Title: A phase 1 study of BGB-A3055 (anti-CCR8) with or without tislelizumab (anti-PD-1) in patients with solid tumors

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Background: BGB-A3055 is a humanized monoclonal antibody targeting C-C motif chemokine receptor 8 (CCR8), a receptor highly expressed on intratumoral regulatory T cells (Tregs). CCR8 overexpression correlates with poor prognosis in certain tumor types. Preclinical studies have shown potent antitumor activity of BGB-A3055. Here, we present results from a phase 1a dose-escalation trial of BGB-A3055 alone (Part A [A]) or combined with tislelizumab (TIS; Part B [B]) in patients (pts) with advanced or metastatic solid tumors (NCT05935098).

Methods: Eligible pts had histologically confirmed advanced or metastatic solid tumors with high prevalence of CCR8 expression. In A, pts received BGB-A3055 (six dose levels) intravenously (IV) every 3 weeks (Q3W). In B, pts received BGB-A3055 (six dose levels) and TIS 200 mg IV Q3W. Primary endpoint was safety; secondary endpoints included preliminary antitumor activity (RECIST v1.1).

Results: As of Nov 19, 2025, 98 pts were treated with BGB-A3055 ± TIS (A: n=42; B: n=56). Median (range) study follow-up was 3.94 (0.9-19.0) months in A and 4.67 (0.5-16.8) months in B.

Treatment-emergent adverse events (TEAEs) are provided in the Table. The most common BGB-A3055-related TEAEs were neutrophil count decreased (23.8%) in A and pyrexia (23.2%) in B. The most common serious TEAE was immune-mediated enterocolitis (A: 4.8%; B: 7.1%). The most common immune-mediated adverse events (imAEs) were rash,

rash maculo-papular, and hypothyroidism in A (7.1% each) and rash maculo-papular in B (17.9%). Dose-limiting toxicities occurred in 1 pt in A (immune-mediated hepatitis) and 3 pts in B (colitis, nephrotic syndrome, and rash maculo-papular in a single pt each). No treatment-related TEAEs leading to death were reported. Maximum tolerated dose was not reached.

Unconfirmed objective response rate was 7.5% (95% confidence interval [CI]: 1.6-20.4; 3 partial responses [PRs]) in A and 18.2% (95% CI: 9.1-30.9; 1 complete response and 9 PRs) in B. Disease control rate was 35.0% (95% CI: 20.6-51.7) in A and 56.4% (95% CI: 42.3-69.7) in B. Among the 13 responders, 6 received prior immunotherapies. Robust Treg reduction was observed in peripheral blood and tumor tissue post-treatment, indicating potent on-target pharmacodynamic activity of BGB-A3055.

Conclusions: BGB-A3055 ± TIS demonstrated a safety profile consistent with selective CCR8 on-target effects in pts with advanced solid tumors and had preliminary antitumor activity.

Table

	Part A **BGB-A3055 monotherapy (n=42)**	**Part B** **BGB-A3055 + TIS (n=56)**
Any TEAE, n (%)	41 (97.6)	55 (98.2)
Grade ≥3	26 (61.9)	47 (83.9)
Serious	17 (40.5)	37 (66.1)
Leading to death	1 (2.4)	3 (5.4)
Leading to treatment discontinuation	9 (21.4)	23 (41.1)
Any BGB-A3055-related TEAE, n (%)	35 (83.3)	53 (94.6)
Grade ≥3	18 (42.9)	31 (55.4)
Serious	5 (11.9)	20 (35.7)
Any imAE, n (%)	15 (35.7)	33 (58.9)