



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG

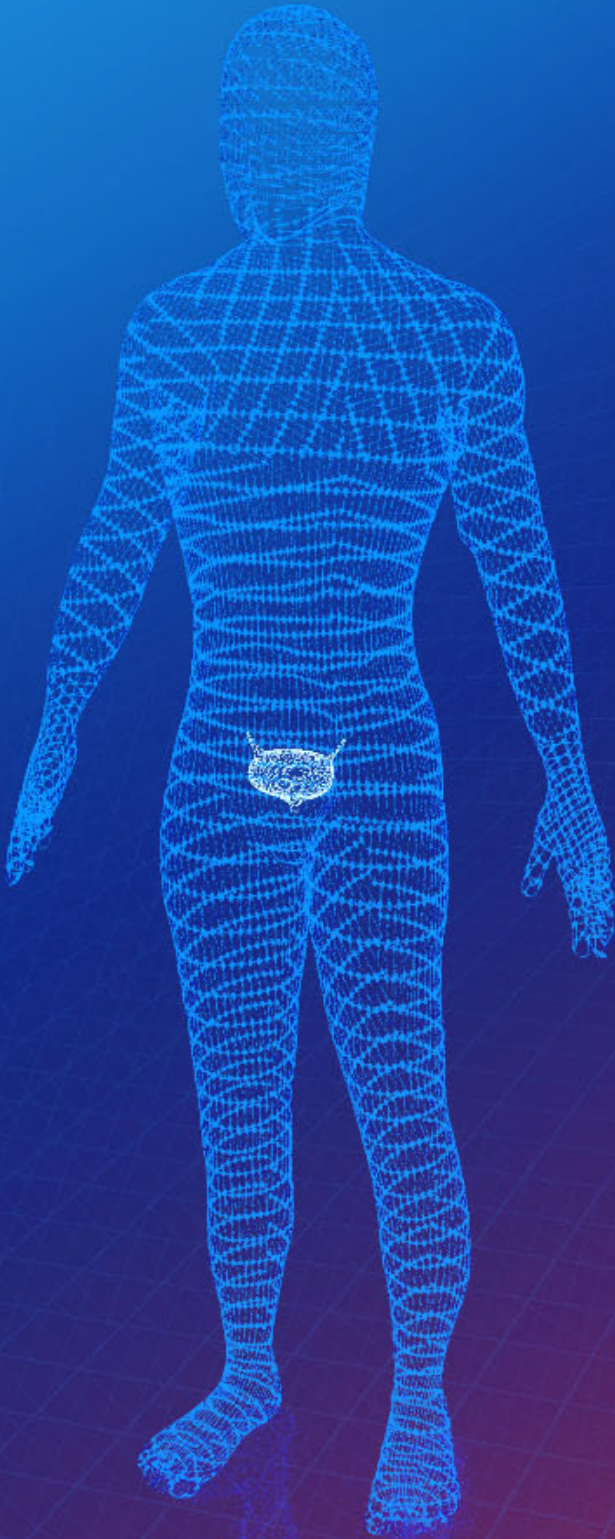


GYNECOLOGIC
ONCOLOGY



SOLID TUMORS

Select an area of investigation
to learn about our clinical trials



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS

Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



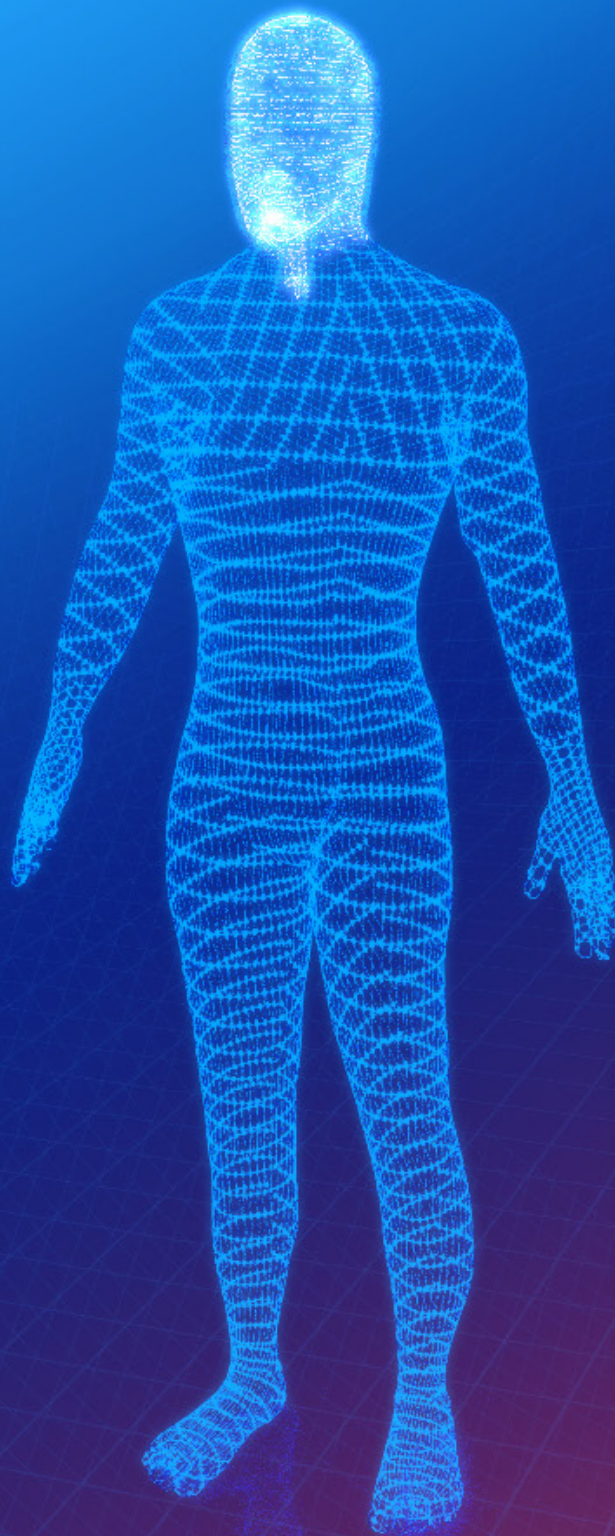
LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



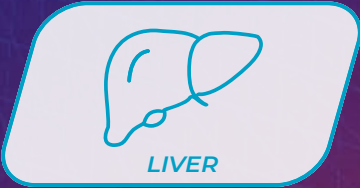
GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



Select an area of investigation
to learn about our clinical trials





Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



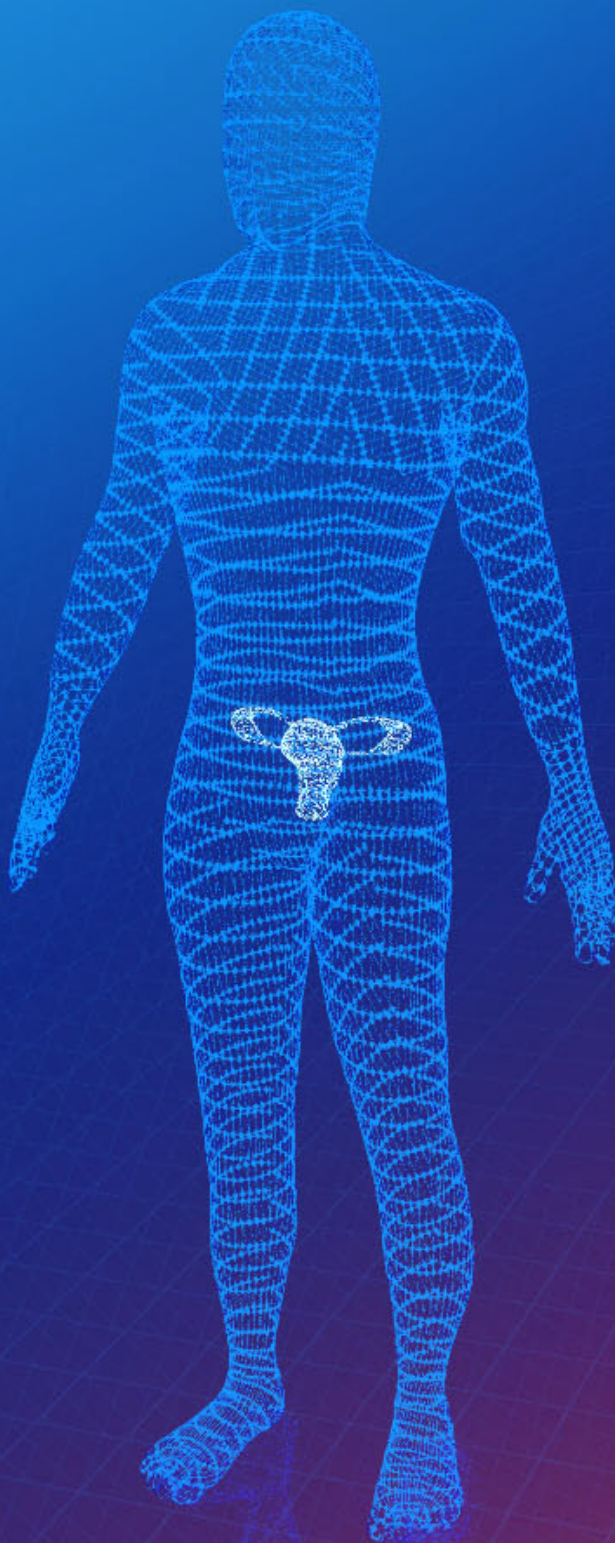
LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



Phase 3

Primary Endpoint: OS in ITT

R
→
1:1

Tislelizumab

Placebo

Safety and Survival Follow-up

Chemotherapy regimen will be administered for up to 6 cycles

☒

NECOLOGIC

**GYNECOLOGIC
ONCOLOGY**



SOLID TUMORS



1019-BGB-A333-MRC-005 May 2023



INVESTIGATIONAL CLINICAL PORTFOLIO

Breast Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Pamiparib (PARP 1/2 inhibitor)	BGB-290-102	China	Advanced triple negative breast cancer	1/2	NCT03333915
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.

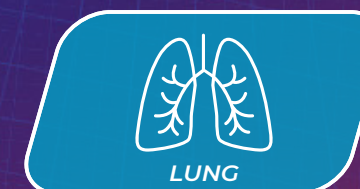
[†]Clinical collaboration with Hutchison Medipharma International.

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

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



Select an area of investigation to learn about our clinical trials






For more information, contact: medicalinformation@beigene.com



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
Tislelizumab	BGB-A317-214	China	1L MSI-H 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	NCT04732494
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
Tislelizumab + Sitravatinib	BGB-900-104§	China	Advanced GC/GEJC	1/2	NCT03941873
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.

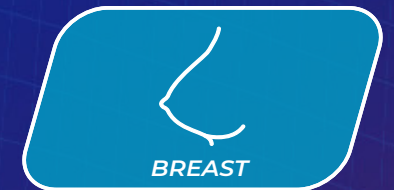
CRC, colorectal cancer; DKK1, Dickkopf-1; dMMR, mismatch repair deficient; ESCC, esophageal squamous cell carcinoma; GC, gastric cancer; GEJC, gastroesophageal junction carcinoma; HER2+, human epidermal growth factor receptor-2 positive; MSI-H, microsatellite instability-high; MSS, microsatellite stable;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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



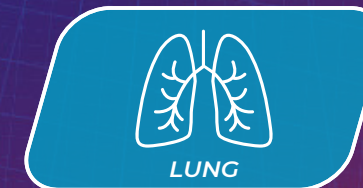
HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

STUDY DESIGN

RATIONALE-311

A Phase 3 Trial in Localized ESCC¹⁻³

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

TREATMENT

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

R
1:1

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.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

STUDY DESIGN

RATIONALE-305

A Phase 3 Trial in Localized ESCC

Tislelizumab in Combination With Chemotherapy as 1L Treatment in Inoperable, Locally Advanced, or Metastatic GC or GEJC¹

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.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

STUDY DESIGN

RATIONALE-306

Tislelizumab in Combination With Chemotherapy as 1L Treatment in Advanced ESCC¹

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

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; BIRC, blinded independent central review committee; DOR, duration of response; ESCC, esophageal squamous 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.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



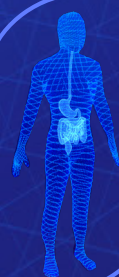
LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



INVESTIGATIONAL CLINICAL PORTFOLIO

Head and Neck Cancer

Investigational Medicinal Product	Study		Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1) + Chemotherapy	BCB-A317-309	 Schema	China, Thailand	1L advanced nasopharyngeal cancer	3	NCT03924986

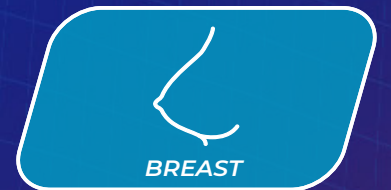
The studies above may relate to investigational products or investigational uses of approved products that have not yet been approved by the applicable regulatory agency in your country or region. For more information contact medicalinformation@beigene.com



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

STUDY DESIGN

RATIONALE-309^{1,2}

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

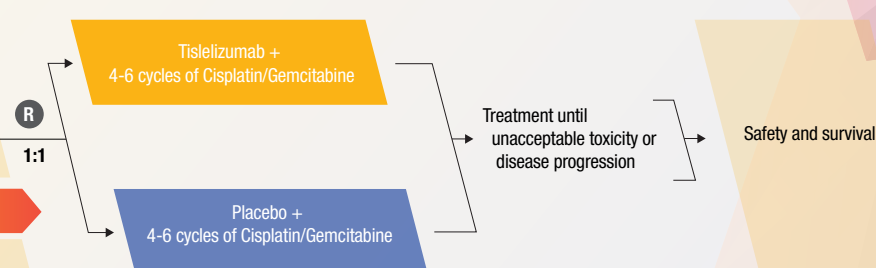
KEY ELIGIBILITY

- Histologically or cytologically confirmed, recurrent or metastatic NPC
- Treatment-naïve 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



FOLLOW-UP

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.

© 2022 BeiGene. Approved as of August 2022.



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS




For more information, contact: medicalinformation@beigene.com

1019-BCB-A333-MRC-005 May 2023



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

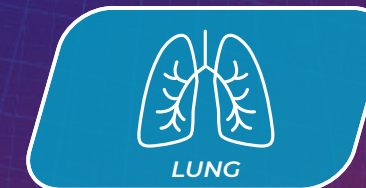
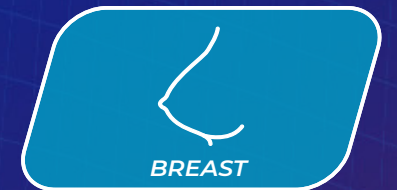
PAGE 1 OF 2 

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.

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



Select an area of investigation to learn about our clinical trials








For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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-3111-115	United States	Bioavailability of zanubrutinib tablets vs capsules in healthy volunteers	1	NCT05547399
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

 PAGE 2 OF 2

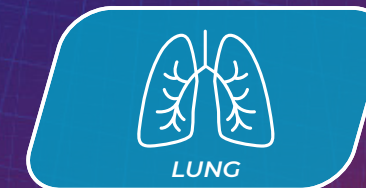
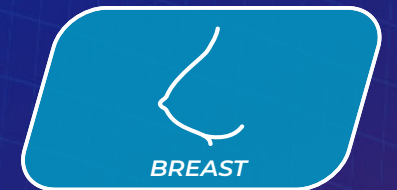
*In collaboration with MEI Pharma.

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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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

Key Eligibility Criteria

- Histologically confirmed R/R cHL
- Either failed to achieve a response or progressed after ASCT **or** received ≥ 2 prior lines of systemic therapy for cHL and was not an ASCT candidate

Screening

R 2:1

Tislelizumab 200 mg IV Q3W
(n=82)

Salvage Chemotherapy
(per investigator)
(n=41)

Treatment for up to 45 months or unacceptable toxicity or disease progression

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.
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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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 Acalabrutinib¹

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

Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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

Key Eligibility Criteria

- Histologically confirmed grade 1-3a FL or MZL requiring systemic therapy
- Previously received ≥ 1 line of systemic therapy including anti-CD20 agent.
- Documented failure to achieve at least PR during or PD after the most recent systemic therapy
- Measurable disease by CT or MRI
- Adequate bone marrow, liver and renal function
- No transformation to aggressive lymphoma
- No clinically significant cardiovascular disease

Cohort 1:
R/R FL

Cohort 2:
R/R MZL

Screening

R 1:1

R 1:1

Zanubrutinib 160 mg PO BID or 320 mg QD
+
Obinutuzumab IV

Lenalidomide PO + Rituximab IV

Zanubrutinib 160 mg PO BID or 320 mg QD
+
Rituximab IV

Lenalidomide PO + Rituximab IV

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.

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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

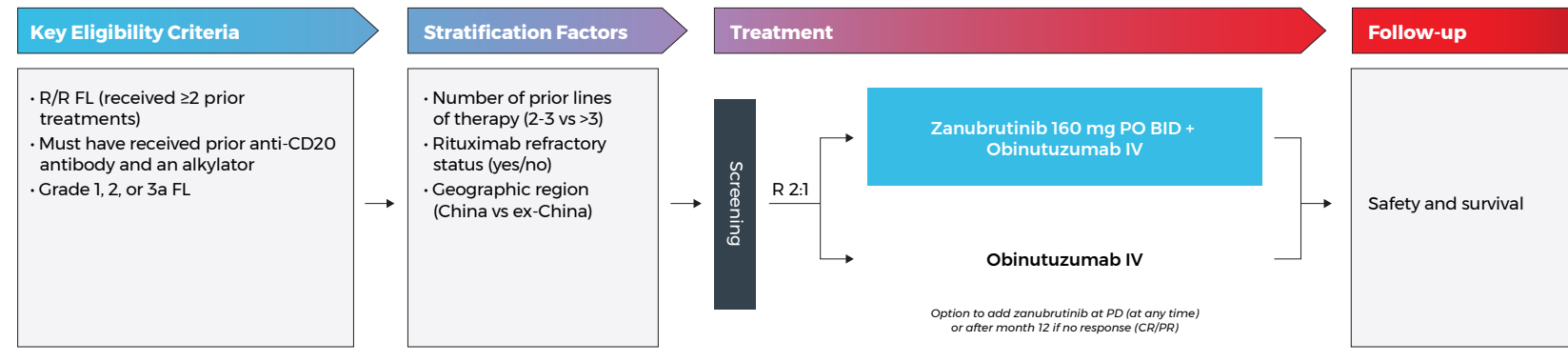


Pivotal Phase 2 Study of Obinutuzumab as Monotherapy or in Combination With Zanubrutinib in R/R FL^{1,2}

Phase 2 Active, not recruiting

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

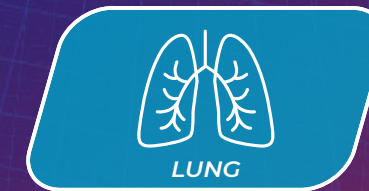
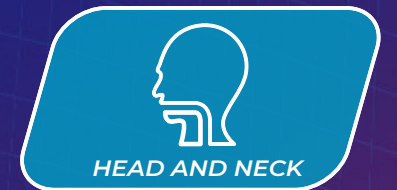
Primary Endpoint: ORR
Key Secondary Endpoints: DOR, PFS, TTR, OS, Safety



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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

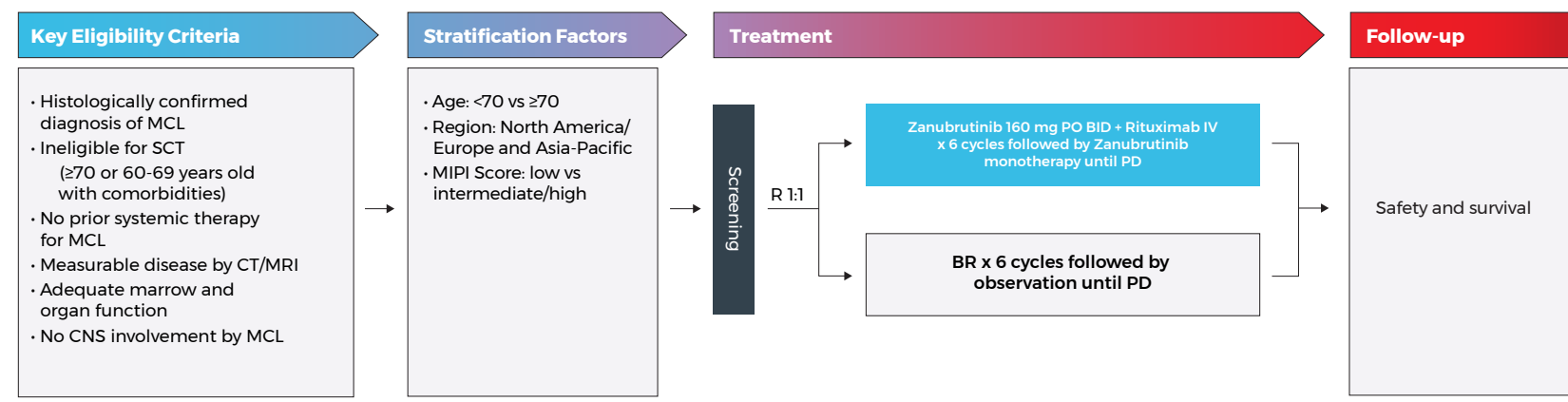


Pivotal Phase 3 Study of Zanubrutinib + Rituximab vs Bendamustine + Rituximab in Previously Untreated MCL Patients Ineligible for SCT^{1,2}

Phase 3 Enrolling

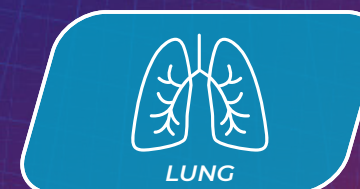
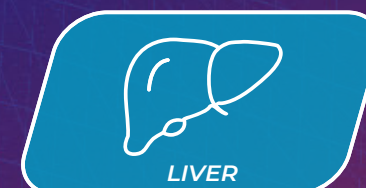
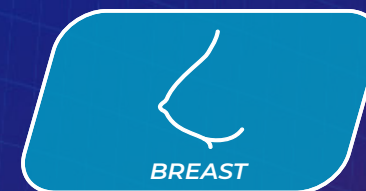
Study Identifiers: BGB-3111-306, NCT04002297
Contact: clinicaltrials@beigene.com

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



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.
For more information, contact: medicalinformation@beigene.com

Select an area of investigation to learn about our clinical trials




For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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-A317-Sitravatinib-303*	China, S. Korea, Thailand	HCC post resection	3	NCT05564338
Tislelizumab + Sitravatinib	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

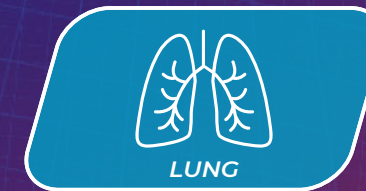
*Partnership with Mirati Therapeutics, Inc.
†In collaboration with Zymeworks Inc.

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

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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

STUDY DESIGN

RATIONALE-301

Tislelizumab vs Sorafenib as 1L Systemic Treatment in Unresectable HCC^{1,2}

Phase 3 Active, not recruiting

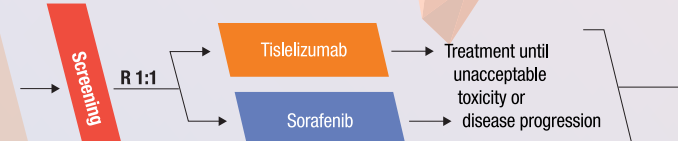
STUDY IDENTIFIER: NCT03412773
CONTACT: clinicaltrials@beigene.com

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



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.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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-A317-304	> Schema	China	1L non-squamous NSCLC	3	NCT03663205
Tislelizumab + Chemotherapy	BGB-A317-307	> Schema	China	1L squamous NSCLC	3	NCT03594747
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 + Concurrent Chemoradiotherapy	AdvanTIG-204		Worldwide	Previously untreated LS-SCLC	2	NCT04952597
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†		Opening soon	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; LS-SCLC, limited-stage small cell lung cancer; 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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

STUDY DESIGN

RATIONALE-303

Tislezumab 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

Tislezumab

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, progression-free survival.

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

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

STUDY DESIGN

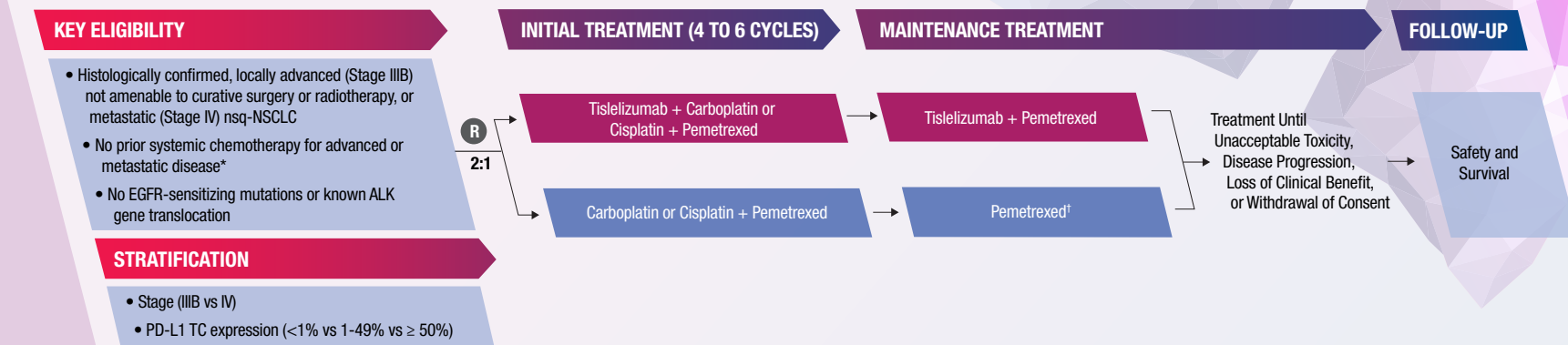
RATIONALE-304

A Phase 3, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Tislelizumab Combined with Platinum-Pemetrexed Versus Platinum-Pemetrexed Alone as First-line Treatment for Patients With Stage IIIB or IV Non-Squamous Non-Small Cell Lung Cancer¹⁻³

Phase 3 Active, not recruiting

STUDY IDENTIFIER: NCT03663205
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: PFS by IRC in ITT population
KEY SECONDARY ENDPOINTS: OS, ORR, PFS by INV, DOR, Safety, HRQoL



*Patients with prior neoadjuvant or adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a disease-free interval of ≥6 months from the last dose of chemotherapy and/or radiotherapy prior to randomization.

†Optional crossover to tislelizumab.

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.

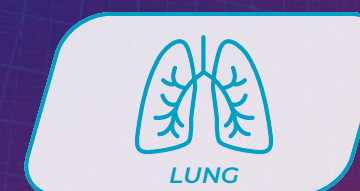
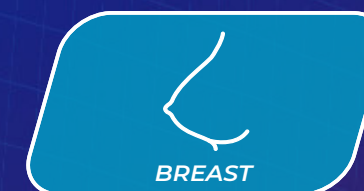
ALK, anaplastic lymphoma kinase; DOR, duration of response; EGFR, epidermal growth factor receptor; HRQoL, health-related quality of life; INV, investigator; IRC, independent review committee; ITT, intent to treat; NSCLC, non-small cell lung cancer; NSQ, non-squamous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; TC, tumor cell.

REFERENCES: 1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03663205>. Accessed December 1, 2022. 2. Data on file. BeiGene, Inc. 3. Lu S, Yu Y, Yu X, et al. RATIONALE 304: tislelizumab plus chemotherapy versus chemotherapy alone as first-line treatment for locally advanced/metastatic nonsquamous non-small cell lung cancer. Presented at: 23rd Annual Chinese Society of Clinical Oncology (CSCO) Meeting; September 19-26, 2020; Virtual. Abstract 7382.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

1019-BCB-A333-MRC-005 May 2023

STUDY DESIGN

RATIONALE-307

A Phase 3, Multicenter, Randomized Open-Label Study to Compare the Efficacy and Safety of Tislelizumab Combined With Paclitaxel Plus Carboplatin or Nab-Paclitaxel Plus Carboplatin Versus Paclitaxel Plus Carboplatin Alone as First-Line Treatment for Untreated Advanced Squamous Non-Small Cell Lung Cancer^{1,2}

Phase 3 Active, not recruiting

STUDY IDENTIFIER: NCT03594747
CONTACT: clinicaltrials@beigene.com

PRIMARY ENDPOINT: PFS by IRC in ITT population
KEY SECONDARY ENDPOINTS: ORR, DOR, OS, Safety

KEY ELIGIBILITY

- Histologically confirmed, locally advanced (Stage IIIB) not amenable to curative surgery or radiotherapy, or metastatic (Stage IV) sq-NSCLC
- No prior systemic chemotherapy for advanced or metastatic disease*
- No EGFR-sensitizing mutations or known ALK gene translocations

STRATIFICATION

- Stage (IIIB vs IV)
- PD-L1 TC expression (<1% vs 1%-49% vs ≥50%)

INITIAL TREATMENT (4 TO 6 CYCLES)

Tislelizumab + Paclitaxel + Carboplatin

Tislelizumab + Nab-Paclitaxel + Carboplatin

Paclitaxel + Carboplatin

MAINTENANCE TREATMENT

Tislelizumab

Upon disease progression crossover to Tislelizumab (optional)

FOLLOW-UP

Treatment Until Unacceptable Toxicity, Disease Progression, Loss of Clinical Benefit, or Withdrawal of Consent

Safety and Survival

*Patients receiving prior neoadjuvant or adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a disease-free interval of ≥6 months from the last dose of chemotherapy and/or radiotherapy prior to randomization.

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; IRC, independent review committee; ITT, intent to treat; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression free survival; SQ, squamous; TC, tumor cell.

REFERENCES: 1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/record/NCT03594747>. Accessed December 1, 2022. 2. Data on file. BeiGene, Inc.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BCB-A333-MRC-005 May 2023

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 Cancer¹⁻³

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

KEY ELIGIBILITY

- Histologically or cytologically confirmed ES-SCLC
- No prior treatment for ES-SCLC
- ECOG PS 0 or 1

STRATIFICATION

- ECOG PS (0 vs 1)
- Choice of platinum (carboplatin or cisplatin)
- Brain metastasis (yes or no)

INDUCTION TREATMENT (UP TO 4 CYCLES)

R
1:1

Tislelizumab + Cisplatin or Carboplatin + Etoposide

Placebo + Cisplatin or Carboplatin + Etoposide

MAINTENANCE TREATMENT

Tislelizumab

Placebo

FOLLOW-UP

Treatment until

- Loss of clinical benefit
- Disease progression
- Unacceptable toxicity
- Withdrawal of consent

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.

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.

© 2022 BeiGene. Approved as of August 2022



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



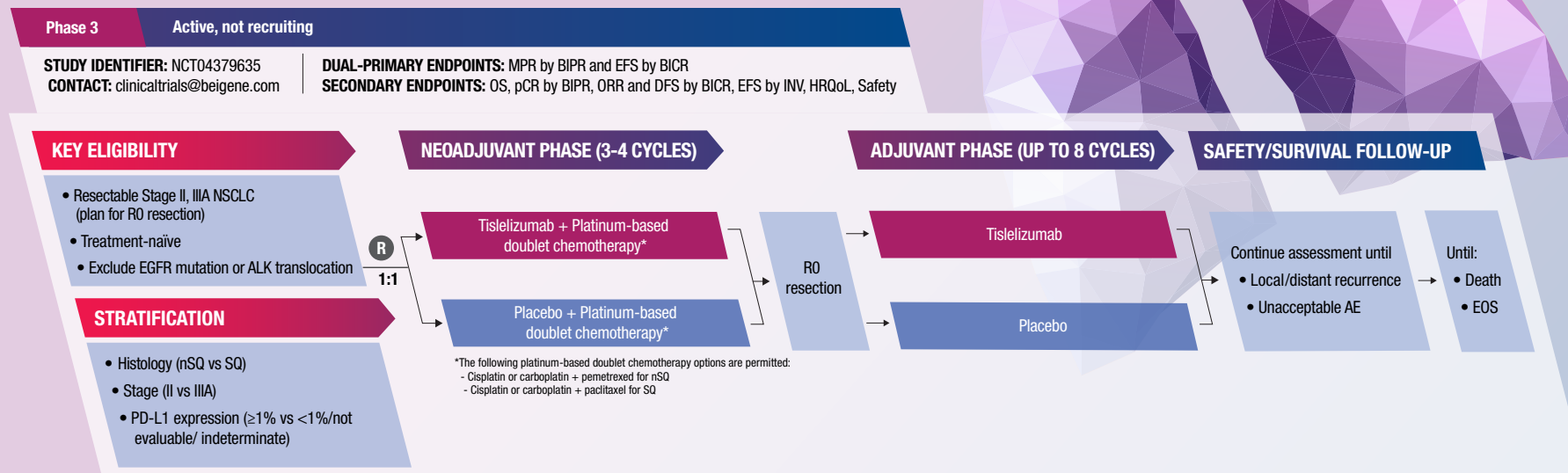
For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023

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}



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.

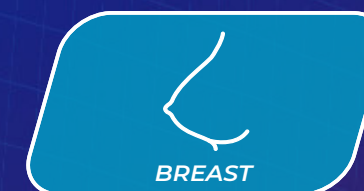
© 2022 BeiGene. Approved as of August 2022.



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



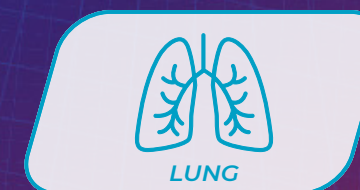
HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



advanTIG

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

Phase 3 Recruiting

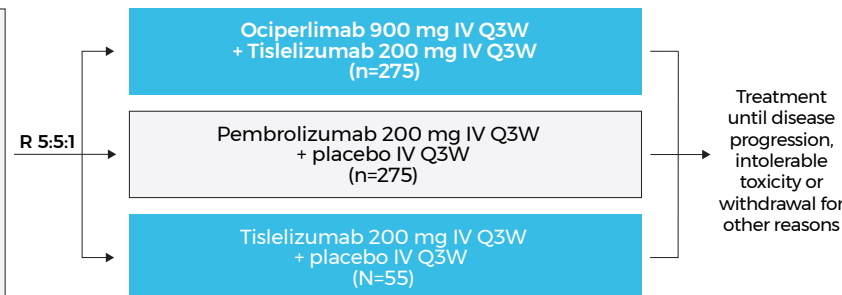
Study Identifier: AdvanTIG-302, NCT04746924
Contact: clinicaltrials@beigene.com

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

Key Eligibility Criteria

- Metastatic non-squamous or squamous NSCLC, or locally advanced or recurrent NSCLC that is not eligible for curative surgery and/or definitive radiotherapy with or without chemoradiotherapy
- Tumor cell PD-L1 expression $\geq 50\%^*$
- No known EGFR, BRAF (V600E), ROS1 mutations, or ALK rearrangements
- No prior systemic treatment for metastatic NSCLC
- No prior checkpoint inhibitor treatment

Treatment



Follow-up

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.

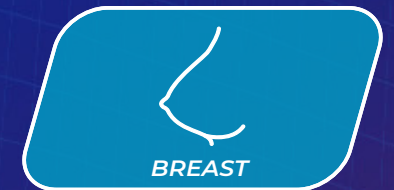
REFERENCES: 1. Socinski MA, Spira AI, Paz-Ares LG. AdvanTIG-302: Anti-TIGIT monoclonal antibody (mAb) ociperlimab (OCI) plus tislelizumab (TIS) vs pembrolizumab (PEM) in programmed death ligand 1 (PD-L1) selected, previously untreated, locally advanced, unresectable or metastatic non-small cell lung 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



Select an area of investigation to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



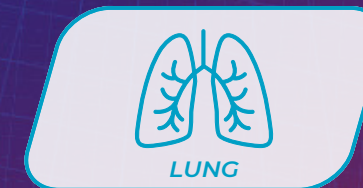
HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS

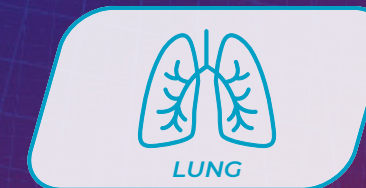
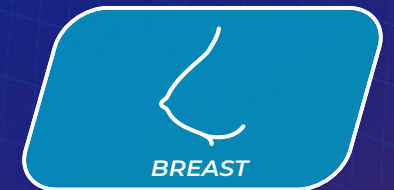
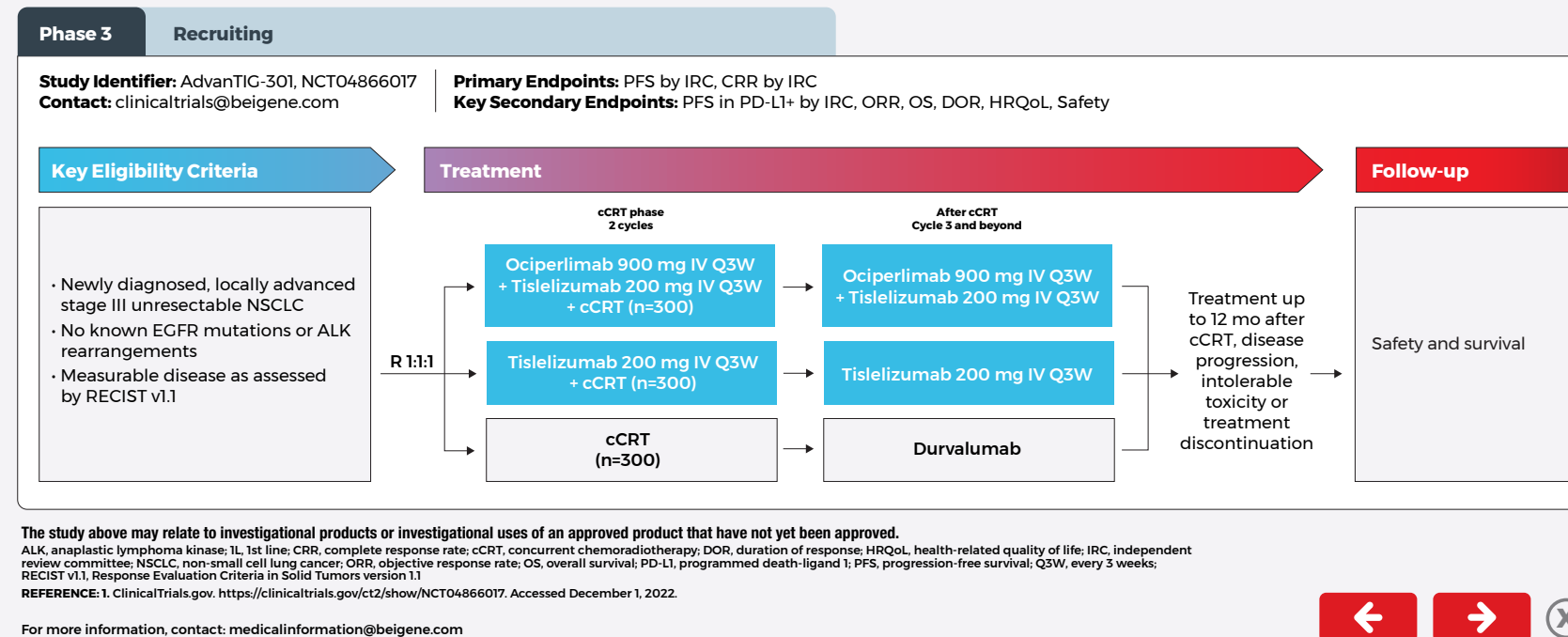


For more information, contact: medicalinformation@beigene.com

1019-BCB-A333-MRC-005 May 2023



Ociperlimab Plus Tislelizumab vs Durvalumab When Co-administered With cCRT in Locally Advanced NSCLC¹





Tislelizumab Plus Sitravatinib in Patients With Locally Advanced or Metastatic NSCLC That Progressed On or After Platinum-Based Chemotherapy and Anti-PD-(L)1 Antibody¹

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.

For more information, contact: medicalinformation@beigene.com



Select an area of investigation
to learn about our clinical trials



BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC
MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC
ONCOLOGY



SOLID TUMORS



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



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
Pamiparib	BGB-290-102	China	Advanced high-grade OC	1/2	NCT03333915
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

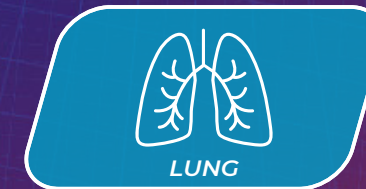
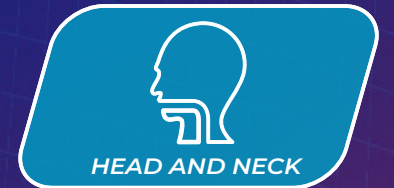
*Clinical collaboration with Hutchison Medipharma International.

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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com



INVESTIGATIONAL CLINICAL PORTFOLIO

Solid Tumors

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-24714 (SMAC mimetic) +/- Chemotherapy	BGB-24714-101	Worldwide	Advanced solid tumors	1	NCT05381909
BGB-3245 (B-RAF inhibitor)	BGB-3245-AU-001	Australia, United States	Advanced solid tumors with B-RAF mutations	1	NCT04249843
BGB-B167 (CEA-4-1BB bispecific antibody) +/- Tislelizumab (Anti-PD-1)	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
Pamiparib (PARP 1/2 inhibitor) + Temozolomide	BGB-290-103	Worldwide	Advanced solid tumors	1	NCT03150810
Tislelizumab	BGB-A317-209	China	Previously treated advanced MSI-high or dMMR solid tumors	2	NCT03736889

PAGE 1 OF 2

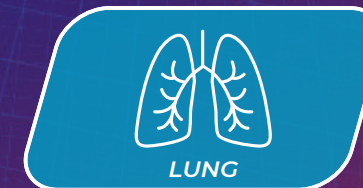
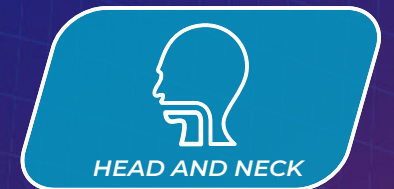
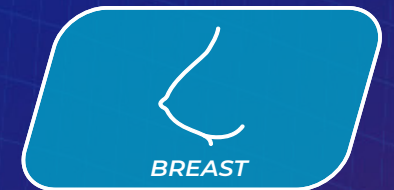
*In collaboration with SpringWorks Therapeutics.

B-RAF, B-Raf proto-oncogene; CEA, carcinoembryonic antigen; dMMR, deficient mismatch repair; HPK1, hematopoietic progenitor kinase 1; MSI, microsatellite instability; PI3Kδ, phosphoinositide 3-kinase delta; SMAC, second mitochondrial-derived activator of caspases.

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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023



INVESTIGATIONAL CLINICAL PORTFOLIO

Solid Tumors

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
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*	Australia, S. Korea, United States	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

◀ PAGE 2 OF 2

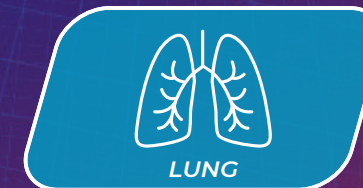
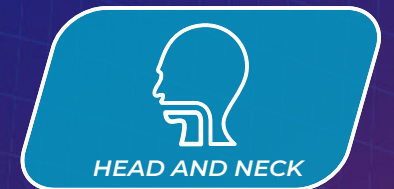
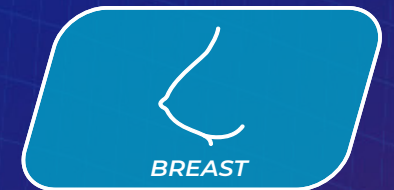
*In collaboration with Nanjing Leads Biolabs.
†Clinical collaboration with Hutchison Medipharma International.

CSF-1R, colony stimulating factor-1 receptor; FGFR, fibroblast growth factor receptor; LAG-3, lymphocyte-activation gene 3; 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.

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



Select an area of investigation to learn about our clinical trials



For more information, contact: medicalinformation@beigene.com

1019-BGB-A333-MRC-005 May 2023