# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 8-K

### CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 17, 2016

### BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction of incorporation)

001-37686

(Commission File Number)

98-1209416

(I.R.S. Employer Identification No.)

c/o Mourant Ozannes Corporate Services (Cayman) Limited 94 Solaris Avenue, Camana Bay Grand Cayman KY1-1108 Cayman Islands

(Address of principal executive offices) (Zip Code)

+1 (345) 949 4123

(Registrant's telephone number, including area code)

#### Not Applicable

(Former name or former address, if changed since last report)

ie appr is:	ropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
	ns:

### Item 8.01 Other Events.

BeiGene, Ltd. (the "Company") is providing certain business updates in the materials attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	<u> </u>	Description	
99.1	BeiGene, Ltd. materials dated November 2016		
		2	

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### BEIGENE, LTD.

Date: November 17, 2016 By: /s/ Howard Liang

Name: Howard Liang

Title: Chief Financial Officer and Chief Strategy Officer

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### **Exhibit Index**

Exhibit No.	Description
99.1	BeiGene, Ltd. materials dated November 2016
	4





November 2016

# **Forward Looking Statements**

Certain statements contained in this 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 those regarding investigational drug candidates and clinical trials and the status and related results thereto, as well those regarding continuing and further development efforts. Such statements, based as they are on the current analysis and expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond BeiGene's control. Such risks include but are not limited to: the impact of general economic conditions, general conditions in the pharmaceutical industries, changes in the global and regional regulatory environments in the jurisdictions in which BeiGene does business, market volatility, fluctuations in costs and changes to the competitive environment. Consequently, actual future results may differ materially from the anticipated results expressed in the forward-looking statements. In the case of forward-looking statements regarding investigational drug candidates and continuing further development efforts, specific risks which could cause actual results to differ materially from BeiGene's current analysis and expectations include: failure to demonstrate the safety, tolerability and efficacy of our drug candidates, final and quality controlled verification of data and the related analyses, the expense and uncertainty of obtaining regulatory approval, including from the FDA, CFDA and EMA, and the possibility of having to conduct additional clinical trials. Further, even if regulatory approval is obtained, pharmaceutical products are generally subject to: stringent on-going governmental regulation, challenges in gaining market acceptance and competition. These statements are also subject to a number of material risks and uncertainties that are described in BeiGene's filings with the Securities and Exchange Commission. The reader should not place undue reliance on any forward-looking statements included in this presentation. These statements speak only as of the date made, and BeiGene is under no obligation and disavows any obligation to update or revise such statements as a result of any event, circumstances or otherwise, unless required by applicable legislation or regulation.



# **Broad Pipeline of Internally Discovered Agents**

Potentially Differentiated and Rationally Designed Pipeline

Program	Mechanism of Action	Commercial Rights	Preclinical	Dose Escalation	Dose Expansion	Registration	Potential Differentiation
BGB-3111	втк	Worldwide			<b>&gt;</b>		Deeper target suppression enabled by improved selectivity and exposure
BGB-A317	PD-1	Worldwide			<b>&gt;</b>		Fc receptor binding has been engineered out
BGB-290	PARP	Worldwide <sup>1</sup>			<b>&gt;</b>	N.	Significant brain penetration, strong DNA trapping and high selectivity
BGB-283	RAF Dimer	China <sup>2</sup>			-		Inhibits monomer and dimer forms of RAF; potential activity in RAS

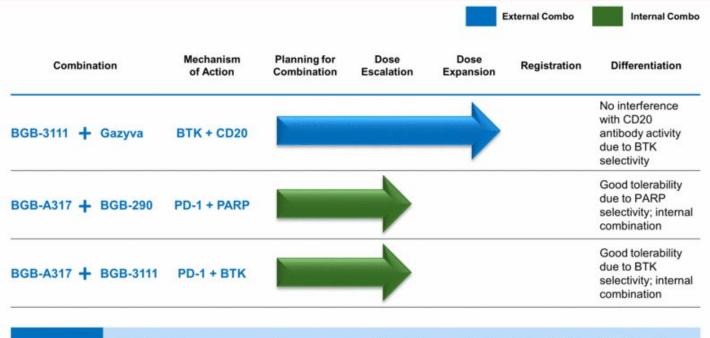
In total, over **800** patients and healthy adults<sup>3</sup> treated across 4 programs including combination trials



BeiGene Note: 1 Limited collaboration with Merck KGaA; 2 Partnered with Merck KGaA outside China; 3 As of November 7, 2016

# **Combinations in Development**

**Broad Internal Portfolio Provides Advantages in Combination Therapy** 



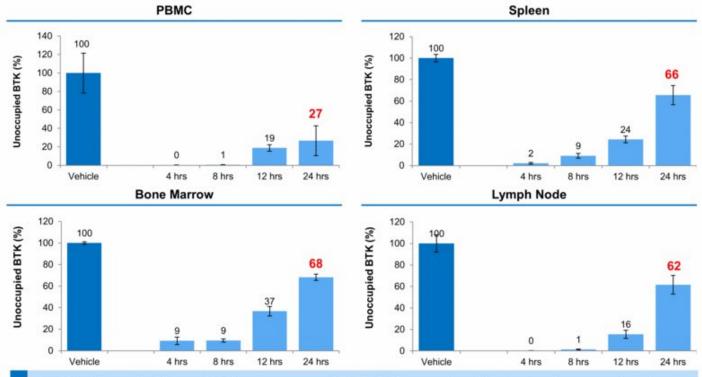
Combination Potential

- We believe we are one of two companies with wholly owned, clinical-stage PD-1 and BTK inhibitors
- We believe we are one of a small number of companies with internal combinations of PD-1 + PARP inhibitors
- Potential for RAF dimer / PD-1 inhibitor combination based on internal data
- Broad preclinical programs target multiple points in the immunity cycle



### Target Inhibition by Ibrutinib in Disease-Relevant Tissues Is Not Sustained

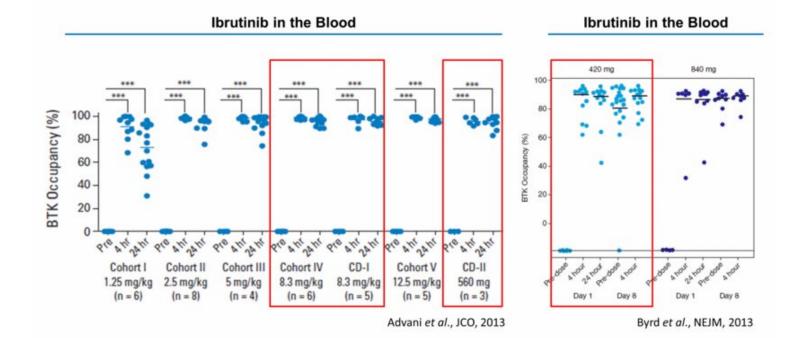
Preclinical models showed significant recovery of target occupancy in disease relevant tissues for ibrutinib



 Better bioavailability and higher exposure of BGB-3111 may allow deeper target suppression in disease-relevant tissues and potentially impact efficacy



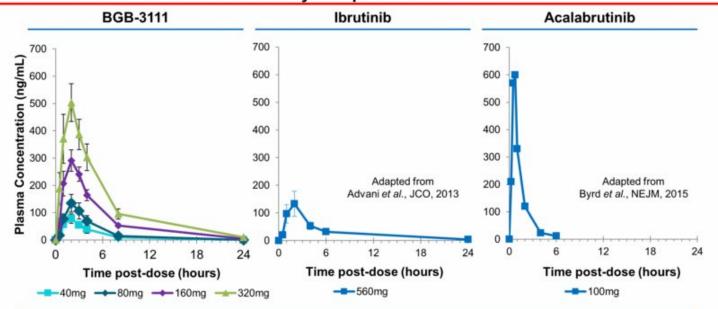
BeiGene Note: PBMC = Peripheral Blood Mononuclear Cell; Source: BeiGene data on file



Approved Ibrutinib Doses: 560 mg for MCL; 420 mg for CLL and WM



Greater Drug Exposure in Humans Seen When Compared with Ibrutinib, and Longer Half-life and Greater In Vitro Potency Compared with Acalabrutinib



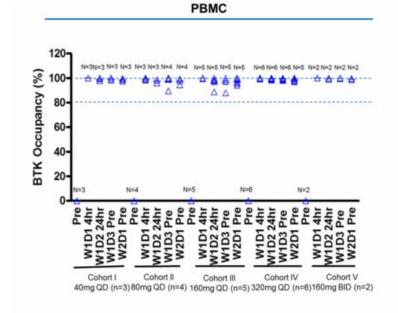
In V	itro BTK Inhibition IC50 Relative to Ib	rutinib
BGB-3111	Ibrutinib	Acalabrutinib
1.11	1	3.4 <sup>2</sup> -7.2 <sup>3</sup>

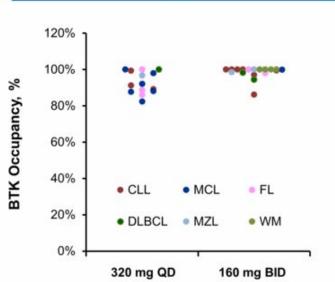
- C<sub>max</sub> and AUC of BGB-3111 at 80 mg is similar to those of ibrutinib at 560 mg
- Free drug exposure of BGB-3111 at 40 mg is comparable to that of ibrutinib at 560 mg
- Distinct profile compared to acalabrutinib which has a short half-life (1 hour)<sup>2</sup> and lower in vitro potency<sup>1-4</sup>



BeiGene Source: 1 Tam et al., ASH, 2015; 2 Byrd et al., NEJM, 2015; 3 Lannutti et al., AACR, 2015, 4BeiGene data on file

### Complete and Sustained BTK Inhibition in Tissues as a Result of High Exposure





Lymph Node

- Complete BTK inhibition in PBMCs at the starting dose (40 mg)
- Paired lymph node biopsies were collected during screening or pre-dose on day 3
- Median trough occupancy: 100% (160 mg BID) vs 94% (320 mg QD), p=0.002
- Proportion ≥90% trough occupancy: 94% (160 mg BID) vs 58% (320 mg QD), p=0.027



BeiGene Note: PBMC = Peripheral Blood Mononuclear Cell; Source: Tam et al. ASH 2015 and Tam et al. 9th IWWM 2016

### Well-Tolerated and Highly Active in R/R CLL/SLL: Phase I Data in CLL

- As of June 10, 2016, 45 patients with chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) have been enrolled in the BGB-3111 first-in-human phase I trial; 29 patients were evaluable
- BGB-3111 was well tolerated:
  - 69% subjects reporting no dose related AE>Gr 1 severity within the first 12 weeks of therapy
  - The most common AEs of any attribution were petechiae / bruising (38%), upper respiratory infection (31%, all Gr 1/2), diarrhea (28%, all Gr 1/2), fatigue (24%, all Gr 1/2), and cough (21%, all Gr 1/2)
  - There are three SAEs (Gr2 cardiac failure, Gr2 pleural effusion and Gr3 purpura) assessed as possibly related to the drug by investigators: Gr3 purpura is the only major bleeding event reported. Three patients had temporary dose interruption for AE, and one discontinued BGB-3111 for AE
- After a median follow-up of 7.5 months (2.9-17.3 months), the response rate is 90% (26/29), with PR in 79% (23/29) and, PR-L in 10% (3/29), SD in 7% (2/29), and non-evaluable response in one patient who discontinued treatment prior to week 12; no instances of disease progression or Richter transformation have occurred
- An updated analysis is currently being conducted for presentation at ASH meeting in December based on data cutoff date of October 3, 2016 and includes an additional 17 patients (all with less than 6 months follow-up). Based on a provisional analysis, which is subject to ongoing data validation, the objective response rate is 93% (43 out of 46 patients). Compared to the analysis for ASH abstract publication, no additional patients have discontinued study treatment for adverse event or progressive disease, and, based on serious adverse event reporting, no new safety signals have been identified.

BeiGene Source: Tam et al., ASH 2016 Abstract

### Phase I Data in Waldenström's Macroglobulinemia

- As of September 9, 2016, 41 patients with Waldenström's Macroglobulinemia (WM) have been enrolled in the BGB-3111 first-in– human phase 1
- 24 WM patients are included in this analysis
  - At least 12 weeks follow-up as of June 10, 2016, the data cut-off date
- Median follow-up for evaluable patients= 8.0 months (3.3–21 months)
- MYD88 and CXCR4 sequencing was not included in the original protocol; samples were requested with additional consenting and this analysis is underway
- Only 1 patient has discontinued BGB-3111 (exacerbation of underlying bronchiectasis while in VGPR); remainder of patients remain on study treatment

# Favorable Safety Profile: Adverse Events Independent of Causality in Phase I Trial in WM

DOD 2444 (**-24)	Grade 1-2		Grade 3-4*		All Grade	
BGB-3111 (n=24)	n	%	n	%	n	%
Upper Respiratory Tract Infection	6	25%	0	0%	6	25%
Diarrhoea	6	25%	0	0%	6	25%
Petechiae/ contusion/ bruising	5	21%	0	0%	5	21%
Nausea	5	21%	0	0%	5	21%
Rash	4	17%	0	0%	4	17%
Neutropenia	3	13%	1	4%	4	17%
Constipation	3	13%	0	0%	3	13%
Events of Special Interest			12 8			
Atrial Fibrillation	1	4%	0	0%	1	4%
Serious Hemorrhage	0	0%	0	0%	0	0%

<sup>\*</sup>Additional ≥Gr3 events: anemia (n=2), foot fracture, renal artery thrombosis, bronchiectasis, thrombocytopenia, hypertension, cryptococcal meningitis (all n=1)

- The most common AEs in WM pts were Gr1-2 upper respiratory infection (25%), diarrhea (25%), and nausea (21%)
- Two SAEs (Gr2 AF and Gr3 cryptococcal meningitis) were assessed as possibly related to the drug by investigators; in both cases, BGB-3111 was temporarily held but safely resumed
- No serious hemorrhage (≥Gr3 or CNS hemorrhage of any grade) was reported

### Deep Responses in WM: Phase I Trial Efficacy Summary in WM

Total
8.0 months (3.3–21 months)
N = 24
0
8 (33%)
12 (50%)
2 (8%)
2 (8%)
20 (83%)
22 (92%)
29.9 g/L to 3.0 g/L (90%)
10.1 g/dl to 13.5 g/dl
8/8 (27–100%)

Modified Sixth International Workshop on WM (IWWM) criteria

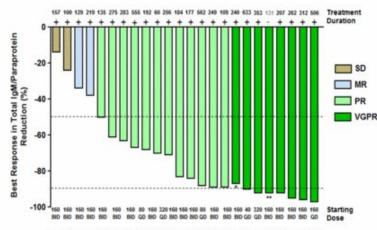
- The preliminary clinical data demonstrate that BGB-3111 is highly active in WM, with an overall response rate of 92%, including major response in 83% and VGPR in 33%, at a median follow-up time of 8.0 months
- At median follow-up of 8 months (up to 21 months), no disease progression has been observed
- An updated analysis is currently being conducted for presentation at ASH meeting in December based on data cutoff date of October 3, 2016 and includes an additional 8 patients (all with less than 6 months follow-up, median 3.8 months). Based on a provisional analysis, which is subject to ongoing data validation, the major response rate is 78% (25 out of 32 patients), with 34% (11 out of 32 patients) of patients achieving VGPR. Compared to the data presented at the IWWM conference, no additional patients have discontinued study treatment for adverse event or progressive disease, and, based on serious adverse event reporting, no new safety signals have been identified.

<sup>\*\*≥90%</sup> IgM reduction (or normal IgM level) and reduction in extramedullary disease (if present at baseline)

### Rapid and Deep Responses in WM and in More Difficult-to-Treat Patients: Phase I Trial in WM

Post-Treatment IgM Reduction (vs. Baseline)

Response by Mutation Status



<sup>\*</sup>The degree of reduction in serum IgM level is the basis of response assessment in Waldenstrom's Macroglobulinemia: ≥25% -<50% = minor response; ≥50% <90% = partial response; ≥90% -<100% = very good partial response; and absence of clonal IgM = complete response.

	Best Response						
Genotype*	CR	VGPR	PR	MR	SD		
MYD88 <sup>L265P</sup> (n=12)	0	6 (50%)	5 (42%)	0	1		
<i>MYD88<sup>WT</sup></i> (n=3)	0	0	1	1	1		

<sup>\*</sup> CXCR4 status is available for seven patients (all CXCR4wt)

Preliminary sequencing data suggest high VGPR rate in patients with the MYD88<sup>L265P</sup> genotype (6/12) as well as documented response in more difficult-to-treat patients with MYD88WT



### Favorable Response Rate and Depth vs. Ibrutinib' in WM: Comparison of Response Rates to Historical Data on Ibrutinib with Comparable Follow-Up Time

Molecule (Trial)	BGB-3111 (Phase I)	Ibrutinib (Treon)	Ibrutinib (PCYC-1127)
Trial Size	24	63	31
Median Follow-Up	8.0 months	6.0 months	7.7 months
Major Response (VGPR)	83% (33% VGPR)	57%* (6% VGPR)	65%# (VGPR NR)
MR	8%	24%	19%
SD	8%	17%	16%
Median IgM Reduction	90%	63%	NR

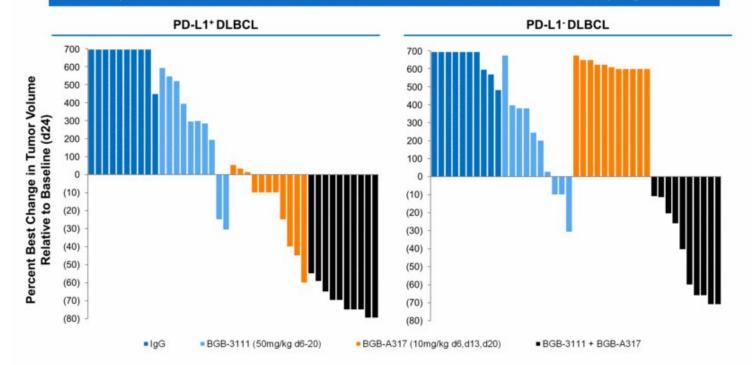


BeiGene Source: Tam et al, IWWM, 2016; Treon et al, ASH, 2013; Dimopoulos et al, Blood, 2015; Treon et al, NEJM, 2015; Dimopoulos et al., EHA, 2016

<sup>^</sup> Cross-trial comparisons \* Long-term follow-up (median treatment duration 19.1 months): Major RR 73%, VGPR (IgM only) 16% # Long-term follow-up (median follow-up 17.1 months): Major RR 71%, VGPR 13% (modified IWWM-6) NR = Not Reported

### Strong Rationale to Combine Our BTK and PD-1 Inhibitors

In Primary DLBCL Tumor Models, the Combination of Our BTK and PD-1 Inhibitors Shows Synergistic Effect



 Enhancement of PD-1 antibody activity by a selective BTK inhibitor in both PD-L1-positive and especially in PD-L1-negative DLBCL models



# **BGB-A317**

### Most Common Treatment-Related Adverse Events

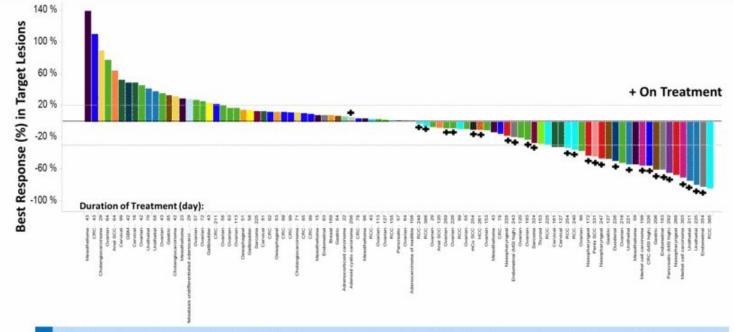
Suntan arran alasa/Fuanta (N49/)	All	Grade	Gr	ade 3-4
System organ class/Events (≥1%)	n	% (N=103)	n	% (N=103)
General disorders and administration site conditions				
Fatigue	20	19.4%	2	1.9%
Gastrointestinal disorders				
Diarrhea	13	12.6%	0	0%
Nausea	8	7.8%	0	0%
Colitis	4	3.9%	1	1.0%
Skin and subcutaneous tissue disorders				
Pruritus	11	10.7%	0	0%
Rash	11	10.7%	0	0%
Endocrine disorders				
Hypothyroidism	7	6.8%	0	0%
Injury, poisoning and procedural complications				
Infusion related reaction	6	5.8%	0	0%
Investigations				
ALT increased	5	4.9%	1	1.0%
GGT increased	1	1.0%	1	1.0%
Vascular disorders				
Hypotension	2	1.9%	2	1.9%
Metabolism and nutrition disorders				
Hyperglycaemia	2	1.9%	2	1.9%
Diabetes mellitus	2	1.9%	1	1.0%
Diabetic ketoacidosis	1	1.0%	1	1.0%
Respiratory, thoracic and mediastinal disorders				
Pneumonitis	2	1.9%	1	1.0%
Dyspnoea	1	1.0%	1	1.0%
Hypoxia	1	1.0%	1	1.0%
Musculoskeletal and connective tissue disorders				
Back pain	2	1.9%	1	1.0%

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BeiGene Source: Phase I data as of September 30, 2016, presented at SITC 2016 (Desai et al)

## **BGB-A317**

### Best Response in Target Lesions from Baseline



- A mixed patient population of 27 different tumor types was included in this data analyses, in which patients with melanoma, NSCLC or head and neck cancer were not enrolled, and patients with RCC and urothelial carcinoma together represented close to 15% of the enrolled patients
- Ninety-nine patients were evaluable for efficacy assessment as of September 30, 2016, and 15 patients achieved confirmed PRs including 3/9 RCC, 3/6 urothelial carcinoma, 2/4 gastric cancer, 2/2 Merkel cell carcinoma, 1/4 NPC, 1/1 penis squamous cell carcinoma, 1/1 duodenal carcinoma, 1/1 evaluable MSI-h CRC, 1/1 MSI-h pancreatic cancer



Note: Ninety-three pts included in the analyses, the remainder 6 pts were not evaluable for target lesion response **BeiGene** Source: Phase I data as of September 30, 2016, presented at SITC 2016 (Desai *et al*)

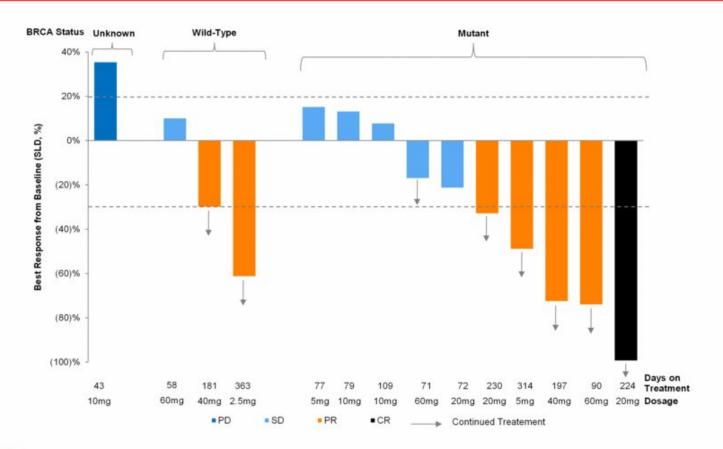
# Well Tolerated to Date, with Minimal Drug-related Adverse Events from Dose Escalation Study

	All (	Grade 3-4		
Description	N(pts)	%(n=29)	N(pts)	%(n=29)
Gastrointestinal Disorders		13.		77 78
Nausea	11	38%	0	
Vomiting	4	14%	0	
Diarrhea	3	10%	0	
Dry Mouth	1	3%	0	
General Disorders and Administration Site Conditions				
Fatigue	8	28%	0	
Nervous System Disorders				
Lethargy	2	7%	0	
Dysgeusia	1	3%	0	
Hypoesthesia	1	3%	0	
Blood and Lymphatic System Disorders				
Neutropenia	2	7%	1	3%
Anaemia	1	3%	1	3%
Thrombocytopenia	1	3%	0	
Metabolism and Nutrition Disorders				
Hypophosphatemia	1	3%	1	3%
Hypokalemia	1	3%	1	3%
Decreased Appetite	1	3%	0	
Vascular Disorders				
Hot Flush	1	3%	0	

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BeiGene Source: Dose escalation data as of June 30, 2015, presented at AACR-NCI-EORTC 2015 meeting (Lickliter et al)

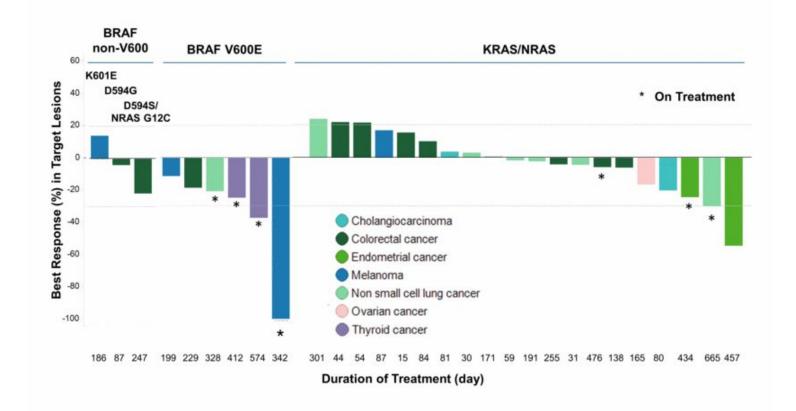
## Significant Activity Seen in Ovarian Cancer Patients



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BeiGene Source: Dose escalation data as of June 30, 2015, presented at AACR-NCI-EORTC 2015 meeting (Lickliter et al)

### Best Objective Response in Target Lesions from Baseline



BeiGene Source: Dose escalation data as of January 31, 2016, presented at AACR 2016 (Desai et al)