



Clinical Trials Appendix

Q2 2024 Results Update

August 7, 2024

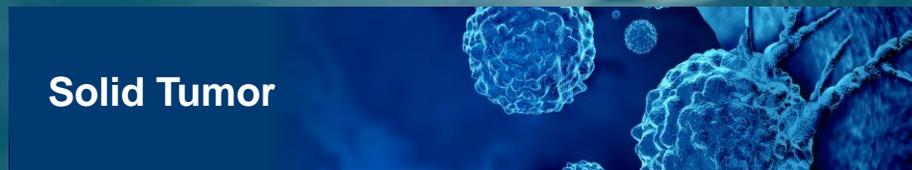
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Our Pipeline Snapshot

Across three therapy areas:



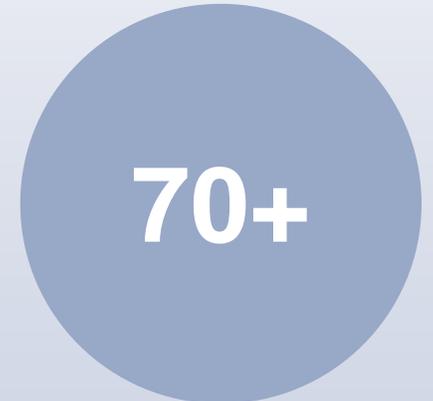
Clinical studies run by BeiGene



Clinical and commercial stage assets



Patients enrolled in clinical trials globally*



Approvals for BRUKINSA[®] (zanubrutinib) globally

*Includes investigator initiated trials (IITs)

BeiGene: Key Upcoming Regulatory Action Catalysts 2H, 2024-2025

Potential Approvals

2H, 2024

Q3

TEVIMBRA – 306 1L ESCC US*

TEVIMBRA – 302 2L ESCC BR

TEVIMBRA – 303 2L NSCLC BR

Q4

BRUKINSA® – 302/304/305 WM and CLL/SLL JP

BRUKINSA – additional ~16 global approvals

TEVIMBRA – 305 1L GC US

TEVIMBRA – 315 Neo/adj NSCLC CN

TEVIMBRA – 306 1L ESCC AUS

1H, 2025

BRUKINSA – R/R MCL UK

BRUKINSA – 114 Tablet formulation US, EU

BRUKINSA – additional ~10 global approvals

TEVIMBRA – 302 2L ESCC Q2W US

TEVIMBRA – 302 2L ESCC JP

TEVIMBRA – 305 1L GC EU, AUS

TEVIMBRA – 306 1L ESCC EU, JP

TEVIMBRA – additional 4 global approvals

2H, 2025

BRUKINSA – R/R FL and CLL BR

BRUKINSA – additional ~10 global approvals

TEVIMBRA – 309 1L NPC EU, AUS

TEVIMBRA – 312 1L ES-SCLC EU

TEVIMBRA – 315 Neo/adj NSCLC EU

TEVIMBRA – additional ~13 global approvals

Zanidatamab – 203 2L BTC CN

* Due to a delay in scheduling clinical inspections, the target PDUFA date of July 2024 was deferred
Refer to Glossary abbreviations

BeiGene: Project Movements Since Q1 2024 Update

New to Phase 1/1b	New to Phase II	New to pivotal trial	New Submission	Approved
<p>BGB-C354 (B7H3 ADC)</p> <p>BGB-45035 (IRAK4 CDAC)</p> <p>BGB-R046 (IL-15 prodrug)</p> <p>BGB-24714 (SMAC) chemo combo expansion</p>	<p>BGB-LBL-007 (LAG3) MSS CRC</p>		<p>Zanidatamab 203 (2L BTC) in CN</p> <p>Tislelizumab (2L ESCC Q2W) in US</p> <p>Tislelizumab 305 (1L GC) in CH</p> <p>Tislelizumab 306 (1L ESCC) in CH</p> <p>Tislelizumab 309 (1L NPC) in AUS</p> <p>Additional 4 Tislelizumab filings</p> <p>Zanubrutinib 212 (R/R FL) in BR</p>	<p>Tislelizumab 303/304/307 (1L NSCLC) in EU, AUS</p> <p>Tislelizumab 305 (1L GC) in CN</p> <p>Tislelizumab 302 (2L ESCC) in AUS, CH</p> <p>Zanubrutinib 212 (R/R FL) in CN</p> <p>Tislelizumab 312 (1L ES-SCLC) in CN</p>

Innovative Solid Tumor NME Early Pipeline

Differentiated molecules with multiple modalities in priority tumor types

Lung



PanKRASi

MTA Cooperative
PRMT5i

EGFR CDAC

CEA ADC

B7H3 ADC*

EGFR x MET Tsp

Breast/Gynecologic



CDK4i*

CDK2i*

Next-gen
BCL2i*

B7H4 ADC*

Claudin6 x CD3

GI



PanKRASi

FGFR2b ADC

CEA ADC

GPC3 x 4-1BB

Pan-Tumor



SMAC Mimetics*

DGKζi*

HPK1i*

CCR8*

IL-15 prodrug*

MUC1 x CD16A

Small molecule

Protein degrader

Bi/Tri-specific

mAb

ADC

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/ Gynecologic Cancers	BGB-B455 Claudin6xCD3 Gyn (other ST)	BGB-43395 · CDK4i Breast (other ST)	BGB-C9074 B7H4 ADC Breast (other ST)	BG-68501 CDK2i Breast (other ST)		
Gastro- intestinal	BG-C137 FGFR2b ADC GI	BG-C477 CEA ADC GI and Lung		BGB-LBL-007 LAG-3 MSS-CRC	BGB-LBL-007 LAG-3 1L ESCC	Zanidatamab HER2 1L HER2+ GEA
	BGB-B2033 GPC3x4-1BB Solid Tumors	BG-53038 Pan-KRAS GI and lung		Zanidatamab HER2 2L+ BTC		
Lung	BG-60366 EGFR-CDAC Lung	BG-T187 EGFRxMET Lung and GI	Ociperlimab TIGIT (Tisle combo dose finding)	Umbrella 1L NSCLC	Umbrella 2L+ NSCLC	Ociperlimab TIGIT 1L NSCLC (PDL1 high)
	BGB-B3227 MUC1xCD16A Lung and GI	BGB-58067 MTA-coop PRMT5 Lung and HNSCC	BGB-C354 B7H3 ADC Lung and HNSCC	Umbrella Neoadjuvant NSCLC	Tarlatamab DLL3xCD3 3L+ SCLC (CN only)	Tarlatamab DLL3xCD3 LS-SCLC (CN only)
		BGB-R046 IL-15 prodrug Solid Tumors				
Pan-tumor /Other		BGB-A3055 CCR8 Solid Tumors	BGB-24714 SMAC Solid Tumors	BGB-26808 HPK1 2G Solid Tumors	BGB-A445 OX40 Melanoma, UC	
		BGB-15025 HPK1 Solid Tumors	Xaluritamig STEAP1x CD3 mCRPC (CN only)	BGB-30813 DGKζ Solid Tumors	Umbrella 1L HNSCC	

BeiGene: Building Leadership in Solid Tumors With LCM

	Phase 1	Phase 2	Phase 3	Approved		
Breast/ Gynecologic Cancers			Pamiparib PARPi 2L+ MTx OC	Pamiparib · PARPi 2L+ gBRCAm OC	Baituowei (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
				Tislelizumab PD-1 1L ESCC	Tislelizumab PD-1 1L NPC	Tislelizumab PD-1 2L/3L+HCC
Lung			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
				Tislelizumab PD-1 1L ES-SCLC		
Pan tumor /Other	Tislelizumab PD-1 Subcutaneous administration		Tislelizumab PD-1 1L UBC	Tislelizumab PD-1 2L UC	Tislelizumab PD-1 MSI-H/dMMR ST	

BeiGene: a Leader in Hematology / I&I portfolio – Innovative NMEs

	Phase 1	Phase 2	Phase 3
AML/MDS, Multiple Myeloma, Other Heme	<p>Sonrotoclax BCL2i AML/MDS</p>	<p>Sonrotoclax BCL2i Multiple Myeloma with t(11;14)</p>	
B-Cell	<p>BGB-21447 BCL2i next gen. B-Cell Malignancies</p>	<p>Ociperlimab TIGIT R/R DLBCL</p>	
	<p>Sonrotoclax BCL2i B-Cell Malig.(China)</p>	<p>Sonrotoclax BCL2i mono & combo w/ zanu (Global)</p>	
	<p>BGB-16673 BTK CDAC B-Cell Malig. (China)</p>	<p>BGB-16673 BTK CDAC B-Cell Malig. (Global)</p>	
		<p>BGB-16673 BTK CDAC R/R MCL & R/R CLL</p>	
		<p>Sonrotoclax BCL2i R/R MCL</p>	
			<p>Sonrotoclax BCL2i TN CLL combo + zanu</p>
I&I	<p>BGB-45035 IRAK4 CDAC</p>		

BeiGene: a Leader in Hematology / I&I With LCM

	Phase 1	Phase 2	Phase 3	Approved			
AML/MDS, Multiple Myeloma, Other Heme		BLINCYTO® CD3/CD19 BiTE Pediatric R/R BP-ALL	Tislelizumab PD-1 R/R cHL (China)	Tislelizumab PD-1 R/R cHL			
B-Cell	Zanubrutinib BTKi R/R DLBCL Revlimid combo	Zanubrutinib BTKi Previous BTKi Tx ibru/acala intolerant	Zanubrutinib BTKi R/R CLL/SLL, WM, MCL (JP)	Zanubrutinib BTKi TN MCL	Zanubrutinib BTKi R/R MZL, R/R FL	Zanubrutinib BTKi TN CLL/SLL	Zanubrutinib BTKi R/R CLL/SLL
		Zanubrutinib BTKi R/R B-cell lymphoma	Zanubrutinib BTKi CD98B R/R DLBCL	Zanubrutinib BTKi TN CLL Venetoclax combo		Zanubrutinib BTKi R/R MCL	Zanubrutinib BTKi R/R MZL
					Zanubrutinib BTKi R/R FL	Zanubrutinib BTKi TN WM	
I&I		Zanubrutinib BTKi Lupus Nephritis		Zanubrutinib BTKi PMN			



Trial detail

- **BRUKINSA[®]** (zanubrutinib)
- **Sonrotoclax**
- **BGB-16673 BTK CDAC**
- **TEVIMBRA[®]** (tislelizumab)
- **Other Solid Tumor Assets**

BRUKINSA®

Foundational asset in hematology portfolio

Trial	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-3111-111	Phase 1	NCT04172246	B-Cell Malignancies	55		TEAEs & ORR	Active (JP)
BGB-3111-215	Phase 2	NCT04116437	Previous BTKi Tx - ibrucacala intolerant	97		TEAEs	Enrolling
BGB-3111-218	Phase 2	NCT05068440	CD79b R/R DLBCL	66		ORR	Enrolling
BGB-3111-306	Phase 3	NCT04002297	TN MCL	510	Rituximab	PFS	Active
BGB-3111-308	Phase 3	NCT05100862	R/R MZL and FL	788	Rituximab, Obinutuzumab	PFS	Enrolling
BGB-3111-LTE1	Phase 3	NCT04170283	B-Cell Malig. LTE	1323		TEAEs	Enrolling
BGB-3111-206	Phase 2	NCT03206970	R/R MCL	86		ORR	Approved
BGB-3111-212	Phase 2	NCT03332017	R/R NHL - FL	217	Obinutuzumab	ORR	Approved
BGB-3111-214	Phase 2	NCT03846427	R/R MZL	68		ORR	Approved
BGB-3111-302	Phase 3	NCT03053440	TN & R/R WM	229		CR/VGPR	Approved



Refer to Glossary abbreviations

Sonrotoclax

Potential best-in-class BCL2 inhibitor with differentiated profile

Trial	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-11417-101	Phase 1	NCT04277637	B-Cell Malignancies	438	Zanubrutinib, Obinutuzumab	TEAEs, MTD	Enrolling
BGB-11417-102	Phase 1	NCT04883957	B-Cell Malignancies	64		TEAEs, MTD	Active (China)
BGB-11417-103	Phase 1	NCT04771130	AML/MDS	265	Azacitidine	TEAEs, CR, mOR	Enrolling
BGB-11417-105	Phase 1	NCT04973605	R/R MM with t(11;14)	181	Dexamethasone, Carfilzomib	TEAEs, ORR, VGPR, CR	Enrolling
BGB-11417-201	Phase 2	NCT05471843	Post-BTKi MCL	122		TEAEs, ORR	Active
BGB-11417-202	Phase 2	NCT05479994	Post-BTKi CLL/SLL	97		ORR	Enrolling
BGB-11417-203	Phase 2	NCT05952037	R/R WM	85	Zanubrutinib	MRR	Enrolling
BGB-11417-301	Phase 3	NCT06073821	TN CLL/SLL	640	Zanubrutinib	PFS	Enrolling

BGB-16673 BTK CDAC

Potential first-in-class BTK degrader

Trial	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-16673-101	Phase 1/2	NCT05006716	B-Cell Malignancies, R/R CLL & R/R MCL	466		TEAEs	Enrolling
BGB-16673-102	Phase 1	NCT05294731	R/R MCL	127		TEAEs, RP2D, ORR	Enrolling

TEVIMBRA®

Poised for global patient impact

Trial	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-A317-103	Phase 1	NCT06091943	Subcutaneous administration	69		Bioavailability and Safety	Enrolling
BGB-HNSCC-201	Phase 2	NCT05909904	1L HNSCC	160	LAG3, TIM3	ORR	Enrolling
BGB-LC-201	Phase 2	NCT05635708	1L NSCLC	319	LAG3, OX40, HPK1, Chemotherapy	ORR	Enrolling
BGB-LC-202	Phase 2	NCT05577702	Neo/adj NSCLC	120	LAG3, Chemotherapy	MPR	Enrolling
BGB-A317-310	Phase 3	NCT03967977	1L UBC	436	Chemotherapy	OS (ITT)	Enrolling
BGB-A317-311	Phase 3	NCT03957590	Localized ESCC	366	Chemotherapy + Radiotherapy	PFS	Maintenance
BGB-A317-312	Phase 3	NCT04005716	1L ES-SCLC	455	Chemotherapy	OS	Closeout
BGB-A317-315	Phase 3	NCT04379635	Neo/adj NSCLC	450	Chemotherapy	MPR, EFS	Filed
BGB-A317-203	Phase 2	NCT03209973	R/R cHL	68		ORR	Approved*
BGB-A317-204	Phase 2	NCT04004221	2L UC	110		ORR	Approved*



* Approved only in China
Refer to Glossary abbreviations

TEVIMBRA®

Poised for global patient impact

Trial	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-A317-208	Phase 2	NCT03419897	2L HCC	250		ORR	Approved*
BGB-A317-209	Phase 2	NCT03736889	Late Line MSI-H or dMMR Solid Tumors	150		ORR	Approved*
BGB-A317-301	Phase 3	NCT03412773	1L HCC	680		OS	Approved*
BGB-A317-302	Phase 3	NCT03430843	2L ESCC	489		OS	Approved
BGB-A317-303	Phase 3	NCT03358875	2/3L NSCLC	805		OS (PDL1+), OS	Approved
BGB-A317-304	Phase 3	NCT03663205	1L Non-sq. NSCLC	334	Chemotherapy	PFS	Approved
BGB-A317-305	Phase 3	NCT03777657	1L GC	978	Chemotherapy	OS	Approved*
BGB-A317-306	Phase 3	NCT03783442	1L ESCC	650	Chemotherapy	OS	Approved*
BGB-A317-307	Phase 3	NCT03594747	1L Sq. NSCLC	342	Chemotherapy	PFS	Approved
BGB-A317-309	Phase 3	NCT03924986	1L NPC	263	Chemotherapy	PFS	Approved*



* Approved only in China
Refer to Glossary abbreviations

Phase 1 Other Solid Tumor Assets

Trial	Asset	MOA	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-A317-30813-101	BGB-30813	DGKζ	Ph1	NCT05904496	Solid Tumors	81	Tislelizumab	TEAE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
BGB-A317-A3055-101	BGB-A3055	CCR8	Ph1	NCT05935098	Solid Tumors	89	Tislelizumab	TEAE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
BGB-C9074-101	BGB-C9074	B7H4 ADC	Ph1	NCT06233942	Solid Tumors	89	Tislelizumab	TEAE, SAE, DLT, MTD, RDFE, ORR, RP2D	Dose escalation
BG-68501-101	BG-68501	CDK2i	Ph1	NCT06257264	Solid Tumors	108	Fulvestrant	AE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
BGB-24714-101	BGB-24714	SMAC	Ph1	NCT05381909	Solid Tumors	229	Chemotherapy	AE, TEAE, SAE, DLT, MTD, RDFE, ORR	Expansion
BGB-C354-101	BGB-C354	B7H3 ADC	Ph1	NCT06422520	Solid Tumors	85	Tislelizumab	AE, SAE, DLT, MTD, RDFE, ORR	Dose escalation

Phase 1 Other Solid Tumor Assets

Trial	Asset	MOA	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-43395-101	BGB-43395	CDK4i	Ph1	NCT06120283	Solid Tumors	225	Fulvestrant, Letrozole	AE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
BGB-43395-102	BGB-43395	CDK4i	Ph1	NCT06253195	Solid Tumors	78	Fulvestrant, Letrozole	AE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
BGB-900-105	BGB-A1217	TIGIT	Ph1	NCT04047862	Solid Tumors	476	Tislelizumab	AE, SAE, DLT, MTD, RDFE, ORR	Maintenance
BGB-A317-15025-101	BGB-15025	HPK1	Ph1	NCT04649385	Solid Tumors	169	Tislelizumab	AE, SAE, DLT, MTD, RDFE, ORR	Expansion
BGB-A317-26808-101	BGB-26808	HPK1 2G	Ph1	NCT05981703	Solid Tumors	90	Tislelizumab	AE, SAE, DLT, MTD, RDFE, ORR	Dose escalation
AMG509 20180146	Xaluritamig	STEAP1xCD3	Ph1	NCT04221542	mCRPC	9 (CN)		TEAE, DLTs	Start-Up
BGB-R046-101	BGB-R046	IL-15 prodrug	Ph1	NCT06487858	Solid Tumors	74 (CN)	Tislelizumab	AE, SAE, DLT, MTD, RDFE, ORR	Dose Escalation

Phase 2 Other Solid Tumor Assets

Trial	Asset	MOA	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
BGB-A317-A445-201	BGB-A445	OX40	Ph2	NCT05661955	Melanoma, UC	191	Tislelizumab	ORR	Enrolling
BGB-LBL-007-201	BGB-LBL-007	LAG3	Ph2	NCT05609370	MSS-CRC	226	Tislelizumab, Chemotherapy, Bevacizumab	PFS, AE, SAE	Enrolling
BGB-LBL-007-202	BGB-LBL-007	LAG3	Ph2	NCT06010303	1L ESCC	120	Tislelizumab, Chemotherapy	ORR	Enrolling
BGB-LC-203	BGB-A445	OX40	Ph2	NCT06029127	2L+ NSCLC	49	Chemotherapy	ORR, OS	Enrolling
ZWI-ZW25-203	Zanidatamab	HER2	Ph2	NCT04466891	2L+ BTC	100		ORR	Close-out
AMG757 20230273	Tarlatamab	DLL3xCD3	Ph2	NA	3L+ SCLC	30 (CN)			Start-Up

Phase 3 Other Solid Tumor Assets

Trial	Asset	MOA	Phase	CT.gov	Population	Total Patients	Combination Molecule	Primary Endpoint(s)	Status
ZWI-ZW25-301	Zanidatamab	HER2	Ph3	NCT05152147	1L HER2+ GEA	459	Tislelizumab ± Chemotherapy	PFS, OS	Enrolling
AdvanTIG-302	Ociperlimab	TIGIT	Ph3	NCT04746924	1L NSCLC (PDL1 H)	671	Tislelizumab	OS	Maintenance
AMG757 20200041	Tarlatamab	DLL3xCD3	Ph3	NCT06211036	ES-SCLC	95 (CN)	Durvalumab	OS	Enrolling
AMG757 20210004	Tarlatamab	DLL3xCD3	Ph3	NCT05740566	Relapsed SCLC	98 (CN)		OS	Enrolling
AMG757 20230016	Tarlatamab	DLL3xCD3	Ph3	NCT06117774	LS-SCLC	77 (CN)		PFS	Enrolling
BGB-290-302	Pamiparib	PARPi	Ph3	NCT03519230	Platinum-sensitive Recurrent OC	216		PFS	Maintenance

Glossary

Disease abbreviations	
AML	Acute myeloid leukemia
BP-ALL	B-precursor acute lymphocytic leukemia
BTC	Biliary tract cancer
CHL	Classic Hodgkin's lymphoma
CLL	Chronic lymphocytic leukemia
dMMR	Deficient DNA mismatch repair
DLBCL	Diffuse large b-cell lymphoma
ES-SCLC	Extensive stage small cell lung cancer
ESCC	Esophageal squamous cell carcinoma
FL	Follicular lymphoma
GEA	Gastroesophageal adenocarcinoma
GC	Gastric cancer
HCC	Hepatocellular cancer
HNSCC	Head & neck squamous cell carcinoma
LS-SCLC	Limited stage small cell lung cancer
MCL	Mantle cell lymphoma
mCRPC	Metastatic castration resistant prostate cancer
MDS	Myelodysplastic syndromes
MM	Multiple myeloma
MSI-H	Microsatellite stability high
MSS CRC	Microsatellite stable colorectal cancer
MZL	Marginal zone lymphoma
Neo/adj	Neoadjuvant/adjuvant
NSCLC	Non-small cell lung cancer
NPC	Nasopharyngeal carcinoma

Disease abbreviations (continued)	
OC	Ovarian cancer
PMN	Primary membranous nephropathy
R/R	Relapsed or refractory
SCLC	Small cell lung cancer
SLL	Small lymphocytic leukemia
UC / UBC	Urinary / bladder cancer
WM	Waldenstrom macroglobulinemia

Other abbreviations	
ADC	Antibody drug conjugate
AE	Adverse events
AUS	Australia
BR	Brazil
CDAC	Chimeric degradation activating compound
CH	Switzerland
CN	China
CR	Complete response
DCR	Disease control rate
DLT	Dose-limiting toxicity
DOR	Duration of response
EFS	Event free survival
LCM	Lifecycle management
LTE	Long-term extension
mAb	Monoclonal antibody
mOR	Modified overall response
MPR	Major pathological response
MTD	Maximum tolerated dose
MTx	Maintenance
ORR	Objective response rate
OS	Overall survival
PCR	Pathologic complete response
PFS	Progression-free survival
RDFE	Recommended dose for expansion
RP2D	Recommended phase 2 dose
SAE	Severe adverse events
TEAE	Treatment emergent adverse events
TN	Treatment naïve
Tsp	Tri-specific antibody
VGPR	Very good partial response



BeiGene