



# BeiGene

## Clinical Trials Appendix

Q1 2024 Results Update

May 8, 2024

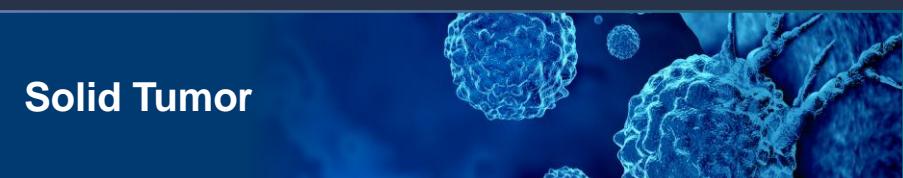
# Disclosures

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Certain statements contained in this presentation and in any accompanying oral presentation, other than statements of fact that are independently verifiable at the date hereof, may constitute forward-looking statements. Examples of such forward-looking statements include statements regarding the projected dates for upcoming regulatory approvals and the estimated number of future approvals; and BeiGene's research, discovery, and pre-clinical and early-stage clinical programs and plans. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and medicines; BeiGene's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent periodic report filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the SEC. All information in this presentation is as of the date of this presentation, and BeiGene undertakes no duty to update such information unless required by law.

# Our Pipeline Snapshot

Across three therapy areas:



130+

Clinical studies run by  
BeiGene

35+

New molecular  
entities (NME) in our  
development pipeline

24,000+

Patients enrolled in  
clinical trials globally\*

70+

Approvals for BRUKINSA  
(zanubrutinib) globally

# BeiGene: Key upcoming regulatory action catalysts 2024 - 2025

Potential Approvals		
1H, 2024	2H, 2024	2025
 <p><b>Q1</b> <b>BRUKINSA</b> – 212 R/R FL US ✓ <b>TEVIMBRA</b> – 302 2L ESCC US ✓</p> <p><b>Q2</b> <b>TEVIMBRA</b> – 302 2L ESCC Australia <b>TEVIMBRA</b> – 303/304/307 1L/2L NSCLC EU ✓</p>	<p><b>Q3</b> <b>TEVIMBRA</b> – 302 2L ESCC Brazil <b>TEVIMBRA</b> – 303 2L NSCLC Brazil <b>TEVIMBRA</b> – 306 1L ESCC US*</p> <p><b>Q4</b> <b>BRUKINSA</b> – 302/304/305 WM and CLL/SLL JP <b>TEVIMBRA</b> – 305 1L GC US <b>TEVIMBRA</b> – 306 1L ESCC Australia</p>	<p><b>BRUKINSA</b> – additional ~20 global approvals <b>TEVIMBRA</b> – 305 1L GC EU <b>TEVIMBRA</b> – 306 1L ESCC EU <b>TEVIMBRA</b> – 309 1L NPC EU <b>TEVIMBRA</b> – 312 1L SCLC EU <b>TEVIMBRA</b> – 302 2L ESCC JP <b>TEVIMBRA</b> – 306 1L ESCC JP <b>TEVIMBRA</b> – 305 1L GC JP <b>TEVIMBRA</b> – additional ~15 global approvals</p>

ESCC-Esophageal squamous cell carcinoma; R/R FL- Relapsed refractory follicular lymphoma; GC- Gastric cancer; NSCLC- Non-small cell lung cancer; Neo/adj NSCLC- neoadjuvant/adjuvant non-small cell lung cancer;

NPC- nasopharyngeal carcinoma; SCLC-Small cell lung cancer

\*Due to a potential delay in scheduling clinical site inspections, the target PDUFA date of July 2024 may be deferred

# BeiGene: Project movements in 2023 – 2024 to date

New to Phase 1	New to Phase II	New to pivotal trial	New to registration	Approved
<p>BGB-26808 (HPK1 2G)</p> <p>BGB-30813 (DGK<math>\zeta</math>)</p> <p>BGB-43395 (CDK4i)</p> <p>BGB-A3055 (CCR8)</p> <p>BGB-A317 tislelizumab (PD-1) SubQ</p> <p>BGB-21447 (next gen BCL2i)</p> <p>BG-68501 (CDK2i)</p> <p>Xaluritamig* (STEAP1 x CD3) initiation activities</p> <p>BG-C9074 (B7H4 ADC)</p>	<p>BGB-16673 BTK CDAC R/R CLL, R/R MCL</p> <p>1L NSCLC umbrella study</p> <p>Neo/adj NSCLC umbrella study</p> <p>BGB-A445 (OX40) Melanoma/RCC/UC novel combo umbrella</p> <p>LBL-007 (LAG3) MSS CRC, 1L ESCC</p>	<p>Tarlatamab* (DLL x CD3) 1L ES-SCLC initiation activities</p> <p>Sonotoclax TN CLL</p>	<p>Tislelizumab 305 (1L GC) in US, EU</p> <p>Tislelizumab 312 (1L ES-SCLC) in CN</p> <p>Tislelizumab 306 (1L ESCC) in US, EU</p> <p>Tislelizumab 315 (Neo/adj NSCLC) in CN</p>	<p>Zanubrutinib 212 (R/R FL) in US, EU</p> <p>Tislelizumab 305 (1L GC) in CN, CN (FA)</p> <p>Tislelizumab 306 (1L ESCC) in CN</p> <p>Tislelizumab 302 (2L ESCC) in EU, US</p> <p>Tislelizumab 301 (1L HCC) in CN</p>

NSCLC- Non-small cell lung cancer; RCC- Renal cell carcinoma; UC-urothelial carcinoma; MSS CRC- microsatellite stable colorectal cancer; ESCC-Esophageal squamous cell carcinoma; ES-SCLC- extended stage small cell lung cancer; LS-SCLC- limited stage small cell lung cancer; TN CLL- treatment naïve chronic lymphocytic leukemia; GC- gastric cancer; Neo/adj NSCLC- neoadjuvant/adjuvant non-small cell lung cancer; R/R FL- relapsed refractory follicular lymphoma; HCC- hepatocellular carcinoma

\*Amgen collaboration, BeiGene has China commercial rights and tiered mid-single digit royalties on net sales outside of China. "Initiation activities" refers to clinical activities, approval is obtained to initiate the study in China.

# BeiGene: Project movements in 2023 – 2024 to date

## Removed from Phase 1

BGB-B167 (CEAx4-1BB)

## Removed from Phase II

Ociperlimab (TIGIT)

1L TNBC  
1L HCC  
2L ESCC  
2L CC

Sitravatinib (RTKi)

## Removed from Phase III

Sitravatinib (RTKi) 2L+ NSCLC

Ociperlimab (TIGIT) LA NSCLC

NSCLC- Non-small cell lung cancer; ESCC-Esophageal squamous cell carcinoma;  
LA NSCLC- locally advanced non-small cell lung cancer; HCC- hepatocellular carcinoma; CC- cervical cancer, TNBC- triple negative breast cancer

CEAx4-1BB- Carcinoembryonic Antigen x 41BB; TIGIT- T cell immunoglobulin and ITIM domain; RTKI- receptor tyrosine kinase inhibitor

# Innovative solid tumor NME early pipeline

Differentiated molecules with multiple modalities in priority tumor types



Lung



Breast/Gynecological



GI



Head & Neck



Pan Tumor

PanKRASi

MTA Cooperative PRMT5i

EGFR CDAC

CEA ADC

B7H3 ADC

EGFR x MET Tsp

MUC1 x CD16A

CDK4i\*

CDK2i\*

Next-gen BCL2i\*

B7H4 ADC\*

Claudin6 x CD3

PanKRASi

FGFR2b ADC

CEA ADC

GPC3 x 4-1BB

MUC1 x CD16A

SMAC Mimetics\*

MTA Cooperative PRMT5i

B7H3 ADC

DGKζi\*

HPK1i\*

CCR8\*

Pro-IL15

Small molecule

mAb

Protein degrader

ADC

Bi/Tri-specific

Cytokine therapy

BeiGene has global rights for CDK2 (Ensem partnership) and B7H4 ADC (DualityBio partnership)

\* In the clinic

# BeiGene: Building leadership in solid tumors with innovative NMEs

	Pre-Clinical	Phase 1	Phase 2	Phase 3
Breast/ Gynecological	BGB-B455 Claudin6xCD3 Gyn (other ST)	BGB-43395 · CDK4 Breast (other ST) (Global and CN studies)  BGB-C9074 B7H4-ADC Breast (other ST)	BGB-10188 PI3kδ Ovarian Cancer  BG-68501 CDK2i Breast (other ST)	
Gastro- intestinal	BG-C137 FGFR2b ADC GI  BGB-B2033 GPC3x4-1BB Solid Tumors	BG-C477 CEA ADC GI and Lung  BG-53038 Pan-KRAS GI and lung	Zanidatamab HER2 1L MBC/GC	BGB-LBL-007 LAG-3 MSS-CRC  Zanidatamab HER2 2L+ BTC
Lung	BG-60366 EGFR-CDAC 2G Lung  BGB-B3227 MUC1xCD16A Lung and GI  BGB-C354 B7H3 ADC Lung and HNSCC	BG-T187 EGFRxMET Lung and GI  BGB-58067 MTA-coop PRMT5 Lung and HNSCC	Ociperlimab TIGIT (Tisle combo dose finding)	Umbrella 1L NSCLC  Umbrella 2L+ NSCLC  Umbrella Neoadjuvant NSCLC  Tarlatamab DLL3xCD3 3L+ SCLC (CN only)
ST - Other	BGB-R046 Pro-IL15 Solid Tumors	BGB-A3055 CCR8 Solid Tumors  BGB-15025 HPK1 Solid Tumors	BGB-24714 SMAC Solid Tumors  Xaliritamig STEAP1x CD3 mCRPC (CN only)	BGB-26808 HPK1 2G Solid Tumors  BGB-30813 DGKζ Solid Tumors  BGB-A445 OX40 Melanoma, RCC, UC  Umbrella 1L HNSCC
				Surzebiclimab TIM-3 1L HNSCC

NSCLC- Non-small cell lung cancer; RCC- Renal cell carcinoma; UC-urothelial carcinoma; MSS CRC- microsatellite stable colorectal cancer; GEA-Gastroesophageal adenocarcinoma; MBC-metastatic breast cancer; HNSCC-Head & Neck squamous cell carcinoma; mCRPC-metastatic castration-resistant prostate cancer; ES-SCLC-extended stage small cell lung cancer; LS-SCLC- limited stage small cell lung cancer; Neo/adj NSCLC- neoadjuvant/adjuvant non-small cell lung cancer;

# BeiGene: Building leadership in solid tumors with LCM

	Phase 1	Phase 2	Phase 3	Approved
Breast/ Gynecological			Pamiparib PARPi 2L+ MTx OC	Pamiparib - PARPi 2L+ gBRCAm OC  Baituwei (Goserelin) Breast, Prostate
Gastro- intestinal			Tislelizumab PD-1 localized ESCC	Tislelizumab PD-1 1L HCC  Tislelizumab PD-1 2L ESCC  Tislelizumab PD-1 1L GC
Lung			Tislelizumab PD-1 1L ES-SCLC	Tislelizumab PD-1 neo/adj NSCLC  Tislelizumab PD-1 1L Non-sq. NSCLC  Tislelizumab PD-1 1L Sq. NSCLC  Tislelizumab PD-1 2/3L NSCLC
ST - Other	Tislelizumab PD-1 Subcutaneous administration		Tislelizumab PD-1 1L UBC	Tislelizumab PD-1 2L UC  Tislelizumab PD-1 R/R cHL  Tislelizumab PD-1 MSI-H/dMMR ST

LCM – life cycle management; NSCLC- Non-small cell lung cancer; NSq-non squamous; Sq squamous; ES-SCLC-extended stage small cell lung cancer; LS-SCLC- limited stage small cell lung cancer; Neo/adj NSCLC- neoadjuvant/adjuvant non-small cell lung cancer; ESCC-Esophageal squamous cell carcinoma; UBC- urinary bladder cancer; OC ovarian cancer; HCC-hepatocellular carcinoma; NPC-nasopharyngeal carcinoma, GC-gastric cancer, MSI-H- microsatellite stability high; dMMR-mismatch repair deficient; R/R CHL- relapsed refractory classic Hodgkins lymphoma

# BeiGene: A leader in hematology / I&I portfolio – innovative NMEs

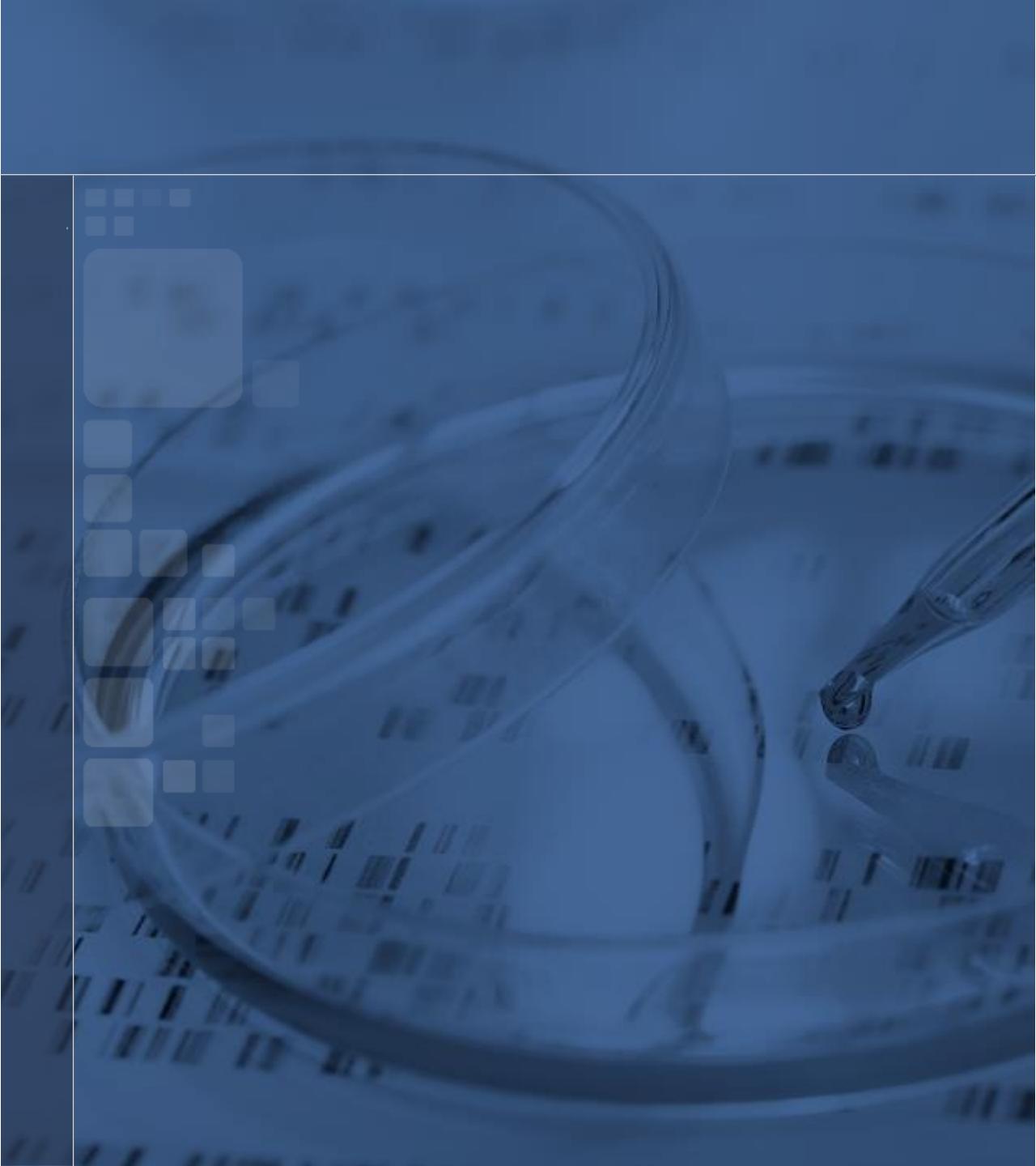
	Pre-Clinical	Phase 1	Phase 2	Phase 3		
AML/MDS		Sonrotoclax BCL2i AML/MDS				
cHL						
B-Cell		BGB-21447 BCL2i 2G B-Cell Malignancies  Sonrotoclax BCL2i B-Cell Malig.(China)  BGB-16673 BTK CDAC B-Cell Malig. (China)	Ocipertimab TIGIT R/R DLBCL  Sonrotoclax BCL2i mono & combo w/ zantu (Global)  BGB-16673 BTK CDAC B-Cell Malig. (Global)	BGB-16673 BTK CDAC R/R MCL & R/R CLL  Sonrotoclax BCL2i post BTKi R/R MCL  Sonrotoclax BCL2i post BTKi CLL/SLL (China)	Sonrotoclax BCL2i post BTKi R/R MCL  Sonrotoclax BCL2i R/R WM	Sonrotoclax BCL2i TN CLL combo + zantu
MM						
Heme - Other						
I&I		BGB-45035 IRAK4 CDAC				

ALL=acute lymphoblastic leukemia; AML=acute myeloid leukemia; cHL=classic Hodgkin lymphoma; CLL=chronic lymphocytic leukemia; DLBCL=diffuse large B-cell lymphoma; FL=follicular lymphoma; MCL=mantle cell lymphoma; MDS=myelodysplastic syndromes; MM=multiple myeloma; WM=Waldenstrom macroglobulinemia; MZL=marginal zone lymphoma; SLL=small lymphocytic lymphoma

# BeiGene: A leader in hematology / I&I with LCM

	Phase 1	Phase 2			Phase 3	Approved		
AML/MDS								
cHL								
B-Cell	Zanubrutinib BTKi R/R DLBCL revlimib combo	Zanubrutinib BTKi Previous BTKi Tx ibrutu/acala intolerant	Zanubrutinib BTKi R/R CLL/SLL (JP)	Zanubrutinib BTKi R/R B-cell lymphoma	Tislelizumab PD-1 R/R cHL (China)	Tislelizumab PD-1 R/R cHL	Zanubrutinib BTKi TN CLL/SLL	Zanubrutinib BTKi R/R CLL/SLL
MM								
Heme - Other	BLINCYTO® CD3/CD19 BiTE Pediatric RR BP-ALL							
I&I	Zanubrutinib BTKi Lupus Nephritis			Zanubrutinib BTKi PMN				

LCM – life cycle management; ALL=acute lymphoblastic leukemia; AML=acute myeloid leukemia; cHL=classic Hodgkin lymphoma; CLL=chronic lymphocytic leukemia; DLBCL=diffuse large B-cell lymphoma; FL=follicular lymphoma; MCL=mantle cell lymphoma; MDS=myelodysplastic syndromes; MM=multiple myeloma; WM=Waldenstrom macroglobulinemia; MZL=marginal zone lymphoma; SLL=small lymphocytic lymphoma



# Trial detail

- **BRUKINSA®** (zanubrutinib)
- **Sonrotoclax**
- **TEVIMBRA®** (tislelizumab)

Trial	Clinicaltrials.gov	Population	Total Patients	Combination molecule	Status
BGB-3111-111	NCT04172246	B-Cell Malignancies (JP only)	55		Active
BGB-3111-215	NCT04116437	Previous BTKi Tx - ibru/acala intolerant	97		Enrolling
BGB-3111-218	NCT05068440	CD79b R/R DLBCL	66		Enrolling
BGB-3111-306	NCT04002297	TN MCL	510	rituximab	Active
BGB-3111-308	NCT05100862	R/R MZL and FL	800	rituximab / obinutuzumab	Enrolling
BGB-3111-LTE1	NCT04170283	B-Cell Malig. Long Term Extension Study	1323		Enrolling
BGB-3111-206	NCT03206970	R/R MCL	86		Approved
BGB-3111-212	NCT03332017	R/R NHL - FL	217	obinutuzumab	Approved
BGB-3111-214	NCT03846427	R/R MZL	68		Approved
BGB-3111-302	NCT03053440	TN & R/R WM	229		Approved
BGB-3111-304	NCT03336333	TN CLL/SLL	784		Approved
BGB-3111-305	NCT03734016	R/R CLL/SLL	652		Approved

# Sonrotoclax

Potential best-in-class BCL2 inhibitor with differentiated profile

Approved medicines

Late-stage development

Early development

Trial	Clinicaltrials.gov	Population	Total Patients	Combination molecule	Status
BGB-11417-101	NCT04277637	B-Cell Malignancies	438	zanubrutinib and obinutuzumab	Enrolling
BGB-11417-102	NCT04883957	B-Cell Malignancies	64		Active
BGB-11417-103	NCT04771130	AML/MDS	265	azacitidine	Enrolling
BGB-11417-105	NCT04973605	R/R MM with t(11;14)	181	dexamethasone and carfilzomib	Enrolling
BGB-11417-201	NCT05471843	Post-BTKi MCL	122		Enrolling
BGB-11417-202	NCT05479994	Post-BTKi CLL/SLL	97		Enrolling
BGB-11417-203	NCT05952037	R/R WM	85	zanubrutinib	Enrolling
BGB-11417-301	NCT06073821	TN CLL/SLL	640	zanubrutinib	Enrolling

Trial	Clinicaltrials.gov	Population	Total Patients	Combination Molecule	Status
BGB-A317-103	NCT06091943	Subcutaneous administration	69		Enrolling
BGB-HNSCC-201	NCT05909904	1L HNSCC	160	LAG3, TIM-3, chemotherapy	Enrolling
BGB-LC-201	NCT05635708	1L NSCLC	319	LAG3, OX40, HPK, chemotherapy	Enrolling
BGB-LC-202	NCT05577702	1L Neo adj/adj NSCLC	120	LAG3, Chemotherapy	Enrolling
BGB-A317-310	NCT03967977	1L UBC	436	Chemotherapy	Enrolling
BGB-A317-311	NCT03957590	Localized ESCC	366	Chemotherapy+ radiotherapy	Active
BGB-A317-312	NCT04005716	1L ES-SCLC	455	Chemotherapy	Closeout
BGB-A317-315	NCT04379635	neo-adjuvant/adjuvant NSCLC	450	Chemotherapy	Filed
BGB-A317-203	NCT03209973	R/R cHL	68		Approved*
BGB-A317-204	NCT04004221	2L UC	110		Approved*
BGB-A317-208	NCT03419897	2L/3L+ HCC	250		Approved*
BGB-A317-209	NCT03736889	Late Line MSI-H or dMMR Solid Tumors	150		Approved*
BGB-A317-301	NCT03412773	1L HCC	680		Approved*
BGB-A317-302	NCT03430843	2L ESCC	489		Approved
BGB-A317-303	NCT03358875	2/3L NSCLC	805		Approved
BGB-A317-304	NCT03663205	1L Non-sq. NSCLC	334	Chemotherapy	Approved
BGB-A317-305	NCT03777657	1L GC	978	Chemotherapy	Approved*
BGB-A317-306	NCT03783442	1L ESCC	650	Chemotherapy	Approved*
BGB-A317-307	NCT03594747	1L Sq. NSCLC	342	Chemotherapy	Approved
BGB-A317-309	NCT03924986	1L NPC	263	Chemotherapy	Approved*

