compared with disease of the right (cecum plus ascending colon, transverse colon: n=77; 28%) or rectum (n=77; 28%).

Conclusions: Preliminary data from the PROMETCO trial provide key insights as to the baseline demographics, disease characteristics and molecular status of real-world mCRC patients. It is anticipated that PROMETCO will provide valuable data on overall survival, treatment patterns, effectiveness, safety, adherence to treatment guidelines, healthcare resource utilisation and PROs in this patient population.

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P-138 Margetuximab combined with anti-PD-1 (retifanlimab) or anti-PD-1/LAG-3 (tebotelimab) +/- chemotherapy in first-line therapy of advanced/metastatic HER2+ gastroesophageal junction or gastric cancer

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Background: Trastuzumab (T), a monoclonal antibody (mAb) targeting HER2, is standard of care 1st-line therapy for advanced HER2+ GEJ/GC patients. Margetuximab (M), an investigational Fc-engineered anti-HER2 mAb, targets the same HER2 epitope but with higher affinity for both 158V (high binding) and 158F (low binding) alleles of activating Fc receptor CD16A. Data suggest margetuximab coordinately enhances both innate and adaptive immunity, including antigen-specific T-cell responses to HER2. PD-1 and LAG-3 are T-cell checkpoint molecules that suppress T-cell function. Retifanlimab (also known as MGA012 or INCMGA00012) is a humanized, hinge-stabilized, IgG4 K anti-PD-1 mAb blocking binding of PD-L1 or PD-L2 to PD-1. Tebotelimab (also known as MGD013) is a humanized Fc-bearing bispecific tetravalent DART® protein that binds to both PD-1 and LAG-3, inhibiting their respective ligand binding. We previously reported that a chemotherapy (CTX)-free regimen of M+PD-1 blockade was well tolerated in gastroesophageal junction or gastric cancer (GEJ/GC) patients, and induced a 30% objective response rate (ORR) in a double-positive biomarker population. This was 2- to 3-fold greater than in historical controls with checkpoint inhibitors alone. This registration-directed trial assesses efficacy, safety, and tolerability of M+checkpoint inhibition ± CTX in metastatic/locally advanced, treatment-naïve, HER2+ GEJ/GC patients.

Trial design: This is a 2-cohort, adaptive open-label phase 2/3 study (NCT04082364). The first single arm, CTX-free cohort A, evaluates M+retifanlimab in HER2+ (immunohistochemistry [IHC] 3+) and PD-L1+ (excluding microsatellite instability high) patients. After 40 patients are evaluated for response/safety, additional patients will be enrolled if the threshold for continuation is met. In randomized cohort B, HER2+ (IHC 3+ or 2+/fluorescent in situ hybridization+) patients are enrolled irrespective of PD-L1 status. Part 1 of cohort B randomizes patients to 1 of 4 arms (50 patients each): control arm (T+CTX) or 1 of 3 experimental arms (M+CTX; M+CTX+retifanlimab; M+CTX+tebotelimab). CTX is investigator's choice XELOX or mFOLFOX-6. Part 2 of cohort B consists of control (T+CTX) vs 1 experimental arm (M+CTX) + either retifanlimab or tebotelimab, depending on results from part 1; with 250 patients each. The primary efficacy endpoint for cohort A (both parts) is ORR per RECIST 1.1; for cohort B part 2 it is overall survival.

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Legal entity responsible for the study: MacroGenics, Inc.

Funding: MacroGenics, Inc.

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P-139 A phase 2 multicohort study (LEAP-005) of lenvatinib plus pembrolizumab in patients with previously treated selected solid tumors: Pancreatic cancer cohort

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Background: Over the past few decades, the global incidence and mortality rates associated with pancreatic cancer have continued to increase. Pancreatic cancer has a particularly poor prognosis, with a 5-year survival rate of only approximately 5%. Patients with pancreatic cancer generally respond poorly to chemotherapy, and their treatment options in the second-line or later setting are limited. In two multicohort, open-label trials, including the phase 1b/2 KEYNOTE-146 (NCT02501096) and phase 2 LEAP-005 (NCT03797326) studies, the combination of the antiangiogenic multikinase inhibitor lenvatinib and the anti–PD-1 monoclonal antibody pembrolizumab demonstrated promising antitumor activity with a manageable safety profile in patients with previously treated (both studies) and untreated (KEYNOTE-146) histologically or cytologically confirmed metastatic (both studies) and/or unresectable (LEAP-005) solid tumors. In the LEAP-005 trial, benefit was seen in cohorts with glioblastoma multiforme and biliary tract cancer (second-line treatment), triple-negative breast cancer (second- and third-line treatment), gastric and colorectal cancer (third-line treatment), and ovarian cancer (fourth-line treatment). Based on these encouraging results and the unmet need for patients with pancreatic cancer, the LEAP-005 protocol was amended to include a pancreatic cancer cohort. Here we describe the LEAP-005 trial design for this cohort.

Trial design: Eligible patients are aged ≥18 years with histologically or cytologically confirmed metastatic pancreatic ductal adenocarcinoma and have received 1 or 2 prior lines of therapy (including ≥1 platinum- or gemcitabine-containing regimen), have measurable disease per RECIST version 1.1, have ECOG performance status of 0 or 1, and provide a tissue sample for evaluation of PD-L1 expression. Patients receive lenvatinib 20 mg once daily plus pembrolizumab 200 mg Q3W for up to 35 cycles of pembrolizumab (approximately 2 years) or until confirmed disease progression, unacceptable toxicity, or withdrawal of consent. Treatment with lenvatinib can continue beyond 2 years in patients experiencing clinical benefit. The primary endpoints are ORR (per RECIST version 1.1 by blinded independent central review) and safety. The primary safety endpoints are treatment-emergent AEs, serious AEs, and discontinuations due to AEs, with AEs graded using National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0. Secondary endpoints include disease control rate (comprising CR, PR, and SD), duration of response, PFS, and OS. Health-related quality of life is assessed using validated patient-reported outcome instruments including the European Organisation for the Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30). Tumor imaging is performed Q9W from treatment initiation for 54 weeks, then Q12W to week 102, and Q24W thereafter. PD-L1 expression is assessed by a central laboratory using PD-L1 IHC 22C3 (Agilent Technologies, Carpinteria, CA). The pancreatic cancer cohort began enrollment in March 2021. An interim analysis is planned when the first 30 patients enrolled have been followed up for approximately 6 months.

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P-140 A phase I study of biweekly abraxane in combination with oxaliplatin and oral S-1/leucovorin as first line treatment for advanced gastric, pancreatic and biliary tract cancers

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Background: Advanced gastric, pancreatic and biliary tract cancer patients have poor prognosis. Platinum, fluoropyrimidine, taxane, irinotecan, and gemcitabine used alone or in combination are commonly used for these patients. However, the overall