-186/Tc-99m-BMEDA complex was incubated with alginate microspheres (minus any liposomes) for direct comparison to LAMs using gamma imaging. Tc-LAMs were intra-arterially delivered to an ex vivo bovine kidney perfusion model to assess embolization. Blood pressure and flow rate of the kidney were recorded. Venous return was collected during microsphere delivery. Five-minute planar gamma image and SPECT was obtained of the embolized kidney and venous return.

**Results:** LAMs were constructed with a mean diameter of 49.5 μm (STDV = 10.4 μm). Re-LAMs demonstrated a radio-labeling efficiency of 51% whereas alginate sphere with no liposomes retained 15% of dose. 2ml of 2.98mCi Tc-LAMs were subsequentially constructed for delivery to the ex vivo kidney. BP was approximately 110/50 with a flow rate of approximately 300 ml/min upon perfusion. The full dose of spheres was nonselectively delivered to the kidney via 3Fr microcatheter. Gamma imaging of venous return demonstrated venous shunting of 3.7% of radioactivity. SPECT demonstrated high activity in the renal cortex with trace dose appreciated along the venous outflow tract.

**Conclusions:** Our novel method for radio-labeling LAMs after production demonstrated success regarding radioactivity retention and embolization capabilities. The proposed method facilitates the manufacture of the LAMs by radiopharmacies, without sacrificing the stability and radioactive retention of the microspheres. Future steps involve optimizing radio-labeling efficiency and maximizing therapeutic dose.

---

**Abstract No. 37**

**LEAP-012 trial in progress: pembrolizumab, lenvatinib, and transarterial chemoembolization combination therapy for intermediate-stage hepatocellular carcinoma not amenable to curative treatment**

D. Madoff1, J. Llovet2, A. El-Khoueiry3, M. Kudo4, R. Finn5, S. Ogasawara6, Z. Ren7, K. Mody8, J. Li9, A. Siegel9, L. Dubrovsky9, A. Vogel10; 1Yale School of Medicine, Yale Cancer Center and Yale New Haven Health, Smilow Cancer Hospital; 2Icahn School of Medicine at Mount Sinai; 3USC Norris Comprehensive Cancer Center; 4Kindai University Faculty of Medicine; 5Geffen School of Medicine, UCLA; 6Graduate School of Medicine, Chiba University; 7Zhongshan Hospital, Fudan University; 8Eisai Inc; 9Merck and Co., Inc; 10Hannover Medical School

**Purpose:** Limited treatment options are available for patients with intermediate hepatocellular carcinoma (HCC). Lenvatinib, a potent multikinase inhibitor, and pembrolizumab, a programmed death receptor-1 blocking antibody, are approved first- and second-line therapies for advanced HCC, respectively. LEAP-012 (NCT04246177) is investigating lenvatinib plus pembrolizumab in combination with transarterial chemoembolization (TACE) versus placebo plus TACE in patients with intermediate HCC.

**Materials and Methods:** LEAP-012 is a randomized double-blind phase 3 study. Adults with confirmed HCC localized to the liver without portal vein thrombosis and not amenable to curative treatment, ≥1 measurable lesion per RECIST v1.1, Eastern Cooperative Oncology Group performance status of 0 or 1, and no previous treatment with locoregional therapy or systemic chemotheraphy for HCC are eligible. Patients will be randomly assigned to receive lenvatinib 8 (body weight < 60 kg) or 12 mg (body weight ≥60 kg) orally once daily plus pembrolizumab 400 mg intravenously every 6 weeks (Q6W) plus TACE or placebo orally once daily plus placebo intravenously Q6W, plus TACE. Response will be assessed by imaging every 9 weeks, and safety will be assessed throughout the study and up to 90 days after the end of treatment. Coprimary end points are overall survival and progression-free survival (PFS) per RECIST v1.1 by blinded independent central review (BICR). Secondary end points are PFS, objective response rate (ORR), disease control rate (DCR), duration of response (DOR), and time to progression (TTP) per modified RECIST by BICR; ORR, DCR, DOR, and TTP per RECIST v1.1 by BICR; and safety. Exploratory end points are PFS, ORR, DCR, DOR, TTP, and time from randomization to second/subsequent progression per RECIST v1.1 by investigator review, identification of molecular biomarkers, and health-related quality of life.

**Results:** Recruitment began in April 2020. The planned sample size is 950 patients.

**Conclusions:** LEAP-012 will elucidate the clinical benefit of adding lenvatinib plus pembrolizumab to the current standard of care TACE for patients with intermediate-stage HCC not amenable to curative treatment.

---

**Abstract No. 38**

**Novel composite score of neutrophil-lymphocyte ratio, platelet-lymphocyte ratio, and aspartate-aminotransferase-lymphocyte ratio predicts overall survival in metastatic colorectal patients undergoing radioembolization**

P. Sharma1, S. Young2, T. Chen3, J. Pontolillo4, P. Moran1, J. Owen5, J. Golzarain6, D. D’Souza7, S. Flanagan2, T. Sanghvi3; 1University of Minnesota Medical Center; 2University of Minnesota; 3Minneapolis VA

**Purpose:** Various measures of systemic inflammation have been shown to predict outcomes in patients with metastatic colorectal cancer (mCRC). However, more work is needed in regards to the utility of systemic inflammatory markers predictive value in mCRC patients undergoing radioembolization. The purpose of this study was to evaluate the usefulness of a novel composite pre-treatment inflammation score for the prediction of radiologic response and overall survival (OS) following radioembolization for metastatic colorectal (mCRC).

**Materials and Methods:** Forty-two patients who underwent radioembolization for mCRC were reviewed. Laboratory values as well as radiologic response according to the European Association for the Study of the Liver (EASL) criteria were recorded. Overall radiologic response (ORR) was defined as those with a partial or complete response. Survival was measured from radioembolization to time of death. Patients were given 1 point each if their neutrophil-lymphocyte ratio (NLR) was ≥5.1, platelet-lymphocyte ratio