STUDY OBJECTIVES AND ENDPOINTS

**Primary Objectives**

- Define safety and tolerability and determine the phase 2 dose of BDC-3042 ± anti-PD-1

**Endpoints**

- Incidence of AEs and SAEs, DLTs, and changes from baseline in vital signs, laboratory values, and ECGs

**Secondary Objectives**

- Evaluate preliminary anti-tumor activity of BDC-3042 ± anti-PD-1

**Endpoints**

- Objective response rate (ORR) according to RECIST v.1.1
- PK variables, including Cmax, AUC0-t, V1, V2, or T1/2
- Incidence of anti-drug antibodies

**Exploratory Objectives**

- Explore potential biomarkers associated with efficacy or safety of BDC-3042 ± anti-PD-1

**Endpoints**

- Evaluation of potential association between baseline biomarkers and BDC-3042 ± anti-PD-1 anti-tumor activity
- Evaluation of changes in additional exploratory biomarkers in tumor tissue and blood related to tumor and immune biology by such methods as gene expression profiling, mutational, protein and tissue image analysis

**STUDY DESIGN**

- Dose escalation will enroll up to 69 patients with metastatic or unresectable TNBC, clear cell renal cell carcinoma, colorectal cancer, head and neck cancer, NSCLC, or ovarian cancer

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**Dose expansion is planned to evaluate the preliminary anti-tumor activity of BDC-3042 ± anti-PD-1**

- **Dose Escalation**
  - Monotherapy – Part 1
  - Combination Therapy – Part 2
  - Cohort 1
  - Cohort 2
  - Cohort 3
  - Cohort 4
  - Cohort 5
  - Cohort 6
  - Cohort 7

**Key Inclusion Criteria**

- Histologically- or cytologically-confirmed, metastatic or unresectable TNBC, clear cell renal cell carcinoma, colorectal cancer, head and neck cancer, NSCLC, or ovarian cancer
- Ovarian cancer may have platinum-sensitive or resistant disease
- MPD, weight > 110 lbs, ECOG 0-1
- Patients must be age > 18 yrs
- Patients must have adequate bone marrow function, hepatic function, renal function, and without active second malignancy

**Key Exclusion Criteria**

- Active systemic yeast infection within 4 weeks before study treatment
- Prior hospitalization for asthma during past year
- CNS metastases except for disease that is asymptomatic, stable, and has not required steroids for at least 14 days prior to study treatment
- Medical condition requiring corticosteroids (> 10 mg daily oral prednisone or equivalent) or other systemic immunosuppressive therapy within 28 days before starting study treatment, except for intermittent or sporadic use of inhaled or topical steroids
- Use of an investigational agent within 28 days prior to starting study treatment

**BIOMARKER ASSESSMENT**

- Screening fresh tissue biopsy is optional. Archival tumor sample may be submitted.
- Serial blood collection for all subjects
- Assess potential association between baseline biomarkers expression and BDC-3042 ± anti-PD-1 anti-tumor activity
- Pro-inflammatory cytokines and chemokines to be evaluated
- Assess additional exploratory biomarkers in tumor tissue and blood related to tumor and immune biology by such methods as gene expression profiling, mutational, protein and tissue image analysis

**SUMMARY**

- BDC-3042 is a novel agonist antibody targeting an immune-activating receptor expressed on TAMs known as Dectin-2
- Nonclinical studies with BDC-3042 have demonstrated its potential to reprogram TAMs and elicit anti-tumor activity as a novel immunotherapeutic approach for diverse human cancers
- BBI-20233042 is a phase 1/2, first-in-human, four-part trial evaluating BDC-3042 ± anti-PD-1 in patients with metastatic or unresectable TNBC, clear cell renal cell carcinoma, colorectal cancer, head and neck cancer, NSCLC, or ovarian cancer (NCT06052852)
- Enrollment in dose escalation is ongoing in the United States

**REFERENCES**