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BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC  
MALIGNANCIES



LIVER



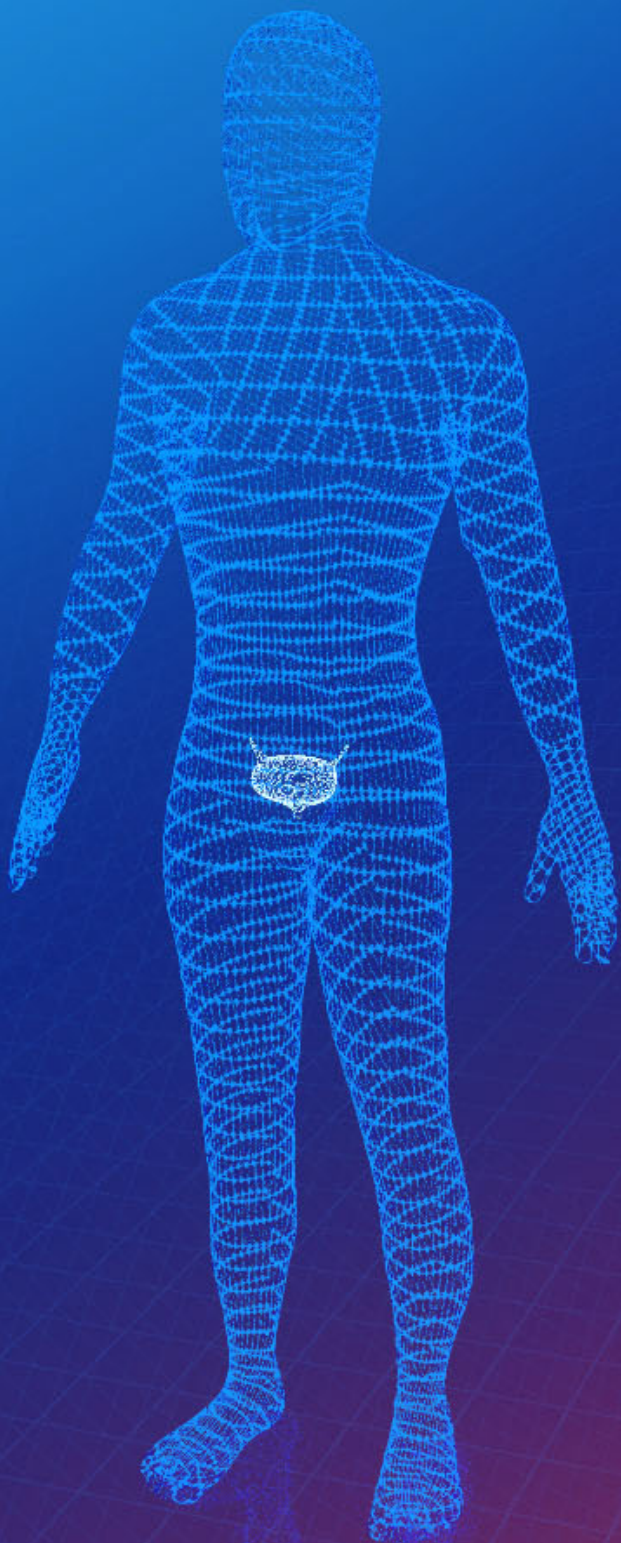
LUNG



GYNECOLOGIC  
ONCOLOGY



SOLID TUMORS



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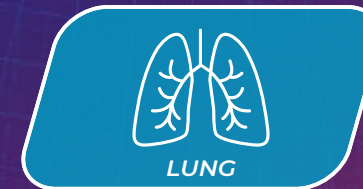
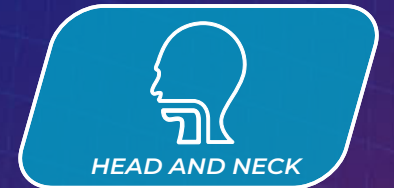


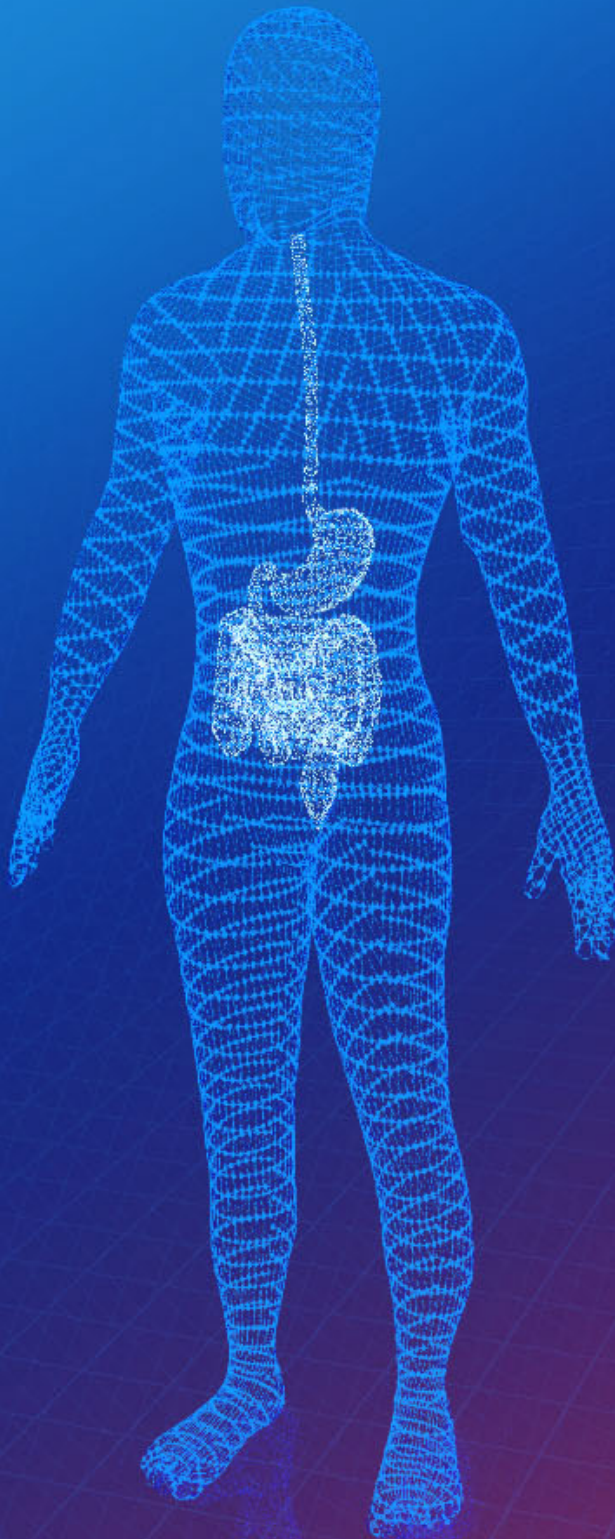
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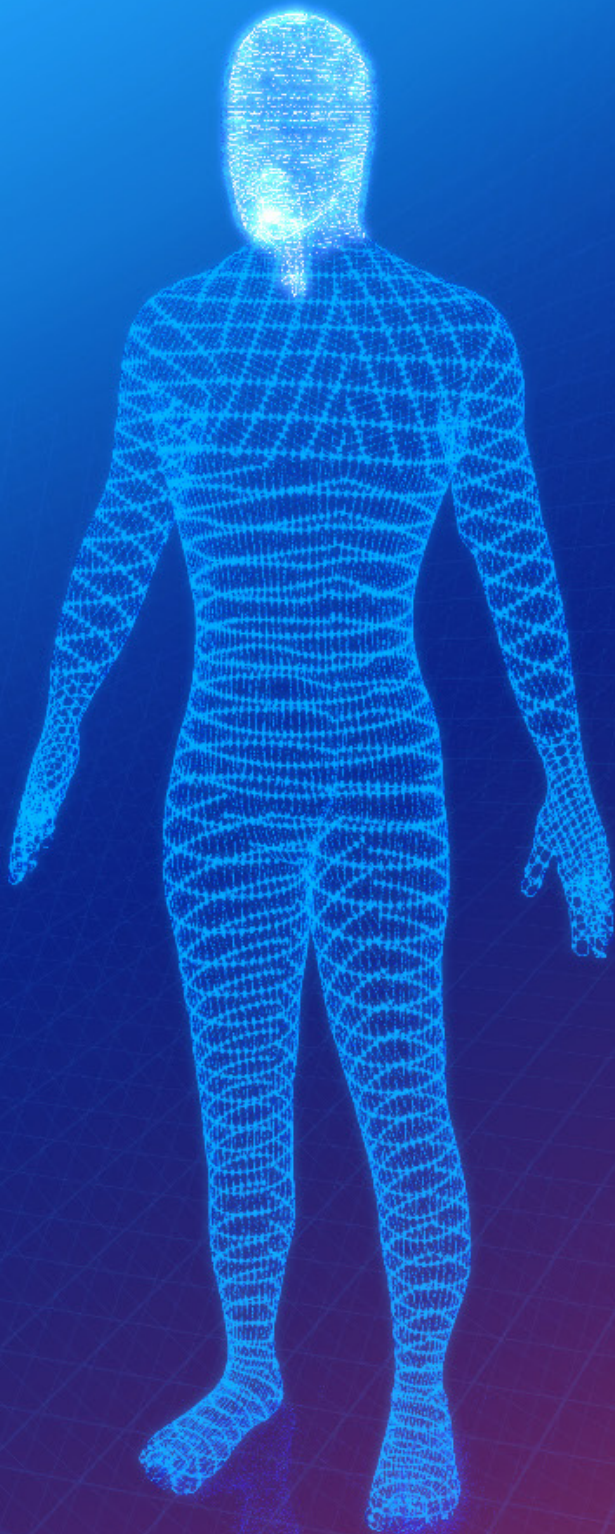
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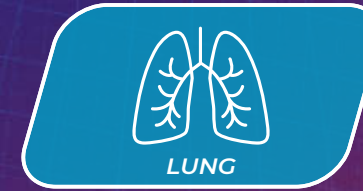
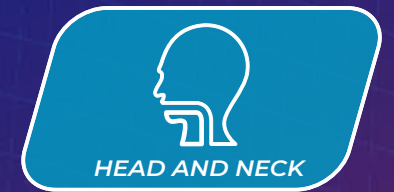
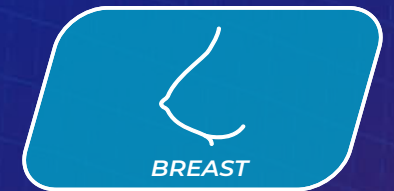


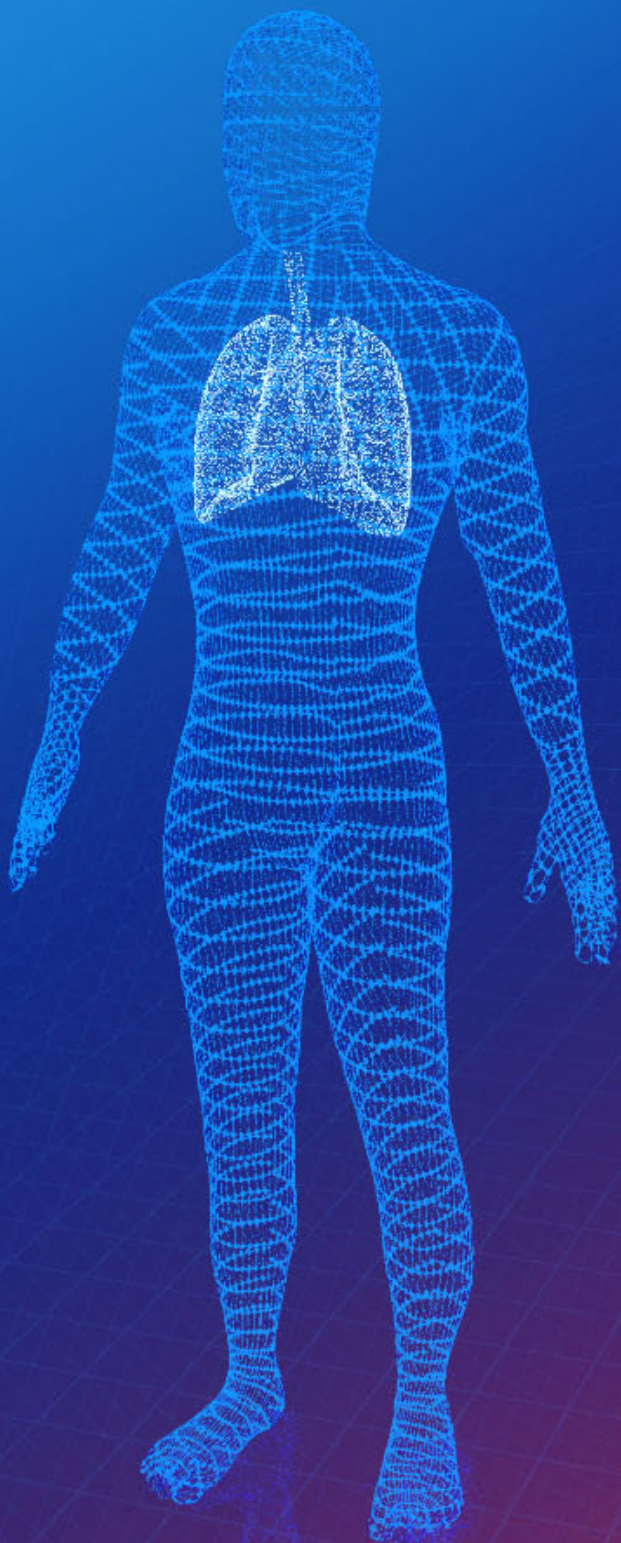
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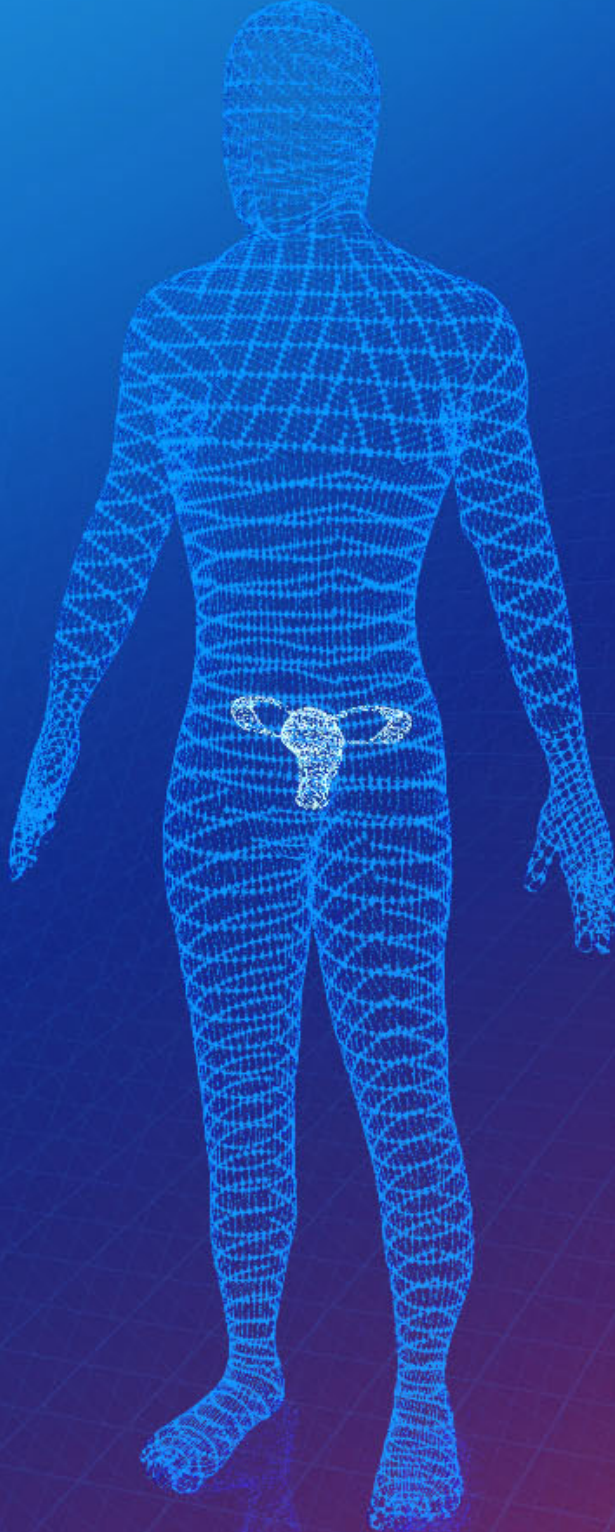
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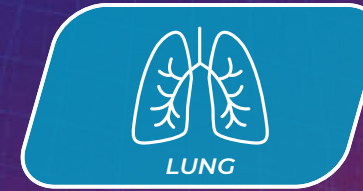
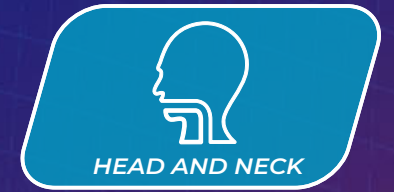
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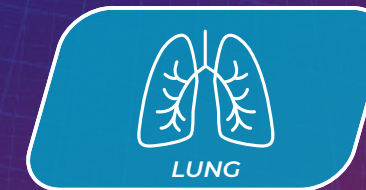
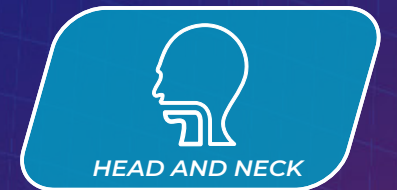
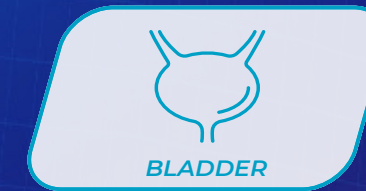
# INVESTIGATIONAL CLINICAL PORTFOLIO

## 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](mailto:medicalinformation@beigene.com)



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## BGB-A317-310 Phase 3 Study in 1L UBC<sup>1,2</sup>

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

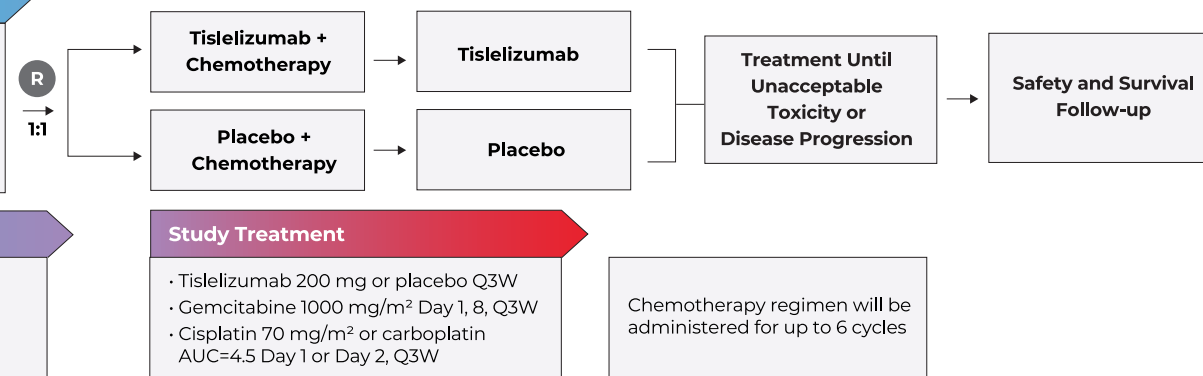
**Primary Endpoint:** OS in ITT  
**Key Secondary Endpoints:** ORR, DOR, HRQOL, Safety, PFS per the investigator, OS rate at 1 and 2 years

### Key Eligibility Criteria

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

### Stratification

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



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

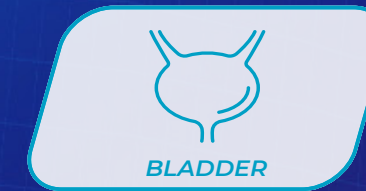
ADA, antidrug antibody; AUC, area under the curve; DCR, disease control rate; DOR, duration of response; HRQoL, health-related quality of life; ITT, intent to treat; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PFS2, progression-free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

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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Breast Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-43395 (CDK4 inhibitor) +/- fulvestrant +/- letrozole	BGB-43955-101	Australia, United States	HR+/HER2- breast cancer	1	NCT06120283
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.

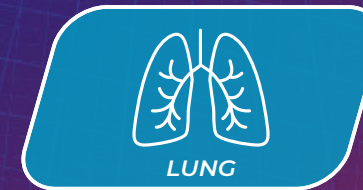
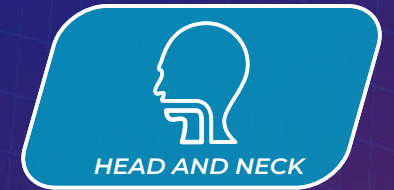
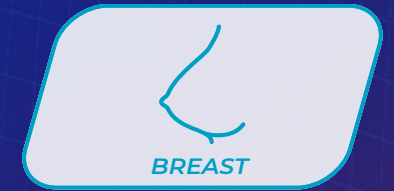
†Clinical collaboration with Hutchison Medipharma International.

CDK4, cyclin-dependent kinase 4; HER2+ BC, human epidermal growth factor receptor-2 positive breast cancer; HR+, hormone receptor positive.

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](mailto:medicalinformation@beigene.com)



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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Gastrointestinal Cancer

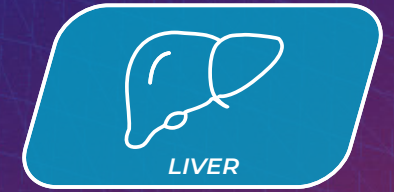
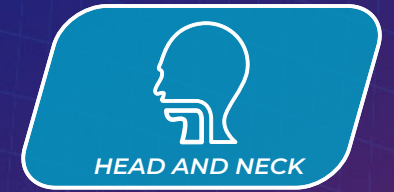
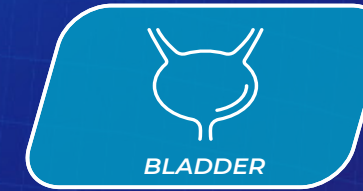
Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-3245 (B-RAF inhibitor) + panitumumab	BGB-3245-EGFR-001*	Opening soon	Advanced metastatic RAS mutant CRC and pancreatic ductal cancers	1	NCT06194877
LBL-007 (anti-LAG-3) +/- Tislelizumab (Anti-PD-1) + 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†	China, S. Korea, Thailand	1L unresectable locally advanced or metastatic ESCC	2	NCT06010303
Tislelizumab	BGB-A317-214	China	Neoadjuvant MSI-high or dMMR CRC	2	NCT05116085
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 + Chemoradiotherapy	BGB-A317-311  Schema	China	Localized ESCC	3	NCT03957590
Tislelizumab + Chemotherapy/ Chemoradiotherapy	BGB-A317-213	China	Resectable ESCC	2	NCT04974047
Tislelizumab + Ociperlimab (Anti-TIGIT)	AdvanTIG-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
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 Mapkure.  
 †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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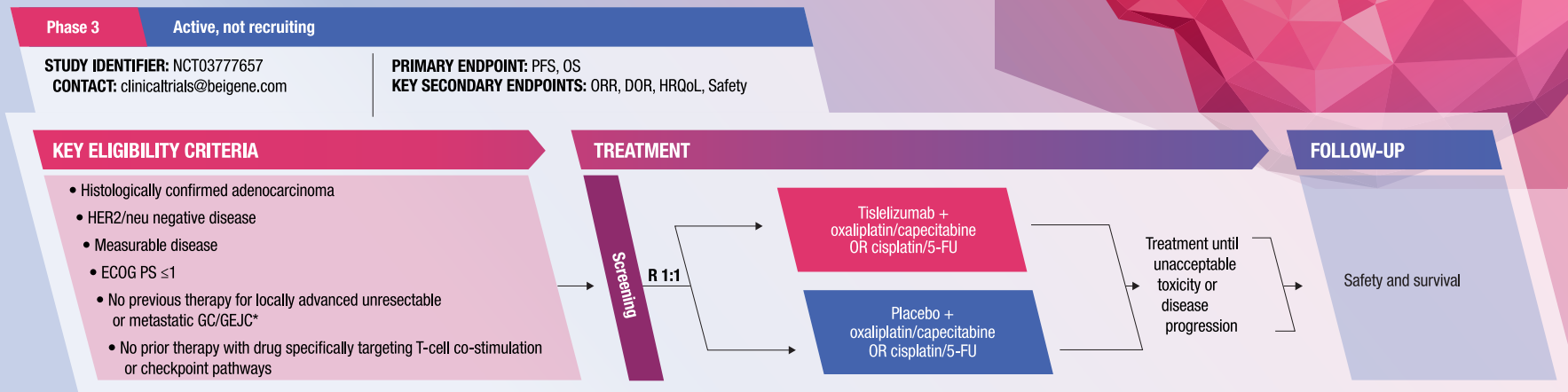


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STUDY DESIGN

# RATIONALE-305

## Tislelizumab in Combination With Chemotherapy as 1L Treatment in Inoperable, Locally Advanced, or Metastatic GC or GEJC<sup>1</sup>



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](mailto: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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- BLADDER
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- GASTROINTESTINAL
- HEAD AND NECK
- HEMATOLOGIC MALIGNANCIES
- LIVER
- LUNG
- GYNECOLOGIC ONCOLOGY
- SOLID TUMORS



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# STUDY DESIGN RATIONALE-306

## Tislelizumab in Combination With Chemotherapy as 1L Treatment in Advanced ESCC<sup>1</sup>

Phase 3 Active, not recruiting

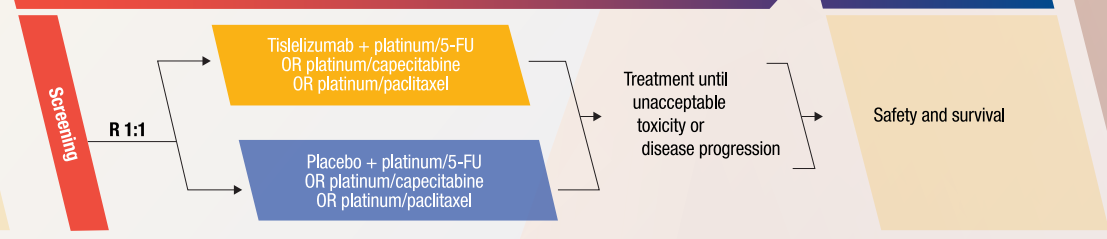
STUDY IDENTIFIER: NCT03783442  
CONTACT: clinicaltrials@beigene.com

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



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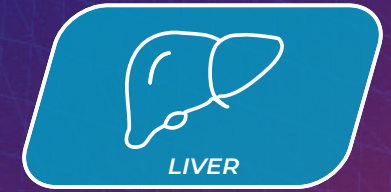
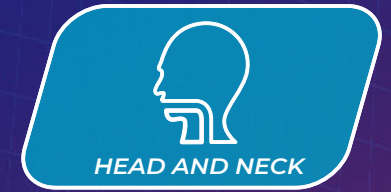
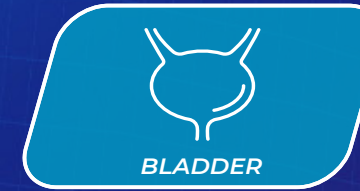
5-FU, 5-fluorouracil; BIRC, blinded independent central review committee; DOR, duration of response; ESCC, esophageal squamous cell carcinoma; HRQoL, health-related quality of life; ORR, overall response rate; OS, overall survival; PD-1, programmed cell death-1; PD-L1, programmed death-ligand 1; PFS,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

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

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## STUDY DESIGN

# RATIONALE -311

## A Phase 3 Trial in Localized ESCC<sup>1-3</sup>

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)

### FOLLOW-UP

Treatment until PD or  
unacceptable toxicity

Safety and survival

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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. TP.

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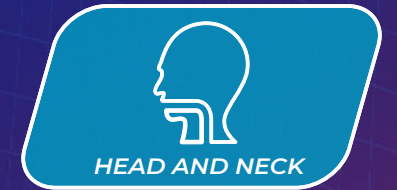
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1019-BGB-A333-MRC-005 March 2024



# INVESTIGATIONAL CLINICAL PORTFOLIO

## Head and Neck Cancer

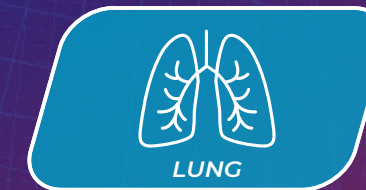
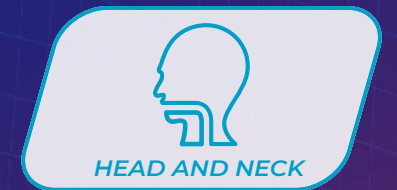
Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Tislelizumab (Anti-PD-1) + Chemotherapy	BGB-A317-309  Schema	China, Thailand	1L advanced nasopharyngeal cancer	3	NCT03924986
Tislelizumab +/- Surzebiclimab (anti-TIM-3) +/- LBL-007 (anti-LAG-3)	BGB-HNSCC-201*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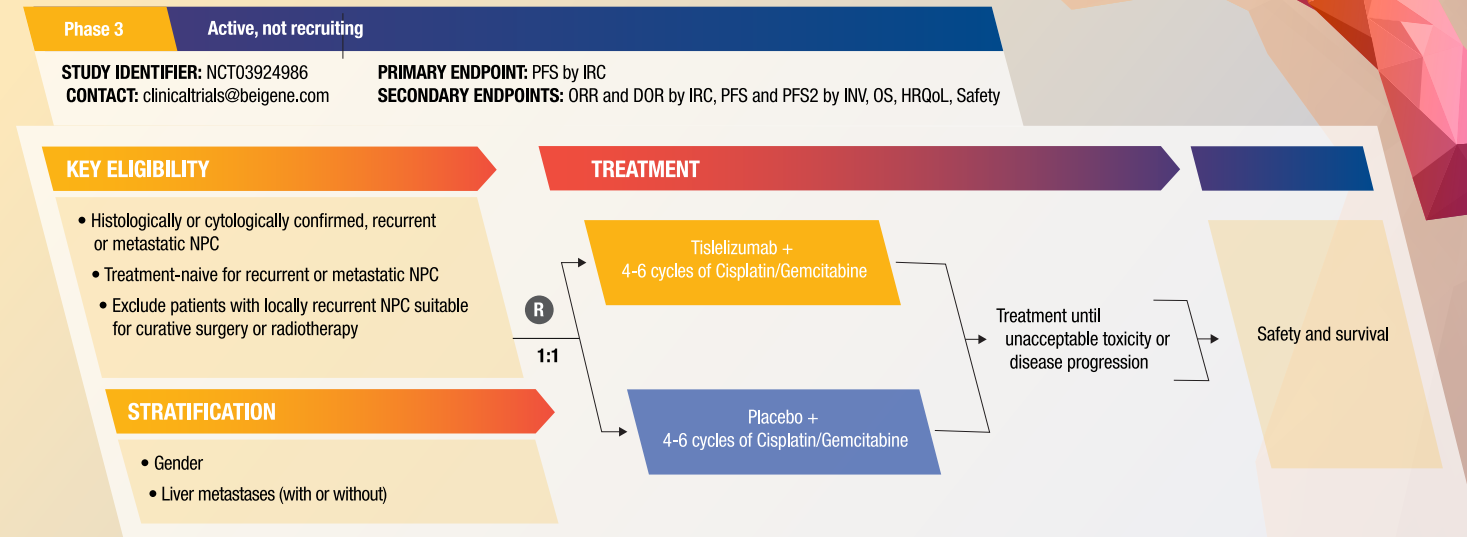


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# STUDY DESIGN RATIONALE-309<sup>1,2</sup>

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



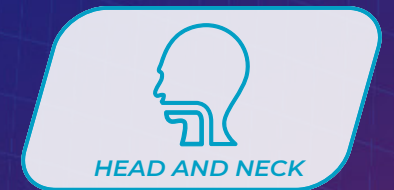
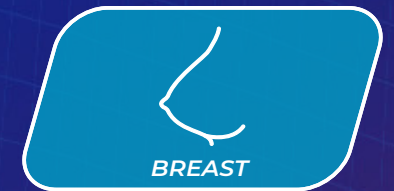
For more information, contact: [medicalinformation@beigene.com](mailto:medicalinformation@beigene.com)

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.

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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Hematologic Malignancies

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
Sonrotoclax + zanubrutinib	BGB-11417-301 <a href="#">▶ Schema</a>	Worldwide	TN CLL	3	NCT06073821
Sonrotoclax monotherapy	BGB-11417-201	China	R/R MCL	2	NCT05471843
Sonrotoclax monotherapy	BGB-11417-202	China	R/R CLL/SLL	2	NCT05479994
Sonrotoclax monotherapy	BGB-11417-203	Worldwide	R/R WM	2	NCT05952037
Sonrotoclax monotherapy	BGB-11417-101	Worldwide	B-cell malignancies	1A/1B	NCT04277637
Sonrotoclax monotherapy	BGB-11417-102	China	B-cell malignancies	1	NCT04883957
Sonrotoclax + Azacitidine +/- Posaconazole	BGB-11417-103	Worldwide	Myeloid malignancies	1B/2	NCT04771130
Sonrotoclax + Dexamethasone +/- Carfilzomib	BGB-11417-105	Worldwide	R/R multiple myeloma with t(11;14)	1B/2	NCT04973605
BGB-16673 (BTK-targeted CDAC)	BGB-16673-101	Worldwide	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

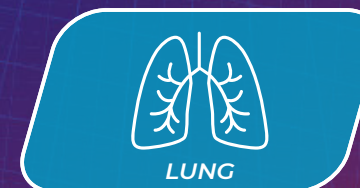
PAGE 1 of 2 ▶

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; TN, treatment naive; 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](mailto:medicalinformation@beigene.com)



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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Hematologic Malignancies

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
BGB-21447 (BCL2 inhibitor)	BGB-21447-101	China	B-cell malignancies	1	NCT05828589
Zanubrutinib	BGB-3111-215  Schema	United States	Previously treated B-cell malignancies	2	NCT04116437
Zanubrutinib	BGB-3111-218	China	R/R DLBCL		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 + Obinutuzumab	BGB-3111-308  Schema	Australia, United States	R/R FL	3	NCT05100862
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
Tislelizumab	BGB-A317-314  Schema	China	R/R cHL	3	NCT04486391
Tislelizumab	BGB-A317-210	Worldwide	R/R cHL	2	NCT04318080
Ociperlimab (Anti-TIGIT) +/- Tislelizumab or Rituximab	AdvanTIG-101	China	R/R DLBCL	1B/2	NCT05267054

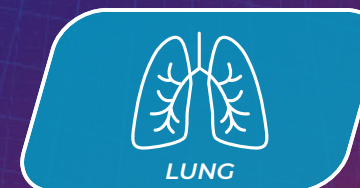
◀ PAGE 2 of 2

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.

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## Study of Sonrotoclax Plus Zanubrutinib Compared With Venetoclax Plus Obinutuzumab in Patients With TN CLL<sup>1</sup>

Phase 3 Planned, not yet recruiting

**Study Identifiers:** BGB-11417-301, NCT06073821  
**Contact:** clinicaltrials@beigene.com

**Primary Endpoint:** PFS by IRC  
**Secondary Endpoints:** uMRD, ORR, PFS, OS, HRQoL, Safety

### Key Eligibility Criteria

- TN CLL
- Measurable disease by CT/MRI
- Adequate bone marrow, liver, and renal function
- No transformation to aggressive lymphoma
- No CNS involvement
- No uncontrolled hypertension

### Treatment

Screening

R 1:1

Sonrotoclax PO + Zanubrutinib for 12 cycles\* after 3 cycles of Zanubrutinib

Venetoclax PO for 12 cycles + Obinutuzumab IV for 6 cycles

### 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.

\*Zanubrutinib monotherapy, 160 mg BID or 320 mg QD for 3 cycles, followed by sonrotoclax combination therapy for a total of 15 cycles.  
BID, twice daily; CT, computed tomography; CLL, chronic lymphocytic leukemia; CNS, central nervous system; CT/MRI, computed tomography/magnetic resonance imaging; HRQoL, health-related quality of life; IRC, independent review committee; IV, intravenous; MRI, magnetic resonance imaging; ORR, overall response rate; PFS, progression-free survival; PO, by mouth; QD, once a day; TN, treatment naïve; uMRD, undetectable measurable disease.

REFERENCE: 1. <https://www.clinicaltrials.gov/study/NCT06073821>. Accessed January 3, 2024.

For more information, contact: [medicalinformation@beigene.com](mailto:medicalinformation@beigene.com)



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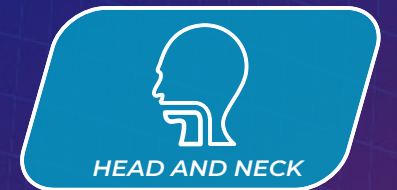
BLADDER



BREAST



GASTROINTESTINAL



HEAD AND NECK



HEMATOLOGIC MALIGNANCIES



LIVER



LUNG



GYNECOLOGIC ONCOLOGY



SOLID TUMORS

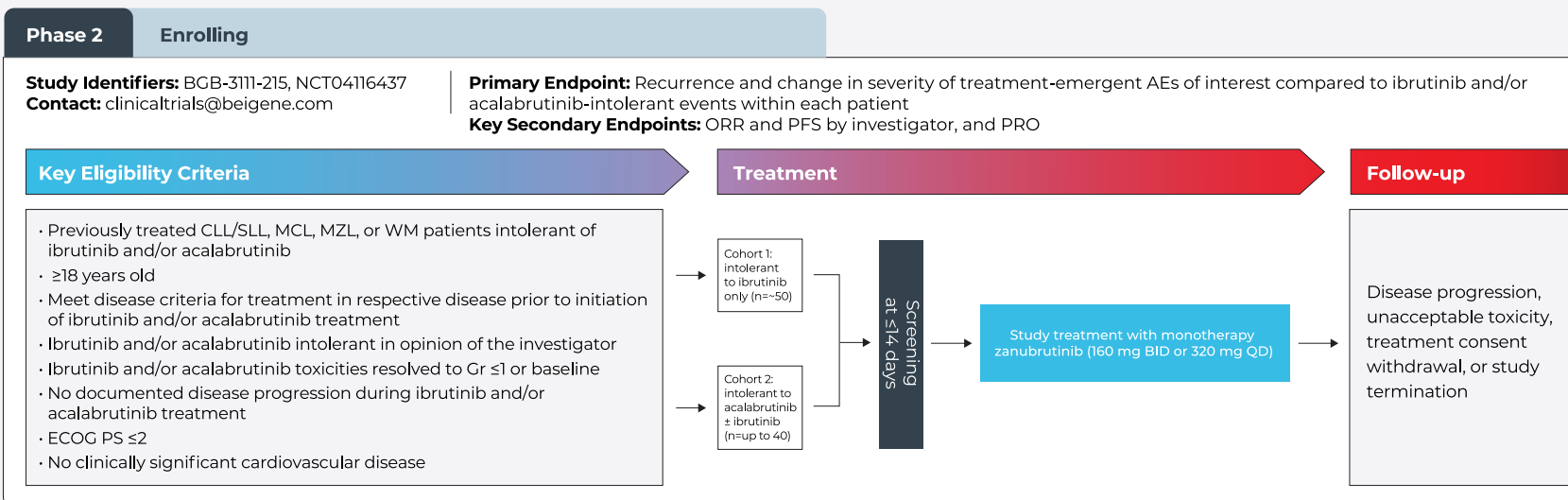


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1019-BGB-A333-MRC-005 March 2024



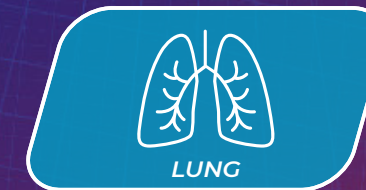
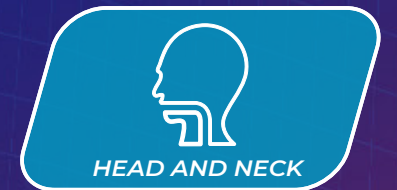
## A Phase 2, Multicenter, Single-Arm Study of Zanubrutinib (BGB-3111) in Patients With Previously Treated B-Cell Lymphoma Intolerant of Prior Treatment of Ibrutinib or Acalabrutinib<sup>1</sup>



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](mailto:medicalinformation@beigene.com)

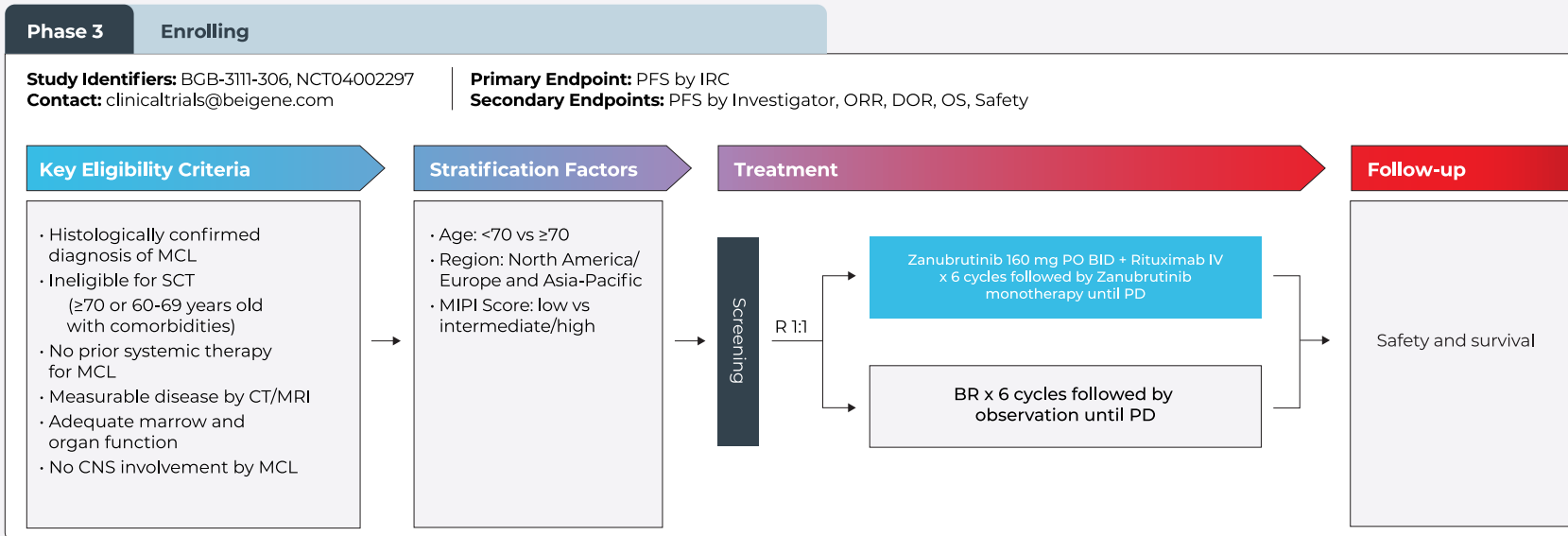


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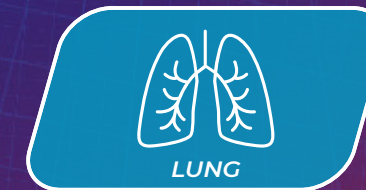
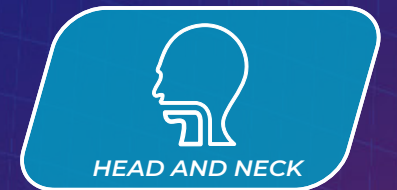
## Pivotal Phase 3 Study of Zanubrutinib + Rituximab vs Bendamustine + Rituximab in Previously Untreated MCL Patients Ineligible for SCT<sup>1,2</sup>



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; CT/MRI, computed tomography/magnetic resonance imaging; 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](mailto:medicalinformation@beigene.com)



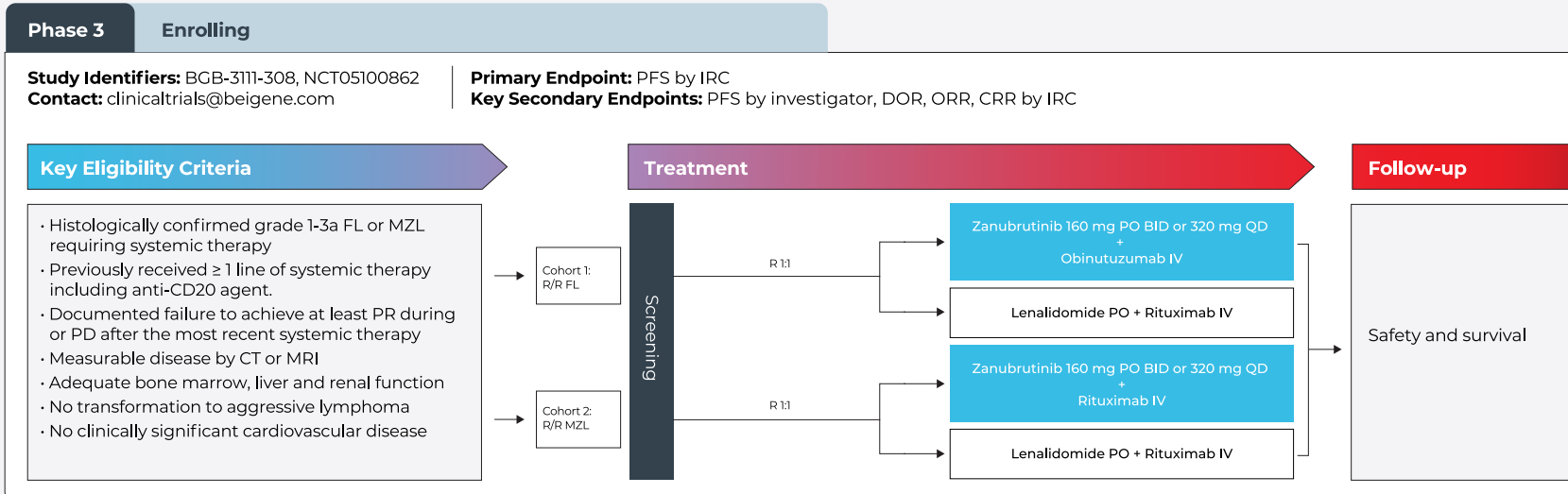
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# A Study of Zanubrutinib Versus Lenalidomide in Participants With Relapsed/Refractory Follicular or Marginal Zone Lymphoma (MAHOGANY)<sup>1</sup>



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

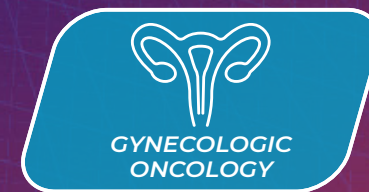
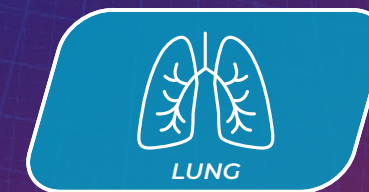
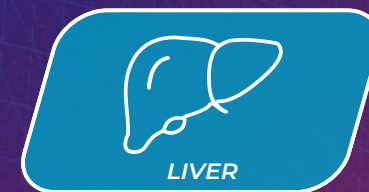
AE, adverse event; BID, twice daily; CT, computed tomography; IRC, Independent Review Committee; IV, intravenous; CRR, Complete Response Rate; DOR, Duration of Response; FL, follicular lymphoma; MRI, magnetic resonance imaging; MZL, marginal zone lymphoma; ORR, overall response rate; PD, progressive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

REFERENCE: 1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05100862>. Accessed May 1, 2023.

For more information, contact: medicalinformation@beigene.com



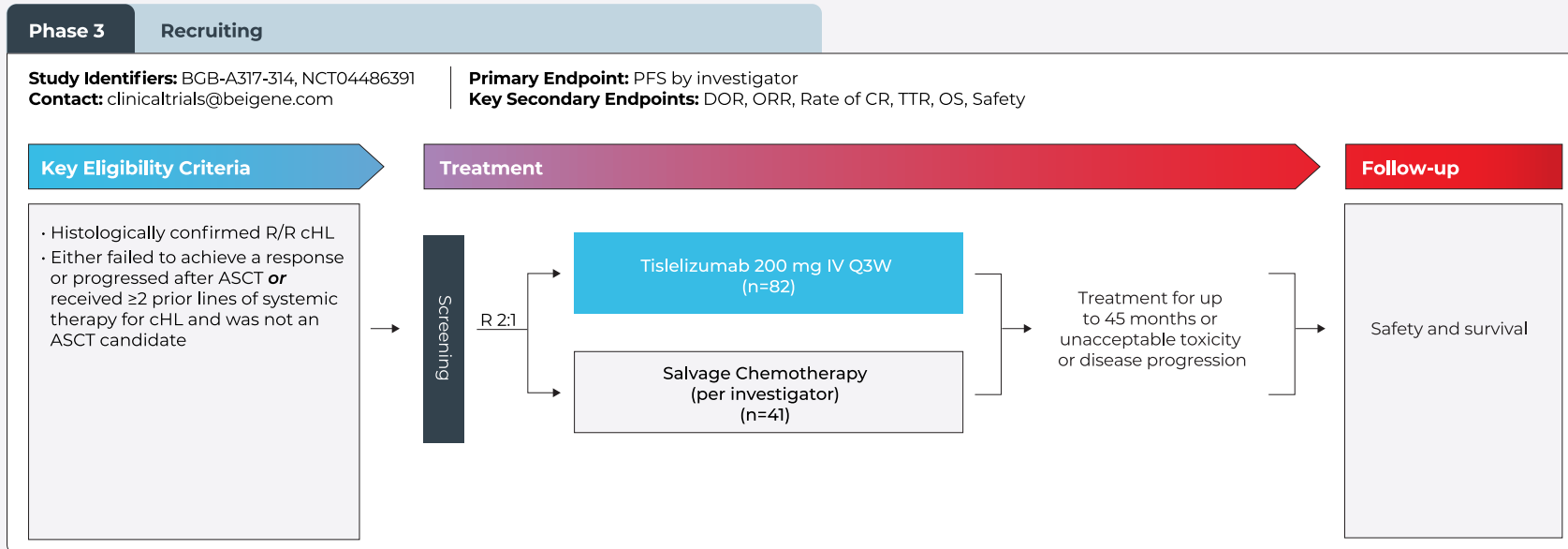
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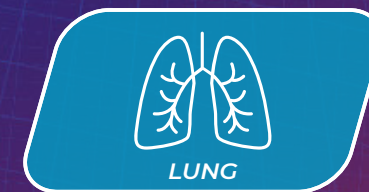
## Tislelizumab Monotherapy vs Salvage Chemotherapy for R/R cHL<sup>1,2</sup>



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.  
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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Liver Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
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
Zanidatamab (Anti-HER2 bispecific antibody)	ZWI-ZW25-203*	Worldwide	2L+ HER2+ biliary tract cancer	2	NCT04466891

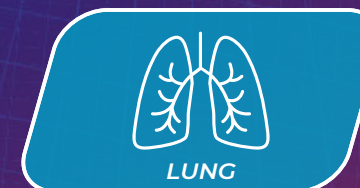
\*In collaboration with Zymeworks Inc.

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

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# INVESTIGATIONAL CLINICAL PORTFOLIO

## Lung Cancer

Investigational Medicinal Product	Study	Geography	Disease Area of Research	Phase	Registry Number
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) + Chemotherapy	AdvanTIG-205	Worldwide	1L NSCLC	2	NCT05014815
Tislelizumab + Ociperlimab	AdvanTIG-302  Schema	Worldwide	1L PD-L1 high advanced NSCLC	3	NCT04746924
Tislelizumab +/- BGB-A445 (Anti-OX40) +/- LBL-007 (Anti-LAG-3) +/- Chemotherapy	BGB-LC-201†	Worldwide	1L advanced, unresectable, or metastatic NSCLC	2	NCT05635708
Tislelizumab +/- Ociperlimab +/- LBL-007	BGB-LC-202†	China	Resectable Stage II/IIIA NSCLC	2	NCT05577702
BGB-A445 +/- Tislelizumab +/- Sitravatinib +/- BGB-15025 (HPK1 inhibitor) +/- Chemotherapy	BGB-LC-203	China, S. Korea	NSCLC after anti-PD-(L)1 therapy	2	NCT06029127

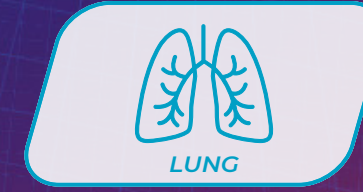
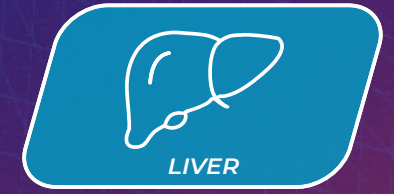
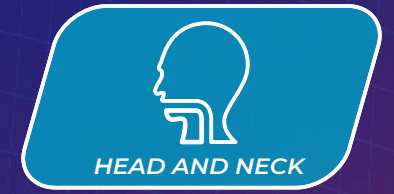
\*Clinical collaboration with Hutchison Medipharma International  
 †In collaboration with Nanjing Leads Biolabs.

ES-SCLC, extensive-stage small cell lung cancer; HPK1, hematopoietic progenitor kinase 1; 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.

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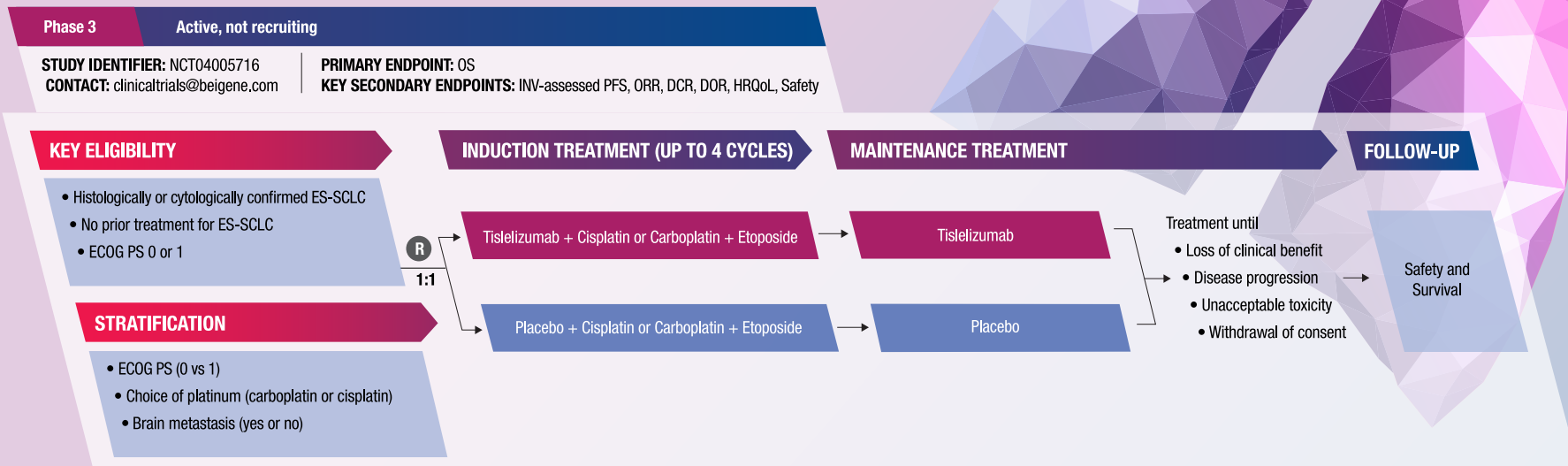
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# STUDY DESIGN

## 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<sup>1-3</sup>



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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.

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



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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<sup>1,2</sup>

Phase 3 Active, not recruiting

STUDY IDENTIFIER: NCT04379635  
CONTACT: [clinicaltrials@beigene.com](mailto: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 ( $\geq 1\%$  vs  $< 1\%$ /not evaluable/ indeterminate)

### NEOADJUVANT PHASE (3-4 CYCLES)

Tislelizumab + Platinum-based doublet chemotherapy\*

R

1:1

Placebo + Platinum-based doublet chemotherapy\*

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

### ADJUVANT PHASE (UP TO 8 CYCLES)

R0 resection

Tislelizumab

Placebo

### SAFETY/SURVIVAL FOLLOW-UP

- Continue assessment until
- Local/distant recurrence
  - Unacceptable AE

- Until:
- Death
  - EOS

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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.

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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BLADDER



BREAST



GASTROINTESTINAL



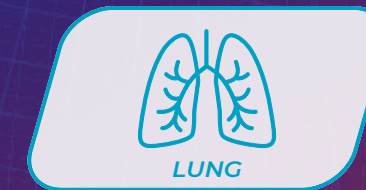
HEAD AND NECK



HEMATOLOGIC MALIGNANCIES



LIVER



LUNG



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1019-BGB-A333-MRC-005 March 2024



advanTIG

## Ociperlimab in Combination With Tislelizumab vs Pembrolizumab in 1L, PD-L1-Selected, Locally Advanced, Unresectable, or Metastatic NSCLC<sup>1,2</sup>

Phase 3 Recruiting

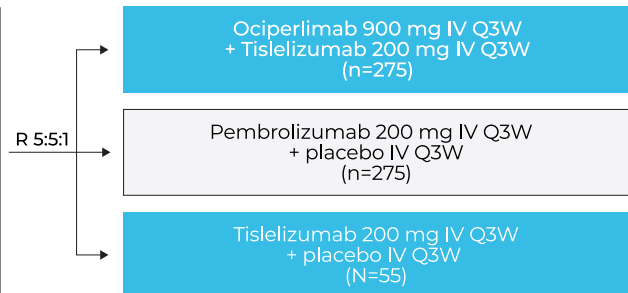
**Study Identifier:** AdvanTIG-302, NCT04746924  
**Contact:** clinicaltrials@beigene.com

**Primary Endpoints:** 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  $\geq 50\%$ <sup>†</sup>
- 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

Treatment until disease progression, intolerable toxicity or withdrawal for other reasons

Safety and survival

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

<sup>†</sup>By investigator, <sup>‡</sup>Determined centrally by VENTANA PD-L1 [SP263] assay.

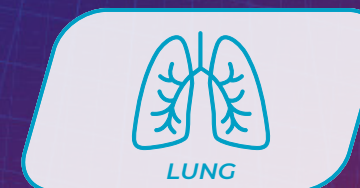
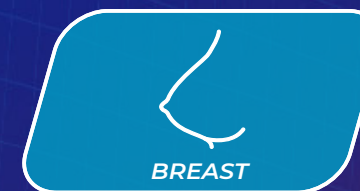
ALK, anaplastic lymphoma kinase; 1L, 1st line; DOR, duration of response; EGFR, epidermal growth factor receptor; HRQoL, health-related quality of life; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival;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

**REFERENCES:** 1. Socinski MA, Spira AL, 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.

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# 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 + Fruquintinib (VEGFR inhibitor)	2020-013-00US3*	United States	Advanced endometrial cancer	1/2	NCT04577963

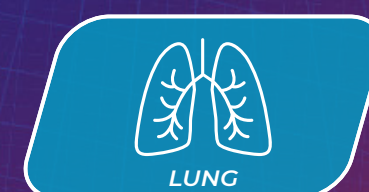
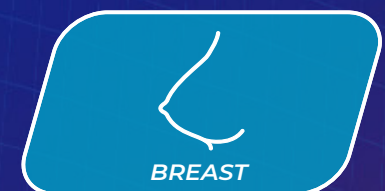
\*Clinical collaboration with Hutchison Medipharma International.

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](mailto: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-43395 (CDK4 inhibitor) +/- fulvestrant +/- letrozole	BGB-43395-101	Australia, United States	HR+/HER2- advanced solid tumors	1	NCT06120283
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, New Zealand, United States	Advanced solid tumors	1	NCT05981703
BGB-30813 (DGKζ inhibitor) +/- Tislelizumab	BGB-A317-30813-101	Worldwide	Advanced or metastatic solid tumors	1	NCT05904496
BGB-A3055 (anti-CCR8) +/- Tislelizumab	BGB-A317-A3055-101	Australia, United States	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-A445 (Anti-OX40) +/- Tislelizumab	BGB-A317-A445-201	China	Select advanced solid tumors	1/2	NCT05661955
BGB-3245 (B-RAF inhibitor)	BGB-3245-AU-001	Australia, United States	Advanced solid tumors with B-RAF mutations	1	NCT04249843

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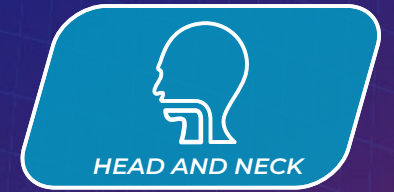
\*In collaboration with SpringWorks Therapeutics.

B-RAF, B-Raf proto-oncogene; CCR8, C-C chemokine receptor 8; CDK4, cyclin-dependent kinase 4; CEA, carcinoembryonic antigen; DGKζ, diacylglycerol kinase zeta; HPK1, hematopoietic progenitor kinase 1; HR+/HER2-, hormone receptor positive/human epidermal growth factor receptor-2 negative; 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-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
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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