non-small cell lung cancer and cHL patients at $3 \times 10^8$ FT500 cells per dose combined with ICI is ongoing.

**Ethics Approval** This study is being conducted in accordance with the Declaration of Helsinki and was approved by all Institutional Review Boards from each clinical site participating in the study. Specific approval numbers can be provided upon request.

**REFERENCE**


**Trial Registration**


**http://dx.doi.org/10.1136/jitc-2020-SITC2020.0380**

**ROLE OF CT SCANS OF ABDOMEN AND PELVIS IN MANAGEMENT OF PATIENTS WITH IMMUNOTHERAPY-INDUCED COLITIS**

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**Background** Colitis is one of the most common immune-related adverse event in patients who receive immune checkpoint inhibitors targeting cytotoxic T-lymphocyte antigen 4 (CTLA-4) and programmed cell death-1 (PD-1). Although radiographic changes are reported on computed tomography such as mild diffuse bowel thickening or segmental colitis, the utility of CT in diagnosis of patients with suspected immune-related colitis is not well studied.

**Methods** CT scans of the abdomen and pelvis of 34 patients on immunotherapy with a clinical diagnosis of immune-related colitis and 19 patients receiving immunotherapy without clinical symptoms of colitis (control) were enrolled in this retrospective study. Segments of the colon (rectum, sigmoid, descending, transverse, ascending and cecum) were assessed independently by two fellowship trained abdominal imaging specialists with 7 and 13 years’ experience who were blinded to the clinical diagnosis. Each segment was assessed for mucosal enhancement, wall thickening, distension, peri-serosal fat stranding. Any disagreements were resolved in consensus. The degree of distension and the spurious assignment of wall thickening were the most common causes for disagreement. The presence of any of the signs was considered as radiographic evidence of colitis.

**Results** CT evidence of colitis was seen in 16 of 34 patients with symptoms of colitis. 7 of 19 patients who did not have symptoms of colitis showed signs of colitis on CT. The sensitivity, specificity, Positive Predictive Value and Negative Predictive Value for colitis on CT is 47%, 63.2%, 69.5% and 40%, respectively.

**Conclusions** CT has a low sensitivity, specificity and negative predictive value for the diagnosis of immunotherapy-induced colitis. CT has no role in the diagnosis of patients suspected of having uncomplicated immune-related colitis and should not be used routinely for management.

**Trial Registration** This protocol is not registered on clinicaltrials.gov.

**Ethics Approval** This protocol was IRB approved on: 11/16/2015 - IRB 4 Chair Designee FWA #: 0000363 OHRP IRB Registration Number: IRB 4 IRB00005015

**Consent** This protocol utilizes an IRB approved waiver of consent.

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**TARGETING INNATE IMMUNITY WITH BXCL701 IN COMBINATION WITH PEMBROLIZUMAB IN PATIENTS WITH ADVANCED SOLID CANCERS: PHASE 2 BASKET STUDY**

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**Background** BXCL701 is an oral competitive inhibitor of DPPs, primarily DPP8/9, that activates inflammasome mediated pyroptosis. BXCL701 therefore, can induce an innate immune reaction and tumor inflammation, bridging between innate and adaptive immunity, potentially leading to synergistic anticancer activity when combined with PD-1 antibody pembrolizumab.

**Methods** This is a phase 2, open-label, single-center study (NCT04171219) of oral BXCL701 0.3 mg BID on days 1–14 and intravenous pembrolizumab 200 mg on day 1 of a 21-day cycle with a safety lead-in to evaluate RECIST/iRECIST response rate in patients with advanced solid cancers. After confirming safety and dose limiting toxicities (DLT) in the first 6 patients, additional patients are being enrolled to a PD-1/PD-L1 antibodies (ab) naïve cohort and PD-1/PD-L1 ab pretreated cohort. Each cohort is planned to enroll 9 patients, and if a partial (PR) or complete response (CR) is observed the cohort is expanded to a total of 17 patients. The treatment is considered promising if at least 3 PRs or CRs are observed in a cohort of 17 patients.

**Results** As of August 24, 2020, 14 patients were treated; 5 patients (prostate cancer, endometrial cancer, uveal melanoma, liposarcoma, basal cell carcinoma) were enrolled in the PD-1/PD-L1 ab naïve cohort and 9 patients (leiomyosarcoma, squamous cell carcinoma of unknown primary, melanoma, myxoid sarcoma, pleomorphic sarcoma, colorectal cancer, anaplastic astrocytoma, prostate cancer) were enrolled to PD-1/PD-L1 ab pretreated cohort. Among all 14 patients, there was 1 episode of grade 4 hypotension (recovered) and 1 episode of grade 5 hypotension attributed to BXCL701. In the PD-1/PD-L1 ab naïve cohort, 3 patients with available imaging, 2 had a PR (uveal melanoma previously treated with PD-1/OX40 fusion protein [-31%] n=1; and microsatellite stable endometrial cancer [-62%], n=1). In the PD-1/PD-L1 ab pretreated cohort, there were no objective responses in 5 patients with available imaging; however, a patient with pleomorphic sarcoma refractory to PD-1 antibody monotherapy demonstrated a tumor shrinkage of -18% on the first restaging imaging.

**Conclusions** BXCL701 in combination with pembrolizumab demonstrated encouraging signals of activity in selected difficult-to-treat cancers. Mitigation strategies to prevent events of high-grade hypotension are being implemented to allow the enrollment continuation.

**Trial Registration** NCT04171219

**Ethics Approval** The study was approved by MD Anderson IRB

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