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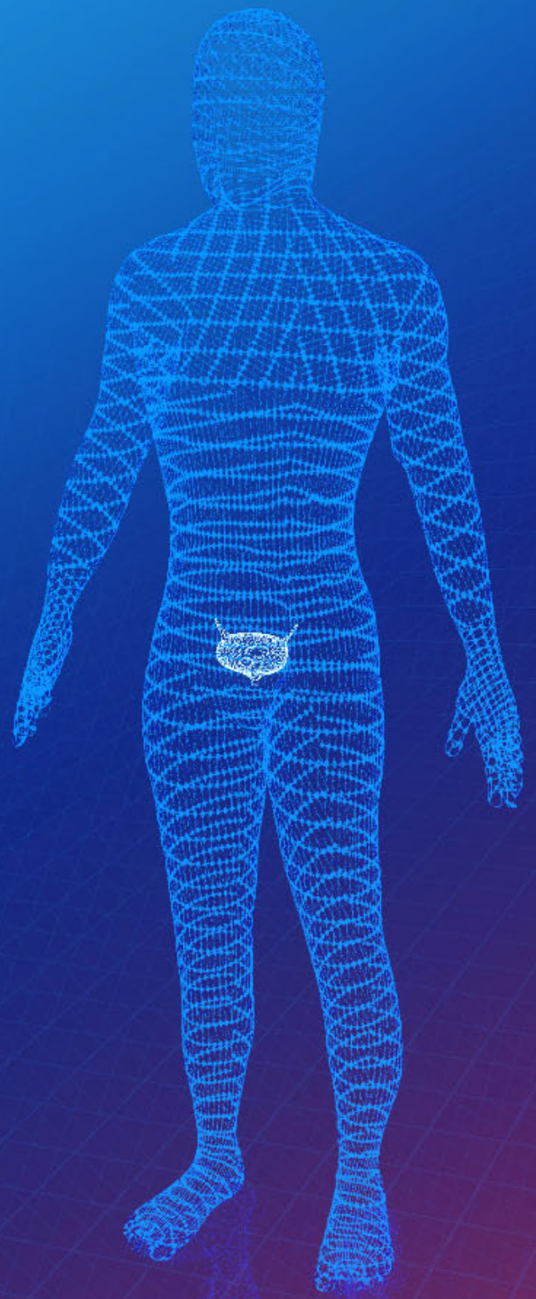
For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 September 2023



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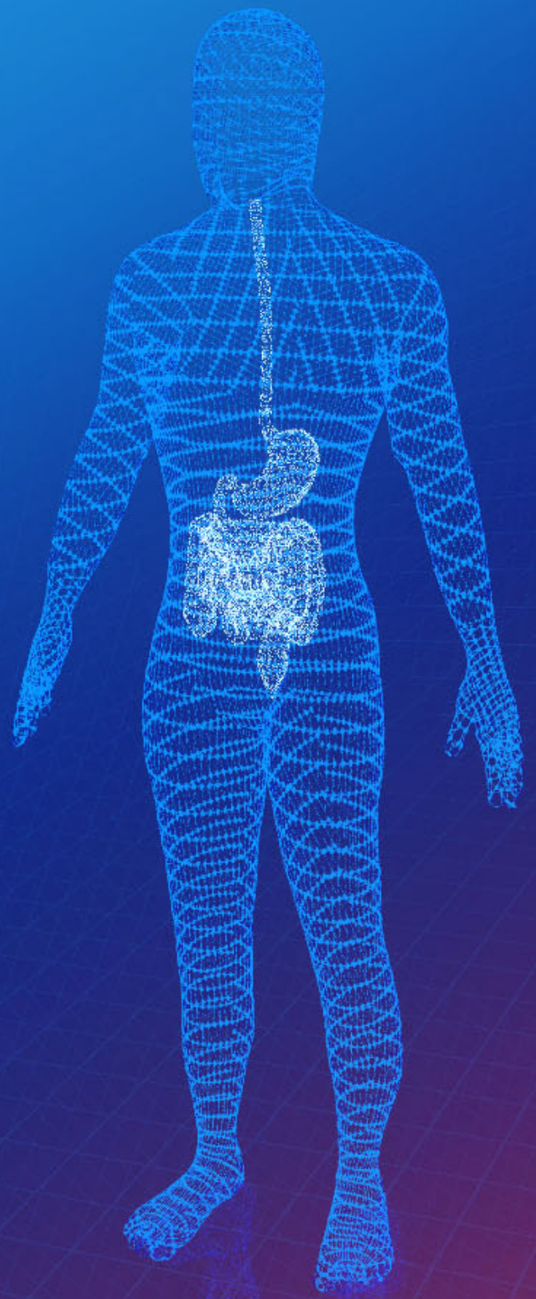

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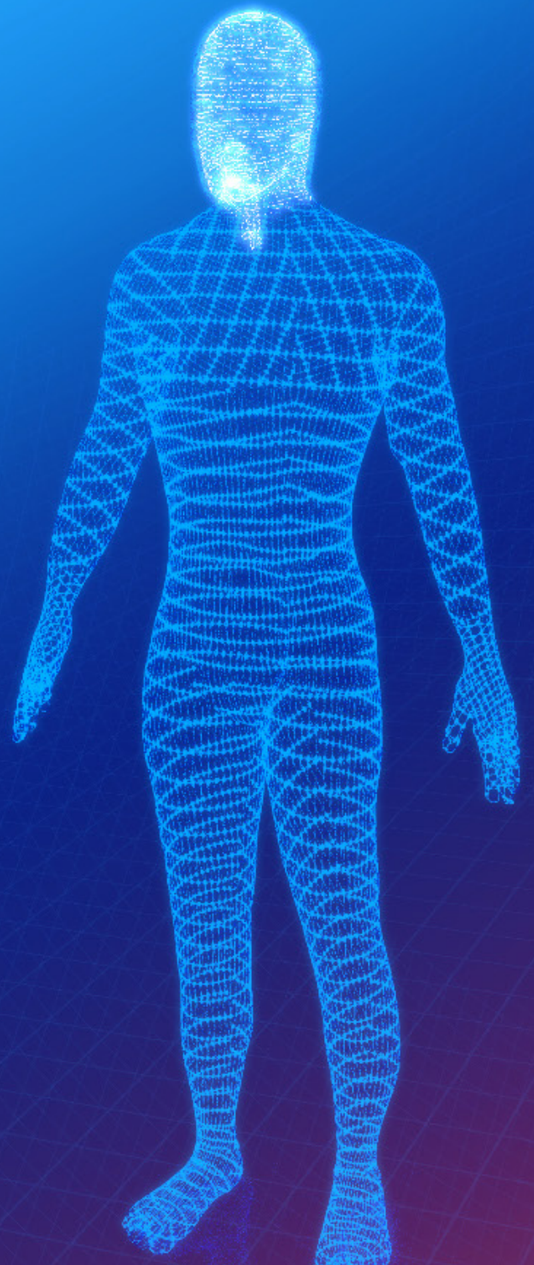

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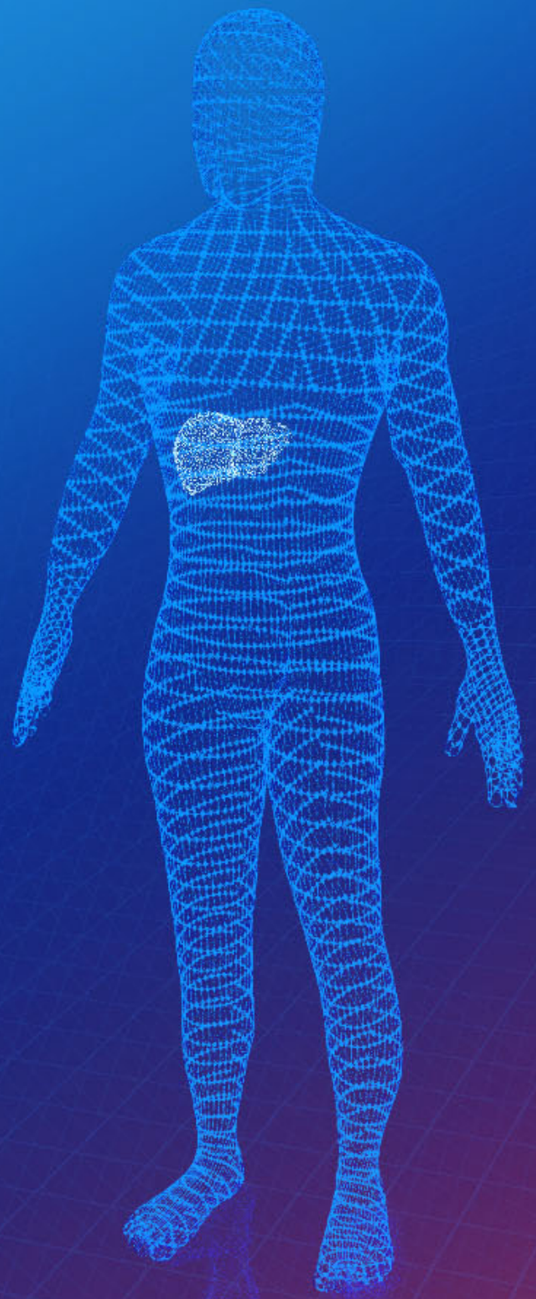

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INVESTIGATIONAL CLINICAL PORTFOLIO

Bladder Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1) + Chemotherapy	BGB-A317-310 > Schema	China	1L advanced UBC	3	NCT03967977

UBC, urothelial bladder cancer.

The studies above may relate to investigational products or investigational uses of approved products that have not yet been approved by the applicable regulatory agency in your country or region. For more information contact **medicalinformation@beigene.com**

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BGB-A317-310 Phase 3 Study in 1L UBC[1,2]

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Either Cisplatin or Carboplatin + Gemcitabine + Tislelizumab (BGB-A317, Anti-PD-1 Antibody) Compared With Either Cisplatin or Carboplatin + Gemcitabine + Placebo as First-line Treatment for Patients With Locally Advanced or Metastatic Urothelial Carcinoma

Phase 3 | **Recruiting**

Study Identifiers: BGB-A317-310, NCT03967977
Contact: clinicaltrials@beigene.com

Primary Endpoint: OS in ITT
Key Secondary Endpoints: ORR, DOR, HRQOL, Safety, PFS per the investigator, OS rate at 1 and 2 years

Key Eligibility Criteria

- Histologically confirmed urothelial carcinoma
- No previous therapy for locally advanced unresectable or metastatic urothelial carcinoma

R → 1:1

- **Tislelizumab + Chemotherapy** → **Tislelizumab**
- **Placebo + Chemotherapy** → **Placebo**

→ **Treatment Until Unacceptable Toxicity or Disease Progression** → **Safety and Survival Follow-up**

Stratification

- Cisplatin vs Carboplatin
- Visceral metastasis (yes vs no)
- PD-L1 expression (high vs low)

Study Treatment

- Tislelizumab 200 mg or placebo Q3W
- Gemcitabine 1000 mg/m^2 Day 1, 8, Q3W
- Cisplatin 70 mg/m^2 or carboplatin AUC=4.5 Day 1 or Day 2, Q3W

Chemotherapy regimen will be administered for up to 6 cycles

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

ADA, antidrug antibody; AUC, area under the curve; DCR, disease control rate; DOR, duration of response; HRQoL, health-related quality of life; ITT, intent to treat; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PFS2, progression-free survival on subsequent treatment; PK, pharmacokinetics; Q3W, every 3 weeks.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03967977. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

For more information, contact: medicalinformation@beigene.com

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INVESTIGATIONAL CLINICAL PORTFOLIO

Breast Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab + Fruquintinib (VEGFR inhibitor)	2020-013-00US3†	United States	Advanced triple negative breast cancer	1/2	NCT04577963
Zanidatamab (Anti-HER2 bispecific antibody) + Chemotherapy +/- Tislelizumab	BGB-A317-ZW25-101*	China, S. Korea	1L HER2+ BC	1/2	NCT04276493

*In collaboration with Zymeworks Inc.
†Clinical collaboration with Hutchison Medipharma International.

HER2+ BC, human epidermal growth factor receptor-2 positive breast cancer.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Gastrointestinal Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
LBL-007 (anti-LAG-3) +/- Tislelizumab (Anti-PD-1) + Bevacizumab + Capecitabine	BGB-A317-LBL-007-201*	Worldwide	Maintenance in unresectable or metastatic MSS/mismatch repair proficient CRC	1/2	NCT05609370
LBL-007 + Tislelizumab + Chemotherapy	BGB-A317-LBL-007-202*	Opening Soon	1L unresectable locally advanced or metastatic ESCC	2	NCT06010303
Tislelizumab	BGB-A317-214	China	Neoadjuvant MSI-high or dMMR CRC	2	NCT05116085
Tislelizumab + Chemoradiotherapy	BGB-A317-311 > Schema	China	Localized ESCC	3	NCT03957590
Tislelizumab + Chemotherapy	BGB-A317-305 > Schema	Worldwide	1L GC/GEJC	3	NCT03777657
Tislelizumab + Chemotherapy	BGB-A317-306 > Schema	Worldwide	1L advanced ESCC	3	NCT03783442
Tislelizumab + Chemotherapy/ Chemoradiotherapy	BGB-A317-213	China	Resectable ESCC	2	NCT04974047
Tislelizumab + Ociperlimab (Anti-TIGIT)	BGB-A317-A1217-203	Worldwide	2L PD-L1+ advanced ESCC	2	
Tislelizumab + DKN-01 (Anti-DKK1) + Chemotherapy	DEK-DKK1-P205†	Worldwide	1L/2L GC/GEJC	2	NCT04363801
Tislelizumab + Fruquintinib (VEGFR inhibitor)	BGB-A317-fruquintinib-201‡	China, S. Korea	Advanced GC/GEJC and CRC	2	NCT04716634
Tislelizumab + Fruquintinib	2020-013-00US3‡	United States	Advanced CRC	1/2	NCT04577963
Tislelizumab + Sitravatinib (Multikinase inhibitor)	BGB-A317-Sitravatinib-203§	China	Advanced ESCC after anti-PD-(L)1 therapy	2	NCT05461794
Zanidatamab (Anti-HER2 bispecific antibody) + Chemotherapy +/- Tislelizumab	ZWI-ZW25-301‖	Worldwide	1L HER2+ advanced/metastatic GC/EC	3	NCT05152147
Zanidatamab + Chemotherapy +/- Tislelizumab	BGB-A317-ZW25-101‖	China, S. Korea	1L HER2+ GC/GEJC	1/2	NCT04276493

*In collaboration with Nanjing Leads Biolabs.
†In collaboration with Leap Therapeutics, Inc.
‡Clinical collaboration with Hutchison Medipharma International.
§Partnership with Mirati Therapeutics, Inc.
‖In collaboration with Zymeworks Inc.

CRC, colorectal cancer; DKK1, Dickkopf-1; dMMR, mismatch repair deficient; ESCC, esophageal squamous cell carcinoma; GC, gastric cancer; GEJC, gastroesophageal junction carcinoma; HER2+, human epidermal growth factor receptor-2 positive; MSI-H, microsatellite instability-high; MSS, microsatellite stable; PD-L1, programmed death-ligand 1; TIGIT, T-cell immunoreceptor with Ig and ITIM domains; VEGFR, vascular endothelial growth factor receptor.

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1019-BGB-A333-MRC-005 September 2023

STUDY DESIGN

RATIONALE-311

A Phase 3 Trial in Localized ESCC[1-3]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03957590
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: PFS by BIRC per RECIST 1.1
SECONDARY ENDPOINTS: ORR and DOR by BIRC per RECIST 1.1, OS, HRQoL, Safety

KEY ELIGIBILITY

- Histologically confirmed ESCC (II-IVa)
- Suitable for cCRT
- Surgery is unsuitable/declined
- ECOG PS 0,1

STRATIFICATION

- Clinical TNM stage: II/III vs IVa
- ECOG PS: 0 vs 1

R 1:1

TREATMENT

Tislelizumab (up to 24 months) + cCRT (2 cycles of Cisplatin/Paclitaxel + radiation)

Placebo (up to 24 months) + cCRT (2 cycles of Cisplatin/Paclitaxel + radiation)

Treatment until PD or unacceptable toxicity

FOLLOW-UP

Safety and survival

For more information, contact: medicalinformation@beigene.com
The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

BIRC, blinded independent review committee; cCRT, concurrent chemoradiotherapy; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HRQoL, health-related quality of life; IRC, independent review committee; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; TNM, tumor nodes metastasis.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03957590. Accessed December 1, 2022. **2.** BeiGene Data on File. (Protocol BGB-A317-311). **3.** Wang W et al. ASCO-GI 2020. TIP.

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STUDY DESIGN

RATIONALE-305

Tislelizumab in Combination With Chemotherapy as 1L Treatment in Inoperable, Locally Advanced, or Metastatic GC or GEJC[1]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03777657
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: PFS, OS
KEY SECONDARY ENDPOINTS: ORR, DOR, HRQoL, Safety

KEY ELIGIBILITY CRITERIA

- Histologically confirmed adenocarcinoma
- HER2/neu negative disease
- Measurable disease
- ECOG PS ≤1
- No previous therapy for locally advanced unresectable or metastatic GC/GEJC*
- No prior therapy with drug specifically targeting T-cell co-stimulation or checkpoint pathways

TREATMENT

Screening → R 1:1

- Tislelizumab + oxaliplatin/capecitabine OR cisplatin/5-FU
- Placebo + oxaliplatin/capecitabine OR cisplatin/5-FU

→ Treatment until unacceptable toxicity or disease progression

FOLLOW-UP

Safety and survival

NOTE: Patients may have received prior neoadjuvant or adjuvant therapy as long as it was completed and they have no recurrence or disease progression for at least 6 months.

For more information, contact: medicalinformation@beigene.com

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

5-FU, 5-fluorouracil; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; GC, gastric cancer; GEJC, gastroesophageal junction carcinoma; HER2, human epidermal growth factor receptor-2; HRQOL, health-related quality of life; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

REFERENCE: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03777657. Accessed December 1, 2022.

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STUDY DESIGN

RATIONALE-306

Tislelizumab in Combination With Chemotherapy as 1L Treatment in Advanced ESCC[1]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03783442
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: OS
KEY SECONDARY ENDPOINTS: PFS, ORR/DOR per RECIST v1.1, OS, HRQOL, and Safety

KEY ELIGIBILITY CRITERIA

- Histologically confirmed diagnosis of ESCC
- Stage IV, unresectable ESCC at first diagnosis OR unresectable, locally advanced recurrent metastatic disease; if there is prior neoadjuvant/adjuvant therapy with platinum-based chemotherapy, a treatment-free interval of at least 6 months is required
  - No prior PD-1 or PD-L1 therapy
  - No evidence of fistula (either esophageal/bronchial or esophageal/aorta)

TREATMENT

Screening → R 1:1

- Tislelizumab + platinum/5-FU OR platinum/capecitabine OR platinum/paclitaxel
- Placebo + platinum/5-FU OR platinum/capecitabine OR platinum/paclitaxel

→ Treatment until unacceptable toxicity or disease progression

FOLLOW-UP

Safety and survival

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The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

5-FU, 5+fluorouracil; BIRC, blinded independant central review committee; DOR, duration of response; ESCC, esophageal squanamous cell carcinoma; HRQoL, health-related quality of life; ORR, overall response rate; OS, overall survival; PD-1, programmed cell death-1; PD-L1, programmed death-ligand 1; PFS, progression-free survival.

REFERENCE: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03783442. Accessed December 1, 2022.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Head and Neck Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1) + Chemotherapy	BGB-A317-309 > Schema	China, Thailand	1L advanced nasopharyngeal cancer	3	NCT03924986
Tislelizumab +/- Surzebiclimab (anti-TIM-3) +/- LBL-007 (anti-LAG-3)	BGB-HNSCC-201*	Australia, China, United States	1L recurrent or metastatic HNSCC	2	NCT05909904

*In collaboration with Nanjing Leads Biolabs.

HNSCC, Head and neck squamous cell carcinoma; LAG-3, Lymphocyte activation gene-3; TIM-3, T cell immunoglobulin and mucin-domain containing-3.

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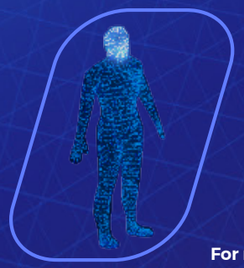

STUDY DESIGN

RATIONALE-309[1,2]

Tislelizumab in Combination With Chemotherapy as 1L Treatment in Recurrent or Metastatic Nasopharyngeal Cancer

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03924986
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: PFS by IRC
SECONDARY ENDPOINTS: ORR and DOR by IRC, PFS and PFS2 by INV, OS, HRQoL, Safety

KEY ELIGIBILITY

- Histologically or cytologically confirmed, recurrent or metastatic NPC
- Treatment-naive for recurrent or metastatic NPC
- Exclude patients with locally recurrent NPC suitable for curative surgery or radiotherapy

STRATIFICATION

- Gender
- Liver metastases (with or without)

TREATMENT

R 1:1

- Tislelizumab + 4-6 cycles of Cisplatin/Gemcitabine
- Placebo + 4-6 cycles of Cisplatin/Gemcitabine

Treatment until unacceptable toxicity or disease progression

FOLLOW-UP

Safety and survival

For more information, contact: medicalinformation@beigene.com

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

DOR, duration of response; HRQoL, health-related quality of life; INV, investigator; IRC, independent review committee; NPC, nasopharyngeal cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on subsequent treatment; Q3W, every 3 weeks.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03924986. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Hematologic Malignancies

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-16673 (BTK-targeted CDAC)	BGB-16673-101	Australia, United States	B-cell malignancies	1	NCT05006716
BGB-16673	BGB-16673-102	China	B-cell malignancies	1	NCT05294731
BGB-10188 (PI3Kδ inhibitor) +/- Zanubrutinib	BGB-A317-3111-10188-101	Australia, China	B-cell malignancies	1/2	NCT04282018
BGB-11417 monotherapy	BGB-11417-101	Worldwide	B-cell malignancies	1A/1B	NCT04277637
BGB-11417 monotherapy	BGB-11417-102	China	B-cell malignancies	1	NCT04883957
BGB-11417 monotherapy	BGB-11417-201	China	R/R MCL	2	NCT05471843
BGB-11417 monotherapy	BGB-11417-202	China	R/R CLL/SLL	2	NCT05479994
BGB-11417 + Azacitidine +/- Posaconazole	BGB-11417-103	Worldwide	Myeloid malignancies	1B/2	NCT04771130
BGB-11417 + Dexamethasone +/- Carfilzomib	BGB-11417-105	Worldwide	R/R multiple myeloma with t(11;14)	1B/2	NCT04973605
Ociperlimab (Anti-TIGIT) +/- Tislelizumab or Rituximab	AdvanTIG-101	China	R/R DLBCL	1B/2	NCT05267054
Tislelizumab	BGB-A317-314 > Schema	China	R/R cHL	3	NCT04486391

PAGE 1 OF 2

B-cell NHL, B-cell non-Hodgkin lymphoma; CDAC, chimeric degradation activating compound; cHL, classical Hodgkin lymphoma; CLL, chronic lymphocytic leukemia; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; GCB, germinal center B-cell like; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma; TIGIT, T-cell immunoreceptor with Ig and ITIM domains; WM, Waldenström macroglobulinemia.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Hematologic Malignancies

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab	BGB-A317-210	Worldwide	R/R cHL	2	NCT04318080
Zandelisib (PI3Kδ inhibitor) +/- Zanubrutinib or Rituximab	ME-401-002*	Switzerland, United States	CLL/SLL, FL, B-cell NHL	1	NCT02914938
Zanubrutinib	BGB-3111-215 > Schema	United States	Previously treated B-cell malignancies	2	NCT04116437
Zanubrutinib	BGB-3111-218	China	R/R DLBCL	2	NCT05068440
Zanubrutinib	BGB-3111-111	Japan	B-cell malignancies	1/2	NCT04172246
Zanubrutinib + Lenalidomide +/- Rituximab	BGB-3111-110	China	R/R DLBCL	1	NCT04436107
Zanubrutinib monotherapy	BGB-3111-114	United States	Bioequivalence of zanubrutinib tablets vs capsules in healthy volunteers	1	NCT05767398
Zanubrutinib + Obinutuzumab	BGB-3111-308 > Schema	Australia, United States	R/R FL	3	NCT05100862
Zanubrutinib + Obinutuzumab	BGB-3111-212 > Schema	Worldwide	R/R FL	2	NCT03332017
Zanubrutinib + Rituximab	BGB-3111-306 > Schema	Worldwide	1L MCL	3	NCT04002297
Zanubrutinib + Rituximab	BGB-3111-308 > Schema	Australia, United States	R/R MZL	3	NCT05100862

*In collaboration with MEI Pharma.

B-cell NHL, B-cell non-Hodgkin lymphoma; cHL, classical Hodgkin lymphoma; CLL, chronic lymphocytic leukemia; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; GCB, germinal center B-cell like; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma.

The studies above may relate to investigational products or investigational uses of approved products that have not yet been approved by the applicable regulatory agency in your country or region. For more information contact **medicalinformation@beigene.com**

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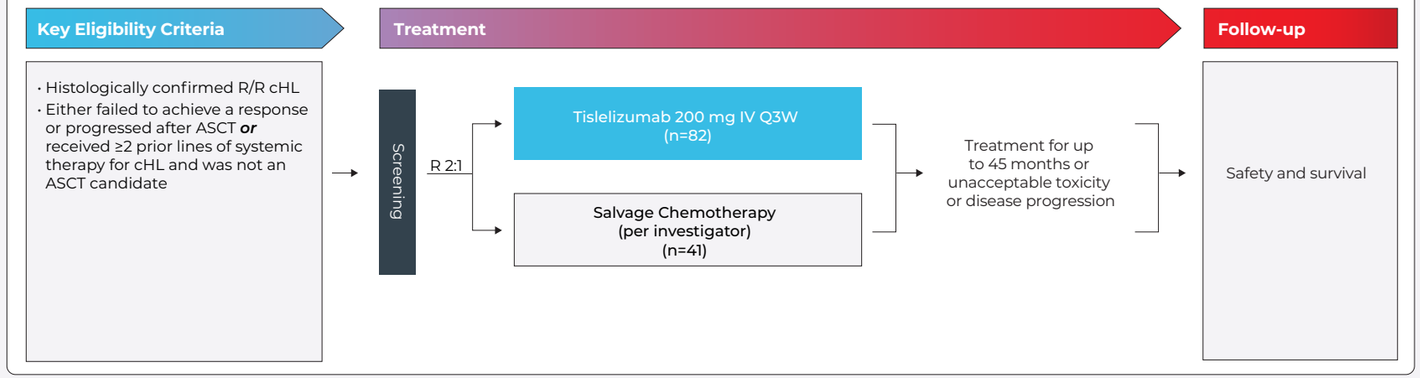
BeiGene

Tislelizumab Monotherapy vs Salvage Chemotherapy for R/R cHL[1,2]

Phase 3 | **Recruiting**

Study Identifiers: BGB-A317-314, NCT04486391
Contact: clinicaltrials@beigene.com

Primary Endpoint: PFS by investigator
Key Secondary Endpoints: DOR, ORR, Rate of CR, TTR, OS, Safety



The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

ASCT, autologous hematopoietic stem cell transplant; cHL, classical Hodgkin's lymphoma; CR, complete response; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; R/R, relapsed/refractory; TTR, time to response.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04486391. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

For more information, contact: medicalinformation@beigene.com

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- SOLID TUMORS

BeiGene

Trial in Progress: A Phase 2, Multicenter, Single-Arm Study of Zanubrutinib (BGB-3111) in Patients With Previously Treated B-Cell Lymphoma Intolerant of Prior Treatment of Ibrutinib or Acalabrutinib[1]

Phase 2 | **Enrolling**

Study Identifiers: BGB-3111-215, NCT04116437
Contact: clinicaltrials@beigene.com

Primary Endpoint: Recurrence and change in severity of treatment-emergent AEs of interest compared to ibrutinib and/or acalabrutinib-intolerant events within each patient
Key Secondary Endpoints: ORR and PFS by investigator, and PRO

Key Eligibility Criteria

- Previously treated CLL/SLL, MCL, MZL, or WM patients intolerant of ibrutinib and/or acalabrutinib
- ≥18 years old
- Meet disease criteria for treatment in respective disease prior to initiation of ibrutinib and/or acalabrutinib treatment
- Ibrutinib and/or acalabrutinib intolerant in opinion of the investigator
- Ibrutinib and/or acalabrutinib toxicities resolved to Gr ≤1 or baseline
- No documented disease progression during ibrutinib and/or acalabrutinib treatment
- ECOG PS ≤2
- No clinically significant cardiovascular disease

Treatment

Cohort 1: intolerant to ibrutinib only (n=~50)

Cohort 2: intolerant to acalabrutinib ± ibrutinib (n=up to 40)

Screening at ≤14 days

Study treatment with monotherapy zanubrutinib (160 mg BID or 320 mg QD)

Follow-up

Disease progression, unacceptable toxicity, treatment consent withdrawal, or study termination

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

AE, adverse event; BID, twice daily; CLL, chronic lymphocytic leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; ORR, overall response rate; PFS, progression-free survival; PRO, patient reported outcomes; QD, once a day. SLL, small lymphocytic lymphoma; WM, Waldenström macroglobulinemia.

REFERENCE: 1. Shadman M, Flinn IW, Levy MY, Porter RF, Burke JM, Zafar SF, et al. Zanubrutinib in patients with previously treated B-cell malignancies intolerant of previous Bruton tyrosine kinase inhibitors in the USA: a phase 2, open-label, single-arm study. *Lancet Haematol*. 2023;10(1):e35-e45. https://www.ncbi.nlm.nih.gov/pubmed/36400069.

For more information, contact: medicalinformation@beigene.com

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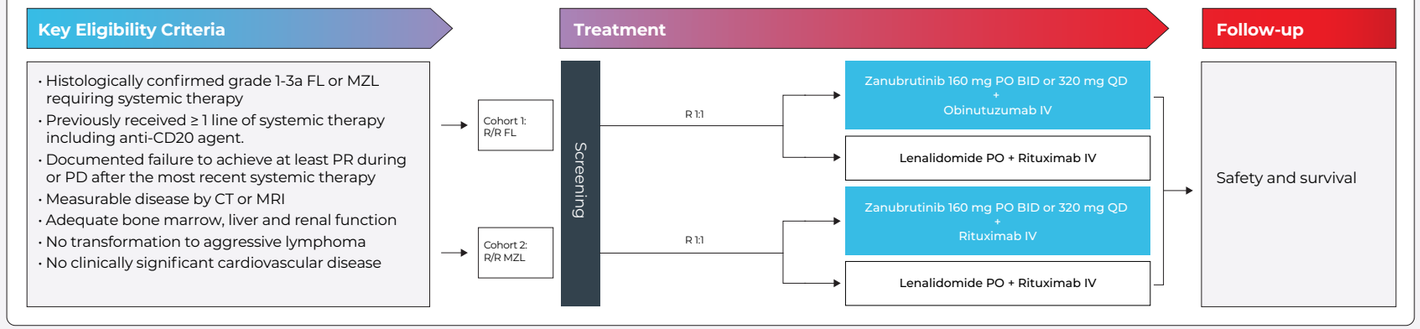
BeiGene

A Study of Zanubrutinib Versus Lenalidomide in Participants With Relapsed/Refractory Follicular or Marginal Zone Lymphoma (MAHOGANY)[1]

Phase 3 | **Enrolling**

Study Identifiers: BGB-3111-308, NCT05100862
Contact: clinicaltrials@beigene.com

Primary Endpoint: PFS by IRC
Key Secondary Endpoints: PFS by investigator, DOR, ORR, CRR by IRC



The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

AE, adverse event; BID, twice daily; ; CT, computed tomography; IRC, Independent Review Committee; IV, intravenous; CRR, Complete Response Rate; DOR, Duration of Response; FL, follicular lymphoma, MRI, magnetic resonance imaging; MZL, marginal zone lymphoma; ORR, overall response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once a day.

REFERENCE: 1. Clinical Trials.gov. https://clinicaltrials.gov/ct2/show/NCT05100862. Accessed May 1, 2023.

For more information, contact: medicalinformation@beigene.com

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BeiGene

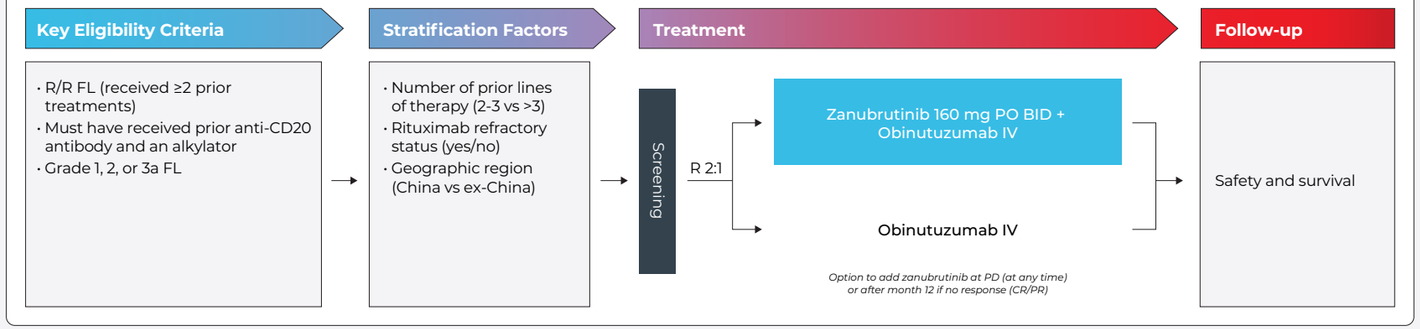
ROSEWOOD
Phase 2 Relapsed/Refractory FL

Pivotal Phase 2 Study of Obinutuzumab as Monotherapy or in Combination With Zanubrutinib in R/R FL[1,2]

Phase 2 | **Active, not recruiting**

Study Identifiers: BGB-3111-212, NCT03332017
Contact: clinicaltrials@beigene.com

Primary Endpoint: ORR
Key Secondary Endpoints: DOR, PFS, TTR, OS, Safety



The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

BID, twice daily; CR, complete response; DOR, duration of response; FL, follicular lymphoma; IV, intravenous; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PO, by mouth; PR, partial response; R/R, relapsed/refractory; TTR, time to response.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03332017. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

For more information, contact: medicalinformation@beigene.com

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- SOLID TUMORS

BeiGene

MANGROVE
Phase 3 Treatment-Naïve MCL

Pivotal Phase 3 Study of Zanubrutinib + Rituximab vs Bendamustine + Rituximab in Previously Untreated MCL Patients Ineligible for SCT[1,2]

Phase 3 | **Enrolling**

Study Identifiers: BGB-3111-306, NCT04002297
Contact: clinicaltrials@beigene.com

Primary Endpoint: PFS by IRC
Secondary Endpoints: PFS by Investigator, ORR, DOR, OS, Safety

Key Eligibility Criteria

- Histologically confirmed diagnosis of MCL
- Ineligible for SCT
  (≥70 or 60-69 years old with comorbidities)
- No prior systemic therapy for MCL
- Measurable disease by CT/MRI
- Adequate marrow and organ function
- No CNS involvement by MCL

Stratification Factors

- Age: <70 vs ≥70
- Region: North America/ Europe and Asia-Pacific
- MIPI Score: low vs intermediate/high

Treatment

Screening

R 1:1

- Zanubrutinib 160 mg PO BID + Rituximab IV x 6 cycles followed by Zanubrutinib monotherapy until PD
- BR x 6 cycles followed by observation until PD

Follow-up

Safety and survival

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

BID, twice daily; BR, bendamustine and rituximab; CNS, central nervous system; DOR, duration of response; IRC, independent review committee; MCL, mantle cell lymphoma; ORR, overall response rate; OS overall survival; PD, progressive disease; PFS, progression-free survival; PO, by mouth; R, randomized; SCT, stem cell transplantation.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04002297. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Liver Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1)	BGB-A317-301 > Schema	Worldwide	1L HCC	3	NCT03412773
Tislelizumab + Lenvatinib (VEGFR kinase inhibitor)	BGB-A317-211	China	1L HCC	2	NCT04401800
Tislelizumab + Ociperlimab + BAT1706 (Anti-VEGF)	AdvanTIG-206	China	1L HCC	2	NCT04948697
Tislelizumab + Sitravatinib (Multikinase inhibitor)	BGB-900-104*	China	Advanced HCC	1/2	NCT03941873
Zanidatamab (Anti-HER2 bispecific antibody)	ZWI-ZW25-203†	Worldwide	2L+ HER2+ biliary tract cancer	2	NCT04466891

*Partnership with Mirati Therapeutics, Inc.
†In collaboration with Zymeworks Inc.

HCC, hepatocellular carcinoma; HER2+, human epidermal growth factor receptor-2 positive; VEGF, vascular endothelial growth factor.

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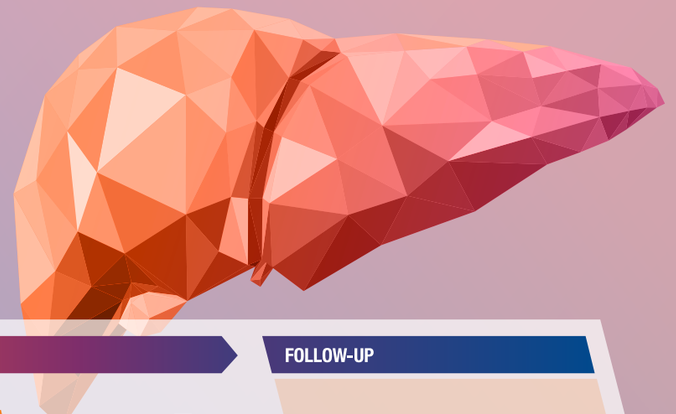
STUDY DESIGN

RATIONALE-301

Tislelizumab vs Sorafenib as 1L Systemic Treatment in Unresectable HCC[1,2]



Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03412773
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: OS
KEY SECONDARY ENDPOINTS: ORR, PFS, DOR, TTP

KEY ELIGIBILITY CRITERIA

- Histologically confirmed, BCLC stage C, or BCLC stage B disease not amenable to or has relapsed after LRT
- Child-Pugh A
- ECOG PS ≤1
- No previous systemic therapy for HCC

TREATMENT

Screening → R 1:1

- Tislelizumab → Treatment until unacceptable toxicity or disease progression
- Sorafenib → Treatment until unacceptable toxicity or disease progression

FOLLOW-UP

Safety and survival

For more information, contact: medicalinformation@beigene.com
The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

BCLC, Barcelona Clinic Liver Cancer; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HCC, hepatocellular carcinoma; LRT, locoregional therapy; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; TTP, time to progression.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03412773. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

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INVESTIGATIONAL CLINICAL PORTFOLIO

Lung Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1)	BGB-A317-303 > Schema	Worldwide	2L/3L NSCLC	3	NCT03358875
Tislelizumab + Chemotherapy	BGB-A317-312 > Schema	China	1L ES-SCLC	3	NCT04005716
Tislelizumab + Chemotherapy	BGB-A317-315 > Schema	China	Resectable stage II or IIIA NSCLC	3	NCT04379635
Tislelizumab + Fruquintinib (VEGFR inhibitor)	BGB-A317-fruquintinib-201*	China, S. Korea	NSCLC	2	NCT04716634
Tislelizumab + Ociperlimab (Anti-TIGIT)	AdvanTIG-302 > Schema	Worldwide	1L PD-L1 high advanced NSCLC	3	NCT04746924
Tislelizumab + Ociperlimab + Chemotherapy	AdvanTIG-205	Worldwide	1L NSCLC	2	NCT05014815
Tislelizumab + Ociperlimab + Concurrent Chemoradiotherapy	AdvanTIG-301 > Schema	Australia, United States	Previously untreated, stage III unresectable NSCLC	3	NCT04866017
Tislelizumab +/- Ociperlimab +/- LBL-007 (Anti-LAG-3)	BGB-LC-202†	China	Resectable Stage II/IIIA NSCLC	2	NCT05577702
Tislelizumab +/- BGB-A445 (Anti-OX40) +/- LBL-007 +/- Chemotherapy	BGB-LC-201†	Worldwide	1L advanced, unresectable, or metastatic NSCLC	2	NCT05635708
Tislelizumab + Sitravatinib (Multikinase inhibitor)	BGB-A317-Sitravatinib 301‡ > Schema	Australia, China	Advanced NSCLC after anti-PD-(L)1 therapy	3	NCT04921358

*Clinical collaboration with Hutchison Medipharma International
†In collaboration with Nanjing Leads Biolabs.
‡Partnership with Mirati Therapeutics, Inc.

ES-SCLC, extensive-stage small cell lung cancer; LAG-3, lymphocyte-activation gene 3; NSCLC, non-small cell lung cancer; PD-L1, programmed death-ligand 1; SCLC, small cell lung cancer; TIGIT, T cell immunoreceptor with Ig and ITIM domains.

The studies above may relate to investigational products or investigational uses of approved products that have not yet been approved by the applicable regulatory agency in your country or region. For more information contact **medicalinformation@beigene.com**

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STUDY DESIGN

RATIONALE-303

Tislelizumab vs Docetaxel in Patients With NSCLC Who Have Progressed on or After a Prior Platinum-Containing Regimen[1,2]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT03358875
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: OS
KEY SECONDARY ENDPOINTS: ORR, DOR, PFS, HRQoL, Safety

KEY ELIGIBILITY CRITERIA

- Histologically confirmed stage IIIB or IV NSCLC with progressive disease during or following treatment with at least one platinum-containing regimen but no more than 2 prior lines of systemic treatment
  - No prior docetaxel or PD-1 or PD-L1 therapy
  - ECOG PS ≤1

TREATMENT

Screening → R 2:1 → Tislelizumab / Docetaxel → Treatment until unacceptable toxicity or disease progression

FOLLOW-UP

Safety and survival

For more information, contact: medicalinformation@beigene.com
The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PD-1, programmed cell death-1; PD-L1, programmed death-ligand 1; PFS, progresssion-free survival.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03358875. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

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STUDY DESIGN

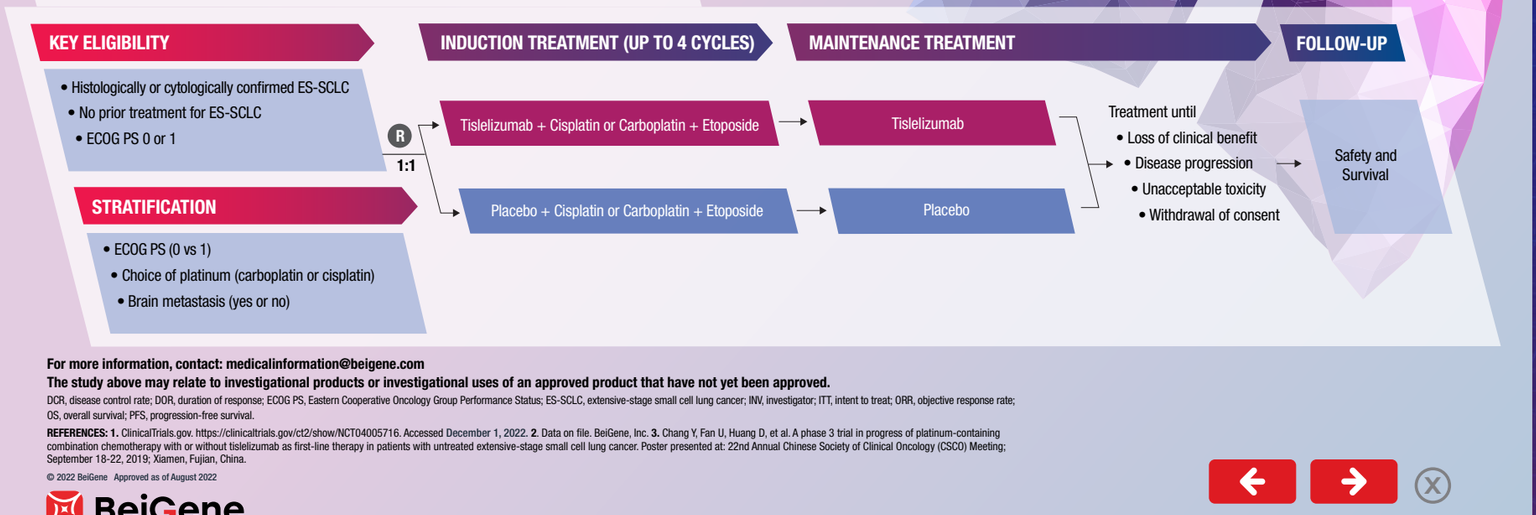
RATIONALE-312

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Study of Platinum Plus Etoposide With or Without Tislelizumab (BGB-A317) in Patients With Untreated Extensive-Stage Small Cell Lung Cancer[1-3]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT04005716
CONTACT: clinicaltrials@beigene.com

CO-PRIMARY ENDPOINTS: OS and INV-assessed PFS
KEY SECONDARY ENDPOINTS: ORR, DCR, DOR, HRQoL, Safety



For more information, contact: medicalinformation@beigene.com

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ES-SCLC, extensive-stage small cell lung cancer; INV, investigator; ITT, intent to treat; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04005716. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc. **3.** Chang Y, Fan U, Huang D, et al. A phase 3 trial in progress of platinum-containing combination chemotherapy with or without tislelizumab as first-line therapy in patients with untreated extensive-stage small cell lung cancer. Poster presented at: 22nd Annual Chinese Society of Clinical Oncology (CSCO) Meeting; September 18-22, 2019; Xiamen, Fujian, China.

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STUDY DESIGN

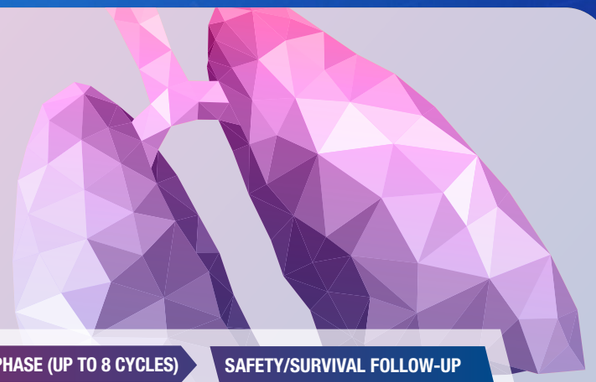
RATIONALE-315

A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Compare the Efficacy and Safety of Neoadjuvant Treatment With Tislelizumab (BGB-A317, Anti-PD-1 Antibody) or Placebo in Combination With Platinum Doublet Chemotherapy Followed by Adjuvant Tislelizumab or Placebo in Resectable Stage II, IIIA Non-Small Cell Lung Cancer[1,2]

Phase 3 | **Active, not recruiting**

STUDY IDENTIFIER: NCT04379635
CONTACT: clinicaltrials@beigene.com

DUAL-PRIMARY ENDPOINTS: MPR by BIPR and EFS by BICR
SECONDARY ENDPOINTS: OS, pCR by BIPR, ORR and DFS by BICR, EFS by INV, HRQoL, Safety



KEY ELIGIBILITY

- Resectable Stage II, IIIA NSCLC (plan for R0 resection)
- Treatment-naïve
- Exclude EGFR mutation or ALK translocation

STRATIFICATION

- Histology (nSQ vs SQ)
- Stage (II vs IIIA)
- PD-L1 expression (≥1% vs <1%/not evaluable/ indeterminate)

NEOADJUVANT PHASE (3-4 CYCLES)

R 1:1

- Tislelizumab + Platinum-based doublet chemotherapy*
- Placebo + Platinum-based doublet chemotherapy*

R0 resection

ADJUVANT PHASE (UP TO 8 CYCLES)

- Tislelizumab
- Placebo

SAFETY/SURVIVAL FOLLOW-UP

Continue assessment until
- Local/distant recurrence
- Unacceptable AE

Until:
- Death
- EOS

*The following platinum-based doublet chemotherapy options are permitted:
- Cisplatin or carboplatin + pemetrexed for nSQ
- Cisplatin or carboplatin + paclitaxel for SQ

For more information, contact: medicalinformation@beigene.com

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

AE, adverse event; ALK, anaplastic lymphoma kinase; BICR, blinded independent central review; BIPR, blinded independent pathology review; DFS, disease-free survival; EFS, event-free survival; EGFR, epidermal growth factor receptor; EOS, end of study; HRQoL, health-related quality of life; INV, investigator; MPR, major pathological response; nSQ, non-squamous; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; pCR, pathological complete response; PD-L1, programmed death-ligand 1; SQ, squamous.

REFERENCES: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04379635. Accessed December 1, 2022. **2.** Data on file. BeiGene, Inc.

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BeiGene

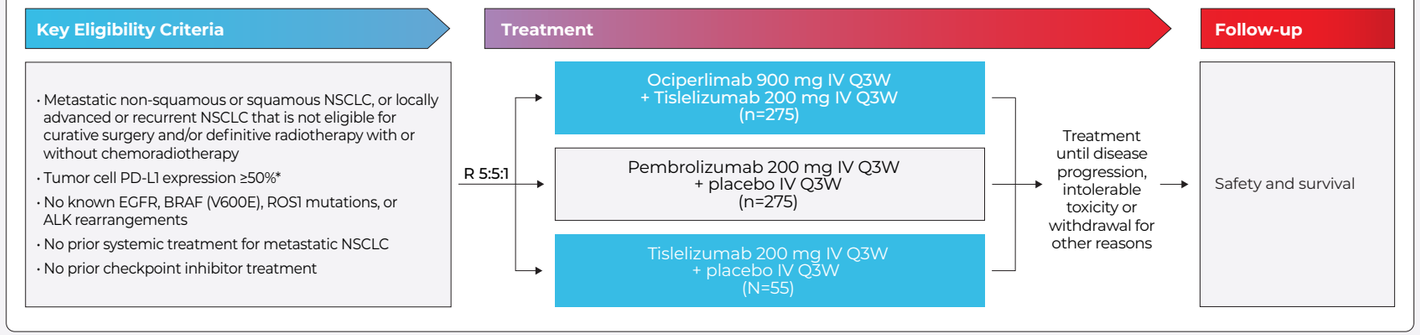
advanTIG

Ociperlimab in Combination With Tislelizumab vs Pembrolizumab in 1L, PD-L1-Selected, Locally Advanced, Unresectable, or Metastatic NSCLC[1,2]

Phase 3 | **Recruiting**

Study Identifier: AdvanTIG-302, NCT04746924
Contact: clinicaltrials@beigene.com

Primary Endpoints: PFS by investigators (Arm A and Arm B); OS between Arm A and Arm B
Key Secondary Endpoints: PFS‡, ORR†, DOR†, HRQoL, TDD, Safety



The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

†By investigator, ‡By blinded independent review committee, *Determined centrally by VENTANA PD-L1 [SP263] assay

ALK, anaplastic lymphoma kinase; 1L, 1st line; DOR, duration of response; EGFR, epidermal growth factor receptor; HRQoL, health-related quality of life; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; Q3W, every 3 weeks; TDD, time to deterioration.

REFERENCES: 1. Socinski MA, Spira AI, Paz-Ares LG. AdvanTIG-302: Anti-TIGIT monoclonal antibody (mAb) ociperlimab (OCI) plus tislelizumab (TIS) vs pembrolizumab(PEM) in programmed death ligand 1 (PD-L1) selected, previously untreated, locally advanced, unresectable ormetastatic non-small cell lung cancer (NSCLC). Presented at: 2021 American Society of Clinical Oncology (ASCO) Annual Meeting; June 4-8, 2021; Virtual. **2.** ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04746924. Accessed December 1, 2022.

For more information, contact: medicalinformation@beigene.com

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BeiGene

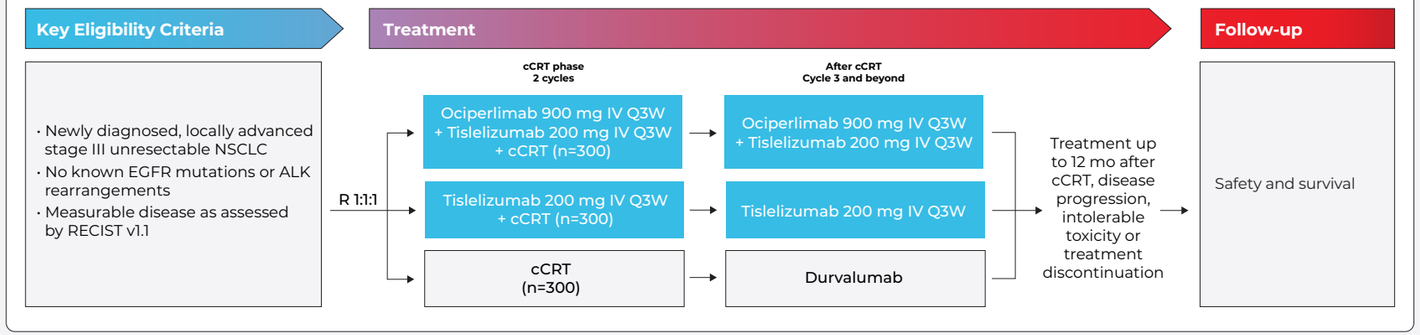
advanTIG

Ociperlimab Plus Tislelizumab vs Durvalumab When Co-administered With cCRT in Locally Advanced NSCLC[1]

Phase 3 | **Recruiting**

Study Identifier: AdvanTIG-301, NCT04866017
Contact: clinicaltrials@beigene.com

Primary Endpoints: PFS by IRC, CRR by IRC
Key Secondary Endpoints: PFS in PD-L1+ by IRC, ORR, OS, DOR, HRQoL, Safety



The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

ALK, anaplastic lymphoma kinase; 1L, 1st line; CRR, complete response rate; cCRT, concurrent chemoradiotherapy; DOR, duration of response; HRQoL, health-related quality of life; IRC, independent review committee; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; Q3W, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1

REFERENCE: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04866017. Accessed December 1, 2022.

For more information, contact: medicalinformation@beigene.com

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- BLADDER
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- GASTROINTESTINAL
- HEAD AND NECK
- HEMATOLOGIC MALIGNANCIES
- LIVER
- LUNG
- GYNECOLOGIC ONCOLOGY
- SOLID TUMORS

BeiGene

Tislelizumab Plus Sitravatinib in Patients With Locally Advanced or Metastatic NSCLC That Progressed On or After Platinum-Based Chemotherapy and Anti-PD-(L)1 Antibody[1]

Phase 3 | **Active, not recruiting**

Study Identifier: BGB-A317-Sitravatinib-301, NCT04921358, SAFFRON-301
Contact: clinicaltrials@beigene.com

Primary Endpoints: OS, PFS by IRC
Key Secondary Endpoints: PFS by investigator, ORR, DOR, DCR, HRQOL, Safety, Plasma concentration of sitravatinib

Key Eligibility Criteria

- Metastatic or unresectable locally advanced histologically confirmed NSCLC
- Able to provide archival/fresh tumor tissues for biomarker analysis
- No known EGFR or BRAF sensitizing mutation or ALK or ROS1 rearrangement
- Disease progression on or after anti-PD-(L)1 containing therapy
- No prior anticancer therapy having the same mechanism of action as sitravatinib

Treatment

R 1:1

- Tislelizumab 200 mg IV Q3W + Sitravatinib 100 mg PO QD (n=210)
- Docetaxel 75 mg/m² IV Q3W (n=210)

Treatment until disease progression or unacceptable toxicity

Follow-up

Safety and survival

The study above may relate to investigational products or investigational uses of an approved product that have not yet been approved.

ALK, anaplastic lymphoma kinase; BRAF, v-raf murine sarcoma viral oncogene homolog B1; DCR, disease control rate; DOR, duration of response; EGFR, epidermal growth factor receptor; HRQoL, health-related quality of life; IRC, independent review committee; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PD-1, programmed death-ligand 1; PD-L1, programmed death ligand-1; PO, orally; Q3W, every 3 weeks; QD, once per day; RECIST, Response Evaluation Criteria in Solid Tumors; ROS1, c-ros oncogene 1.

REFERENCE: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04921358. Accessed December 1, 2022.

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BeiGene

INVESTIGATIONAL CLINICAL PORTFOLIO

Gynecologic Oncology

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Pamiparib (PARP 1/2 inhibitor)	BGB-290-302	China	2L/3L maintenance platinum-sensitive OC	3	NCT03519230
Tislelizumab (Anti-PD-1) + Ociperlimab (Anti-TIGIT)	BGB-A317-A1217-202	Worldwide	2L+ cervical cancer	2	NCT04693234
Tislelizumab + Fruquintinib (VEGFR inhibitor)	2020-013-00US3*	United States	Advanced endometrial cancer	1/2	NCT04577963

*Clinical collaboration with Hutchison Medipharma International.

OC, ovarian cancer; TIGIT, T-cell immunoreceptor with Ig and ITIM domains; VEGFR, vascular endothelial growth factor receptor.

The studies above may relate to investigational products or investigational uses of approved products that have not yet been approved by the applicable regulatory agency in your country or region. For more information contact **medicalinformation@beigene.com**

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INVESTIGATIONAL CLINICAL PORTFOLIO

Solid Tumors

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-3245 (B-RAF inhibitor)	BGB-3245-AU-001	Australia, United States	Advanced solid tumors with B-RAF mutations	1	NCT04249843
BGB-24714 (SMAC mimetic) +/- Chemotherapy	BGB-24714-101	Worldwide	Advanced solid tumors	1	NCT05381909
BGB-26808 (HPK1 inhibitor) +/- Tislelizumab (anti-PD-1)	BGB-A317-26808-101	Australia	Advanced solid tumors	1	NCT05981703
BGB-30813 (DGKζ inhibitor) +/- Tislelizumab	BGB-A317-30813-101	Australia, United States	Advanced or metastatic solid tumors	1	NCT05904496
BGB-A3055 (anti-CCR8) +/- Tislelizumab	BGB-A317-A3055-101	Australia	Select advanced or metastatic solid tumors	1	NCT05935098
BGB-B167 (CEA-4-1BB bispecific antibody) +/- Tislelizumab	BGB-A317-B167-101	Australia, United States	Advanced solid tumors	1	NCT05494762
BGB-B167 +/- Tislelizumab	BGB-A317-B167-102	China	Advanced or metastatic solid tumors	1	NCT05644626
BGB-A445 (Anti-OX40) +/- Tislelizumab	BGB-A317-A445-201	China	Select advanced solid tumors	1/2	NCT05661955
Tislelizumab + BGB-A445	BGB-A317-A445-101	Worldwide	Advanced solid tumors	1	NCT04215978
Lifirafenib (RAF inhibitor) + Mirdametinib (MEK inhibitor)	BGB-283/PD-0325901-AU-001*	Australia, United States	Advanced solid tumors	1	NCT03905148

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*In collaboration with SpringWorks Therapeutics.

B-RAF, B-Raf proto-oncogene; CEA, carcinoembryonic antigen; CCR8, C-C chemokine receptor 8; DGKζ, diacylglycerol kinase zeta; HPK1, hematopoietic progenitor kinase 1; PI3Kδ, phosphoinositide 3-kinase delta; SMAC, second mitochondrial-derived activator of caspases.

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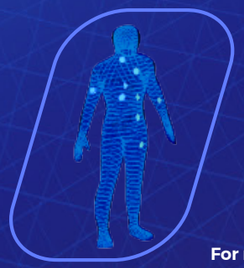

INVESTIGATIONAL CLINICAL PORTFOLIO

Solid Tumors

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab	BGB-A317-209	China	Previously treated advanced MSI-high or dMMR solid tumors	2	NCT03736889
Tislelizumab + BGB-10188 (PI3Kδ inhibitor)	BGB-A317-3111-10188-101	Australia, China	Advanced solid tumors	1/2	NCT04282018
Tislelizumab + BGB-15025 (HPK1 Inhibitor)	BGB-A317-15025-101	Worldwide	Advanced solid tumors	1	NCT04649385
Tislelizumab +/- Surzebiclimab (anti-TIM-3) +/- LBL-007 (anti-LAG-3)	BGB-900-102*	Worldwide	Advanced solid tumors	1/2	NCT03744468
Tislelizumab + Lenvatinib (Tyrosine kinase inhibitor)	BGB-A317-212	China	Advanced solid tumors	2	NCT05014828
Tislelizumab + Surufatinib (VEGFR, FGFR, CSF-1R inhibitor)	2020-012-GLOB1†	United States	Advanced solid tumors	1/2	NCT04579757
Tislelizumab + Ociperlimab (Anti-TIGIT)	BGB-900-105	Worldwide	Advanced solid tumors	1	NCT04047862

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*In collaboration with Nanjing Leads Biolabs.
†Clinical collaboration with Hutchison Medipharma International.

CSF-1R, colony stimulating factor-1 receptor; dMMR, deficient mismatch repair; FGFR, fibroblast growth factor receptor; LAG-3, lymphocyte-activation gene 3; MSI, microsatellite instability; TIGIT, T-cell immunoreceptor with Ig and ITIM domains; TIM-3, T cell immunoglobulin and mucin domain-containing protein 3; VEGFR, vascular endothelial growth factor receptor.

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