

# 当前 BeiGene

January 7, 2018

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## **BeiGene Company Overview**

- Founded in 2010 in Beijing as an R&D organization focused on developing best-in-class oncology therapeutics
  - Three proprietary programs: zanubrutinib (BTK inhibitor), tislelizumab (PD-1 antibody) and pamiparib (PARB inhibitor) have initially come from these efforts
- In the past few years, BeiGene has evolved into a fully integrated, global biotechnology company
  - Integrated, global team with over 850 employees and a deep presence in both US and China
  - Full capabilities from R&D to manufacturing, with a commercial presence in China
- Poised to realize two significant, program-based opportunities
  - Globally commercialize zanubrutinib, a potentially best-in-class BTK inhibitor
    - Data to date supportive of BIC activity, supporting broad registrational program, including head-to-head comparisons with ibrutinib ongoing or planned in WM and CLL
    - Global development team with deep expertise in lymphoid malignancies
  - Develop and successfully commercialize a PD-1 inhibitor in a rapidly and favorably evolving China market
    - Experienced and dedicated China-based development team
    - Established commercial team (via Celgene deal)
    - Only China developed PD-1 undertaking broad global development and likely to have global label
    - Large-scale biologics manufacturing capabilities under construction

Significant regulatory reforms in China provide access to over twice the cancer patients accessible for global development in EU and US

- Few multinational pharmaceutical companies have the ability to operate effectively in China
- We believe BeiGene is well-positioned to take advantage of the opportunity
- Celgene collaboration on tislelizumab leverages this China opportunity and BeiGene's strong China presence by integrating global and China development
  - Nine global Phase 3 studies planned (including US and China), with additional studies ongoing
  - Potential NDA filing in China in 2018
  - Collaboration provides commercial infrastructure and marketed product portfolio in China, positioning BeiGene well for planned launch of internally developed products



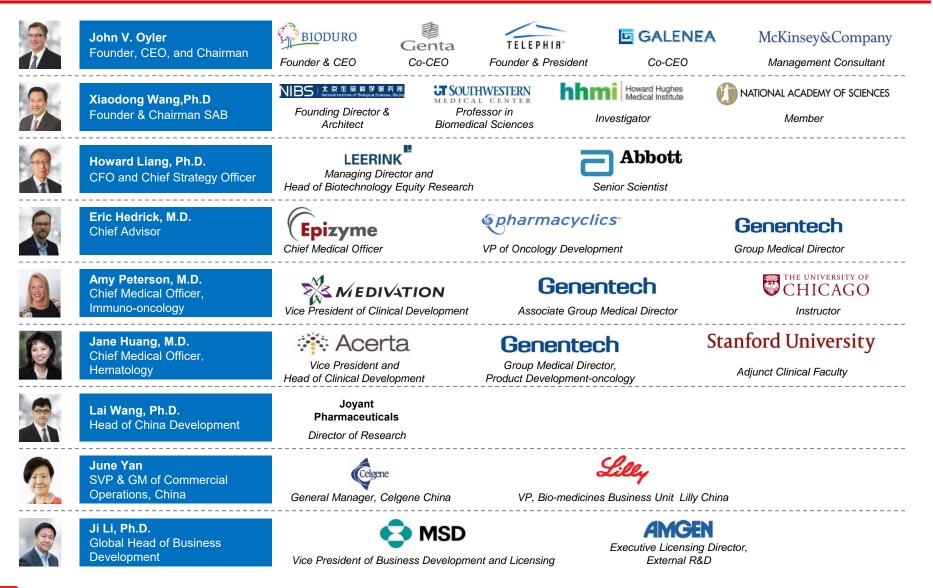
## **Broad Capabilities in China and Globally**

#### 850+ person global biotech company poised in the near-term to potentially:

- Bring a potentially best-in-class BTK inhibitor to the global market
- Develop and successfully commercialize a PD-1 inhibitor in a rapidly and favorably evolving China market
- Drive continued development and commercialization of novel cancer therapeutics for the global market over time

Research	Development	Manufacturing Commercial
Proprietary cancer biology platform	<ul> <li>Over 40 ongoing clinical trials with over 2,000</li> </ul>	<ul> <li>Commercial-scale small</li> <li>Integration of Celgene</li> <li>China commercial</li> </ul>
<ul> <li>World-renowned scientific advisory board</li> </ul>	patients dosed (including 650+ in China)	biologics manufacturing organization that mark facility in Suzhou ABRAXANE®,
Working relationships with key Chinese cancer	<ul> <li>Global clinical team: US (150+), China (140+), AU (10+)</li> </ul>	<ul> <li>Building 24,000 L state of the art GE commercial-scale</li> <li>REVLIMID®, and VIDAZA®</li> <li>Growing team to bolst</li> </ul>
	<ul> <li>Strong relationships with</li> </ul>	biologics manufacturing commercial infrastruct
Experienced leadership team driving R&D innovation engine	leading KOLs in China and globally	facility in Guangzhou Commercial organizat supports potential laur
<ul> <li>150+ research team</li> </ul>	<ul> <li>Single clinical trials designed for both global and China registration</li> </ul>	of pipeline products in China

## **Experienced Leadership Team**



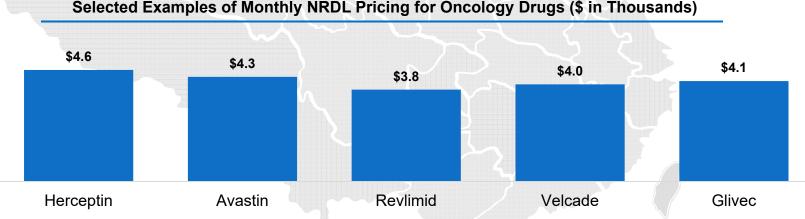
# CFDA Reforms Expected to Make China Integral to Global Oncology Development and Commercialization

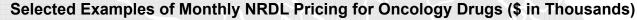
#### CFDA reforms expand China's role in global development

- Reforms expand patient access to clinical trials and encourage China centers to be part of global early phase studies by addressing application backlogs and potentially accelerating CTA approval time under CFDA proposed changes
- CFDA joined ICH in June 2017 and set international quality standards for China trials, further facilitating China data to contribute to global clinical development
- Ability to effectively operate in China can significantly enhance global development
  - With patient access often a key limiting factor in oncology development, adding China could significantly
    accelerate enrollment of global clinical trials (greater than EU and US combined)
  - KOL relationships critical to successfully incorporating China
  - Few global biopharmaceutical companies have the ability to leverage this opportunity
  - May substantially reduce overall cost
- China's commitment to national reimbursement makes China an increasingly critical market for leading oncology assets
  - Fundamental shift from a niche, high-priced market to a volume market due to reimbursement
  - Change implies a need for large-scale, truly national distribution with medical expertise
  - We believe BeiGene's combination of a world class clinical development and operations team and an experienced commercial team in China is unique and differentiates us from others
    - Over 300 development professionals support assets from clinical trial design to regulatory approval in China and globally, with strong KOL relationships
  - Over 170 commercial professionals (and growing) currently supporting oncology drug sales nationwide in China
  - Emphasis on quality has long been the focus for BeiGene
  - BeiGene is already a first mover in a new paradigm as it initiates with Celgene nine trials designed for both China and global approval

# China Commercial Opportunity Expected to Expand Significantly

- China is the second largest pharmaceutical market as measured by patients and drug revenue, and growing dramatically
  - Total drug sales of \$115bn in 2015, historic oncology growth >20%, prior to recent reforms
- Expanding reimbursement coverage could significantly increase commercial opportunity
  - The latest National Reimbursed Drug List (updated July 2017) includes premium, innovative drugs
  - Patient out-of-pocket pay has been reduced (~40-80%)
  - Provincial-level reimbursement is also expanding, e.g. Zhejiang just added a list of premium drugs to its critical illness program, such as Tasigna, Sutent, Abraxane, and Zelboraf







\* Monthly cost is based on NRDL price, PAP not included in calculation as only limited PAP were continued after NRDL inclusion; exchange rate: 1 RMB to 0.15062 dollars. Source: CFDA Southern Medicine Economic Research Institute; NDRL update, McKinsey Research (September 2017), Wall Street research

# Near-Term Opportunities Through Celgene Collaboration

- Broad development strategy leverages BeiGene's China capabilities, while addressing the market opportunity for PD-1, both in China and globally
- Nine pivotal, global clinical trials planned to run in conjunction with Celgene
  - Focus on four highest incidence solid tumors in Asia (NSCLC, Gastric, Esophageal, HCC)
  - Two BeiGene-led trials already in-progress: 1L HCC (vs. sorafenib) and 2L NSCLC (vs. docetaxel)
  - Potential for first NDA filing for tislelizumab in China in 2018
- BeiGene is leading six of the nine global trials, Celgene is funding some and can opt-in to others
  - Upon an opt-in, BeiGene will be reimbursed for agreed-upon development costs based on an attractive multiple that varies according to the stage of development
  - These 6 trials are first wave of dual purpose (China and Global) designed trials to be initiated
  - Strong economic and strategic synergy that makes this broad of a program attractive
- BeiGene has begun marketing in-licensed products in China already, and is preparing for potential additional China product launches to form a commercial organization with critical mass to succeed
  - Sales in China of in-licensed products in 2017 and expectation of additional sales in 2018 (ABRAXANE®, REVLIMID®, and VIDAZA®)
  - Integration of Celgene's China commercial team, combined with additional hires to form an expanding commercial organization in China



# **Overview of Zanubrutinib (BGB-3111)**

#### **Potentially Best-in-Class BTK Inhibitor**

Overview	<ul> <li>Potential pharmacologic advantages of zanubrutinib could allow for complete, sustained, and selective BTK inhibition in all tissue compartments</li> <li>— Development hypothesis: This may translate into higher quality responses and tolerability advantages over ibrutinib</li> </ul>
Clinical Data	<ul> <li>Clinical experience to date supports best-in-class hypothesis         <ul> <li>Strong suggestion of deeper responses in WM</li> <li>Favorable response rate, depth and durability in CLL</li> <li>Potentially differentiated activity in combination with CD20 antibodies – high overall and complete response rates in FL with obinutuzumab combination</li> </ul> </li> <li>Paucity of treatment discontinuations for adverse events or progression in CLL and WM</li> </ul>
Development Plan	<ul> <li>Broad global registrational trial plan in multiple indications, including CLL, WM, and FL (potential for global first in class approval)</li> <li>Accelerated approval trials in China for CLL, MCL, and WM</li> <li>Head-to-head Phase 3 trial versus ibrutinib in WM ongoing, head-to-head Phase 3 trial in relapsed/refractory CLL planned</li> </ul>
Key Expected Catalysts in 2018	<ul> <li>Present updated Phase I monotherapy or combination data at a medical conference</li> <li>Present China pivotal trial data</li> <li>Initiate head-to-head Phase 3 trial versus ibrutinib in R/R CLL</li> <li>NDA submission in China</li> <li>Completion of global WM registrational trial enrollment (Q3)</li> </ul>



# Zanubrutinib Clinical Program

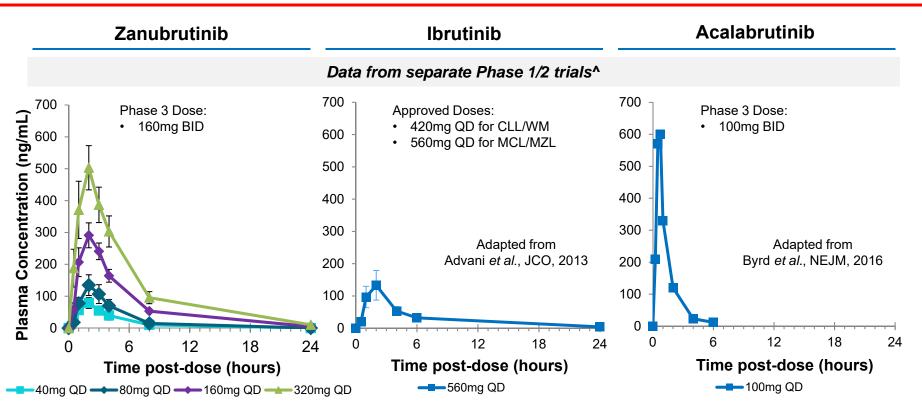
_						China Glo	bal (ex-China)	
Program	Commercial	Dose Escalation		Dose Exp	Dose Expansion*		Pivotal**	
(Target)	Rights	Preclinical	Phase 1a	Phase 1b	Phase 2	Phase 2	Phase 3	
		Waldenstrom's ma	croglobulinemia (WM)	-		1		
		WM						
	Worldwide	Treatment-naïve chronic lymphocytic leukemia (CLL)						
Zanubrutinib (BGB-3111) (BTK)		Relapsed / Refract	tory (R/R) CLL					
(=,		R/R mantle cell lyr	mphoma					
		R/R diffuse large E	3-cell lymphoma					
		B-cell malignancie	S					
Zanubrutinib + Gazyva®	Worldwide	R/R follicular lymp	homa					
(BTK + CD20)	WONGWIGE	B-cell malignancie	S					

#### Over 800 patients and healthy adults' enrolled across zanubrutinib program, including combination trials



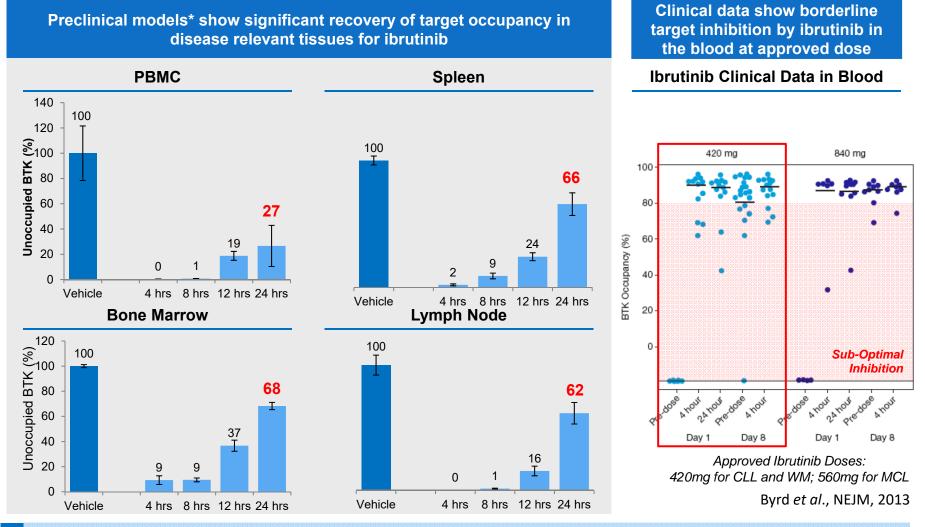
\*Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or 3 clinical trials. \*\*Confirmatory clinical trials post approval are required for accelerated approvals. 1As of December 1, 2017.

## Zanubrutinib Pharmacokinetics Profile



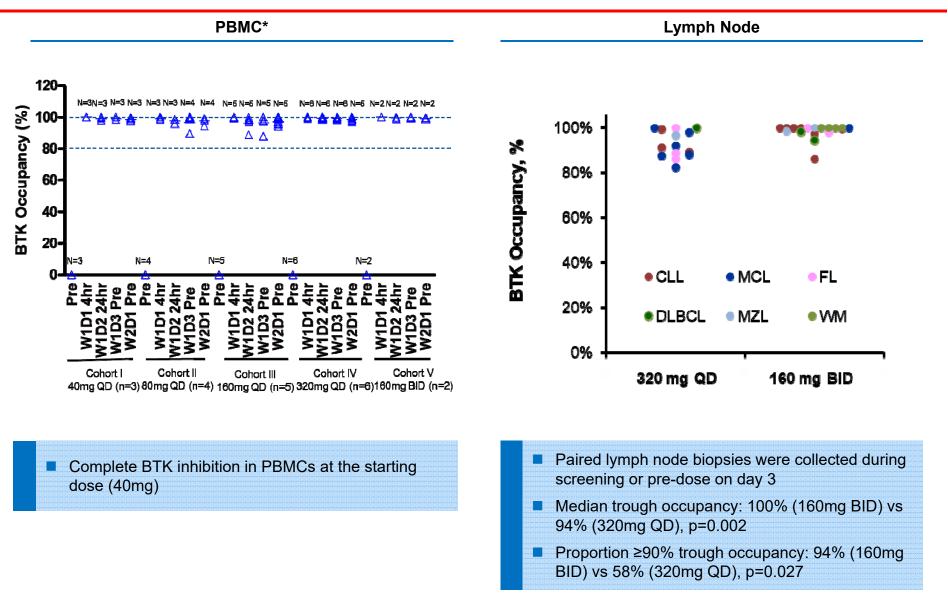
- C<sub>max</sub> and AUC of zanubrutinib at 80mg QD appear to be similar to those of ibrutinib at 560mg
- Free drug exposure of zanubrutinib at 40mg QD appears to be comparable to that of ibrutinib at 560mg
- Distinct profile compared to acalabrutinib which has a short half-life (1 hour)<sup>2</sup> and lower in vitro BTK inhibition IC50<sup>1-4</sup>
- In vitro BTK inhibition IC50 relative to ibrutinib: 1.1<sup>1</sup> (zanubrutinib) and 3.4<sup>2</sup>-7.2<sup>3</sup> (acalabrutinib)

### **BTK Occupancy Is Not Sustained With Ibrutinib**

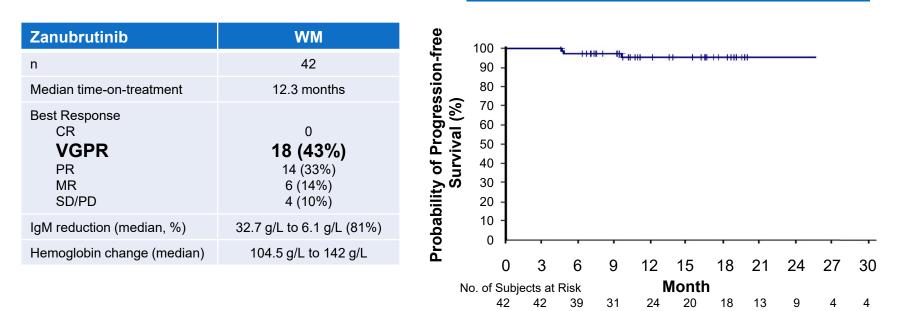


# Potentially better bioavailability and higher exposure of zanubrutinib may allow deeper target suppression in disease-relevant tissues

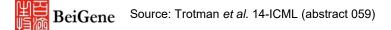
#### **Zanubrutinib** Complete and Sustained BTK Occupancy to Date in Blood and Lymph Nodes



### Zanubrutinib In WM Favorable Response to Date in Depth and Durability

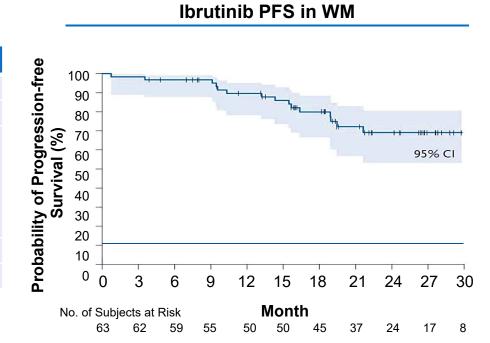


#### Zanubrutinib PFS in WM



## Ibrutinib In WM

lbrutinib	WM
n	63
Median time-on-treatment	19.1 months
Best Response CR <b>VGPR</b> PR MR SD/PD	0 <b>10 (16%)</b> 36 (57%) 11 (17%) 6 (10%)
IgM reduction (median, %)	35.2 g/L to 8.8 g/L (75%)
Hemoglobin change (median)	105 g/L to 138 g/L



### Zanubrutinib in CLL Highly Active With Encouraging Response Durability

#### Response PFS TN CLL **Total CLL** Zanubrutinib **R/R CLL** 100 90 16 50 66 n 80 Probability of Progression-free Median follow-up 7.6 14.0 10.5 (mo) 70 **Best Response** 60 Survival (%) ORR 16 (100%) 46 (92%) 62 (94%) 1 (6%) 1 (2%) 2 (3%) 50 CR PR 13 (81%) 41 (82%) 54 (82%) 40 PR-L 2 (13%) 4 (8%) 6 (9%) SD 3 (6%) 3 (5%) 0 30 Non-evaluable\* 0 1 (2%) 1 (2%) 20-10 + Censored \* D/C prior to first assessment 0 12 30 18 24 6 ۵

36

4

Month

37

53 45

27

25

19

11

9

6

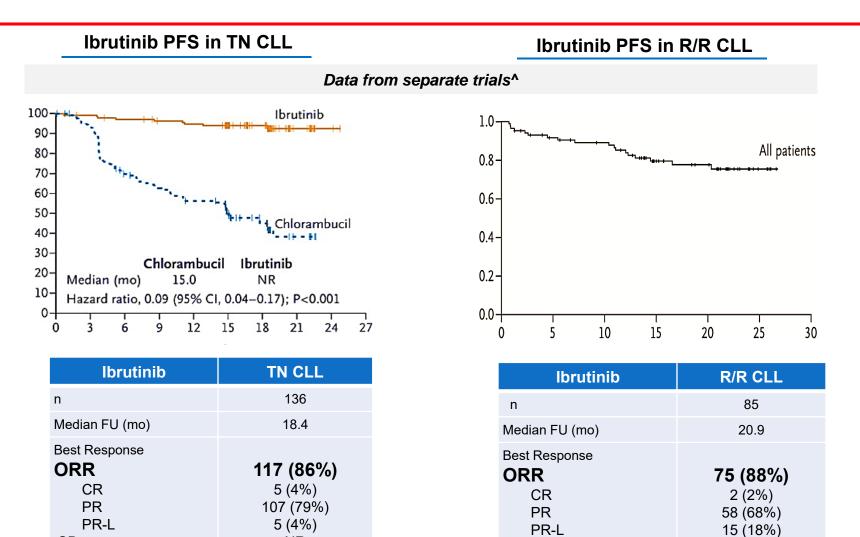
No. of Subjects at Risk

62

66

66

# Ibrutinib in CLL



NR

NR

Burger, et al New Engl J Med 2015
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SD

PD

SD

PD

NR

NR

## **Ibrutinib** Discontinuation for Toxicity or Progression in CLL

	Treatment-Naïve (n=80)	Relapsed/ Refractory (n=536)	
Median Follow up	14.5 months		
Total Treatment D/C	19 (24%)	231 (43%)	
Toxicity/ Tolerability	12 (15%)	117 (22%)	
CLL Progression	3 (4%)	49 (9%)	
Transformation (RT or HD)	0 (0%)	10 (2%)	
Death Unrelated to Treatment	1 (1%)	28 (5%)	
Physician or Patient Decision	2 (2%)	15 (3%)	
Transplant	0 (0%)	8 (1.5%)	
Financial Concerns	0 (0%)	1 (0.2%)	
Secondary Malignancy	1 (1%)	2 (0.5%)	



### Zanubrutinib Discontinuation for Toxicity or Progression in CLL Is Uncommon

	Treatment-Naïve (n=18)	Relapsed/ Refractory (n=51)		
Median Follow up	10.3 months			
Total Treatment D/C	0 (0%)	2 (4%)		
Toxicity/ Tolerability	0 (0%)	1 (2%)		
CLL Progression	0 (0%)	0 (0%)		
Transformation (RT or HD)	0 (0%)	1 (2%)		

### Zanubrutinib Tolerability in Over 600 Patients to Date

#### Adverse Events of Interest for BTK Inhibitors in Patients Treated with Zanubrutinib

AE of Interest (All Causes)	Zanubrutinib (Including Patients Enrolled in Combo Studies)	AE of Interest (All Causes)	Zanubrutinib (Single Agent Only)	
Patient Number	N = 641	Patient Number	N = 424	
Mean Exposure Time	7.7 mo	Mean Exposure Time	8.1 mo	
Atrial Fibrillation	1.7%	Diarrhea (All Gr)	14.2%	
Serious Hemorrhage	1.9%	Diarrhea (Gr 3-5)	0.7%	

- No new safety or tolerability signals observed, such as headache and hypertension
- Concomitant use of vitamin K antagonists was allowed in these zanubrutinib trials
- Paucity of treatment discontinuations for adverse events



# Zanubrutinib Plus Obinutuzumab Combination in Follicular Lymphoma

Overall response rate and complete responses to date compare favorably to those achieved with respective single-agents and recently approved therapies

FL^	Zanubrutinib + Obinutuzumab <sup>1</sup> Zanubrutinib <sup>2</sup>		lbrutinib <sup>3</sup>	Obinutuzumab⁴	Idelalisib <sup>5</sup>
Source	ASH17	ASH17 ASH17		JCO2013	NEJM2014
n	21	17	110	40	72
Population	Prior alkylator and CD20, mixed Rituxan-sensitive and –refractory Median 2 prior lines of therapy, range 1- 8		Prior alkylator and CD20, last response <12 months Alixed Rituxan- sensitive and - refractory		Alkylator and Rituxan-refractory relapse
Follow-up (med)	12.1 mo	7.8 mo	27.7 mo	33.7 mo	NR
ORR	76%	41%	21%	50%	54%
CR	38%	18%	11%	18%	6%



Source: 1 Tam *et al.*, ASH (abstract 1745), 2017; 2 Tam *et al.*, ASH (abstract 152), 2017; 3 Gopal, et al ASH 2016; 4 Salles, et al J Clin Oncol 2013; 5 Gopal, et al N Engl J Med 2014

# Zanubrutinib Responses Across Multiple B-Cell Malignancies

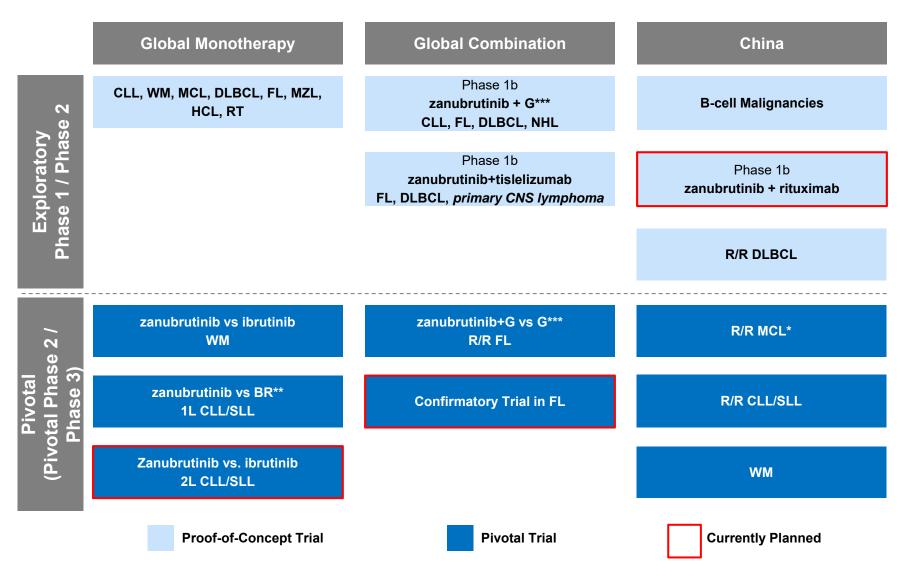
- Data on a total of 192 patients presented at 14-ICML and ASH 2017
- Despite relatively early follow-up, responses observed in multiple B-cell malignancies
- Consistency across tumor types suggests that zanubrutinib is a highly active BTK inhibitor

Zanubrutinib	TN CLL	R/R CLL	WM	MZL	MCL	FL	DLBCL
Source	14-ICML	14-ICML	14-ICML	ASH17	ASH17	ASH17	ASH17
n	16	50	42	9	32	17	26
Follow-up (med)	7.6 mo	14.0 mo	12.3 mo	7.0 mo	9.5 mo	7.8 mo	4.2 mo
Prior Lines (med)	0	2 (1-7)	1 (1-8)	2 (1-8)	2 (1-10)	2 (1-8)	2 (1-10)
ORR	100%	92%	90%	78%	88%	41%	31%
CR	6%	2%	0	0	25%	18%	15%
VGPR			43%				
PR/PR-L	94%	90%	33%	78%	63%	24%	15%
MR			14%				



# **Broad Clinical Development Plan for Zanubrutinib**

#### First NDA Filing in China Expected in 2018





# Tislelizumab (BGB-A317)

#### **Broad Global and China-Focused Development Program**

Overview	<ul> <li>Tislelizumab is a PD-1 checkpoint inhibitor currently under development in a wide range of solid tumor indications         <ul> <li>Potential differentiation from currently approved PD-1 antibodies in an engineered Fc region, which is believed to minimize potentially negative interactions with other immune cells<sup>1</sup></li> </ul> </li> <li>Anti-PD-1/PD-L1 antibody therapies represent a large commercial opportunity in China/ Asia         <ul> <li>BeiGene retains Asia ex-Japan rights plus hematological malignancies globally</li> </ul> </li> </ul>
Development Plan	<ul> <li>Broad development program designed to capture worldwide commercial opportunity         <ul> <li>Nine global pivotal studies across four indications in partnership with Celgene (NSCLC, gastric, esophageal, HCC)</li> <li>Two potential fast-to-market pivotal trials are ongoing in China</li> <li>Additional China-focused Phase 3 trials planned</li> <li>Combinations with BTK, PARP, chemo underway</li> </ul> </li> </ul>
Clinical Data	<ul> <li>Clinical experience in more than 800 patients has demonstrated proof-of-principle and encouraging clinical activity</li> </ul>
Expected 2018 Catalysts	<ul> <li>Present updated Phase I monotherapy or combination data at a medical conference</li> <li>Present China pivotal trial data</li> <li>NDA submission in China</li> <li>Initiate additional Phase 3 trials</li> </ul>



# **Tislelizumab Clinical Program**

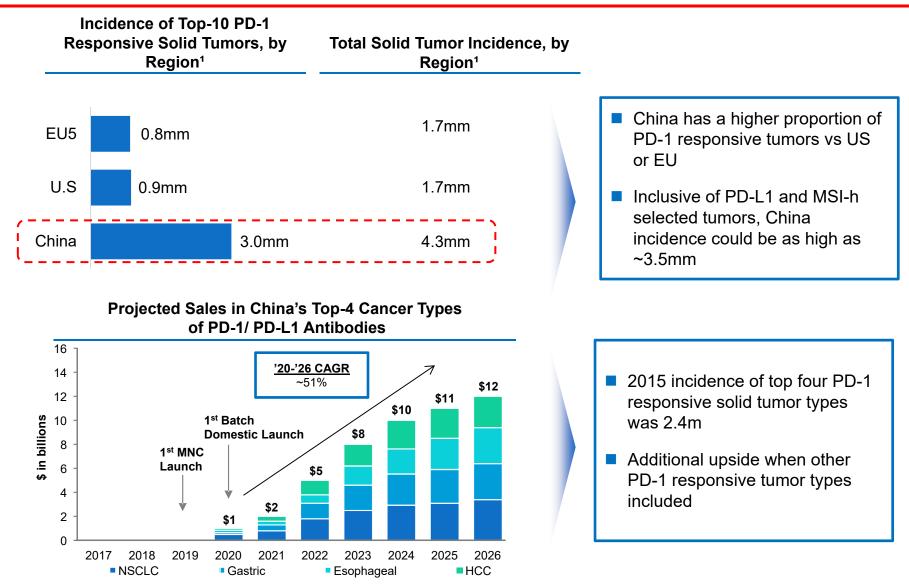
						China Glo	obal (ex-China)	
Program	Commercial	Dose Escalation Dose Expans			pansion*	Pivotal**		
(Target)	Rights	Preclinical	Phase 1a	Phase 1b	Phase 2	Phase 2	Phase 3	
		2L non-small cell l	ung cancer					
			1L hepatocellular carcinoma					
Tislelizumab (BGB-A317) (PD-1)	Worldwide (Heme Malignancies); Asia ex-Japan	R/R Hodgkin's lym	nphoma					
	(Solid Tumors) <sup>1</sup>	2L+ urothelial card	cinoma					
		Solid tumors						
Tislelizumab + Pamiparib (PD-1 + PARP)	Worldwide	Solid tumors						
Tislelizumab + Zanubrutinib (PD-1 + BTK)	Worldwide	Hematological tun	nors					

#### Over 800 patients<sup>2</sup> enrolled across tislelizumab program, including combination trials



\*Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or 3 clinical trials. \*\*Confirmatory clinical trials post approval are BeiGene required for accelerated approvals. <sup>1</sup> Celgene has the right to develop and commercialize tislelizumab in solid tumors in the United States, European Union, Japan and 25 the rest-of-world outside of Asia. <sup>2</sup> As of December 1, 2017.

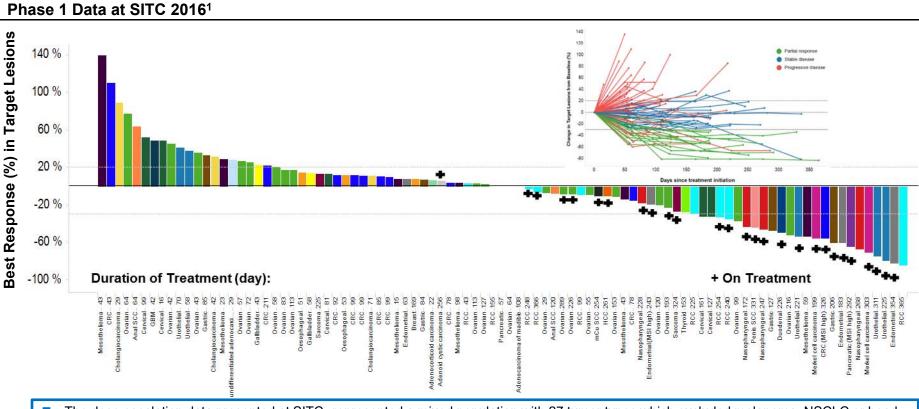
# Anti-PD-1 Antibody Therapies Represent a Large Market Opportunity, Particularly in China



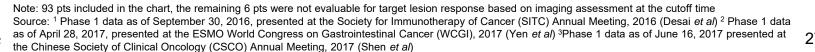
BeiGene

Source: LEK Analysis, Data from World Health Organization (2012); Chen et al., *CA Cancer J Clin*, 2016; SEER.cancer.gov <sup>1</sup> China data is from 2015, U.S. data is from 2017, and EU5 data is from 2012.

### Tislelizumab Phase 1 Data Demonstrated Proof of Principle and Clinical Activity



- The dose escalation data presented at SITC<sub>1</sub> represented a mixed population with 27 tumor types which excluded melanoma, NSCLC or head and neck cancer; nearly 15% of the enrolled patients had RCC or urothelial carcinoma (UC)
- In the SITC<sup>1</sup> analysis, 99 patients were evaluable for efficacy 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, and 1/1 MSI-h pancreatic cancer patients
- In early data presented at ESMO WCGI 2017<sup>2</sup> from hepatocellular carcinoma patients enrolled in dose-escalation and dose-expansion portions of the Phase I trial, there were 3 PRs (1 confirmed, 2 unconfirmed) and 9 cases of SD in 27 efficacy-evaluable patients
- In early data presented from the China Phase 1 trial at CSCO 2017<sup>3</sup>, the PK profile in Chinese patients was consistent with global trials. In 12 evaluable patients, there were 2 PRs (1 confirmed, 1 unconfirmed) and 3 cases of SD.



# **Tislelizumab Response Data**

- Data on a total of 159 patients presented at ESMO 2017 and ESMO WCGI 2017
- Objective responses observed with limited follow-up in multiple disease-specific Phase 1 expansion cohorts

Tumor Type	Gastric Cancer	Esophageal Cancer	Head & Neck SCC	Ovarian Cancer	Hepatocellular Carcinoma
Median Treatment Duration	45 days (4-457)	50 days (1-246)	104 days (30-339)	71 days (29-540)	64 days (1-471)
Evaluable Patients	N=34	N=31 N=17		N=50	N=27
PR Confirmed Unconfirmed	4 	2 3	3 	2 	1 2
SD	3	6	6	20	9
Pts Remaining on Treatment*	18	9	3	6	24
Source	ESMO 2017 <sup>1</sup>	ESMO 2017 <sup>1</sup>	ESMO 2017 <sup>2</sup>	ESMO 2017 <sup>3</sup>	WCGI 20174

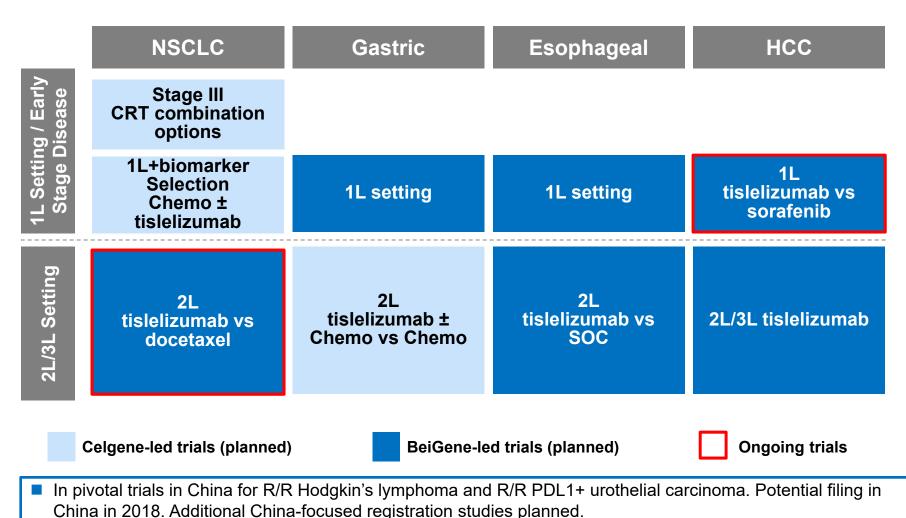
Note: For additional safety and efficacy data, see the BeiGene press releases issued June 29, 2017 and September 11, 2017

\*At the time of the data cutoff.



Sources:<sup>1</sup>Phase 1 data as of June 8, 2017, presented at the ESMO 2017 Congress (Desai *et al*, Abstract 387P) <sup>2</sup>Phase 1 data as of June 8, 2017, presented at the ESMO 2017 Congress (Horvath *et al*, Abstract 388P) <sup>3</sup>Phase 1 data as of June 8, 2017, presented at the ESMO 2017 Congress (Meniawy *et al*, Abstract 389P) <sup>4</sup>Phase 1 data as of April 28, 2017, presented at the ESMO World Congress on Gastrointestinal Cancer (WCGI), 2017 (Yen *et al*).

# Tislelizumab – Broad, Global Clinical Trial Plan in Collaboration With Celgene for Multiple Solid Tumors



Leveraging China prevalent cancers in the global clinical development, NSCLC, gastric cancer, esophageal, and HCC



#### Pamiparib (BGB-290) Selective Inhibitor of PARP1 and PARP2

Overview	Highly selective PARP1 and PARP2 inhibitor with significant brain penetration and strong PARP trapping activity in preclinical studies
Development Plan	<ul> <li>Two ongoing global Phase 1b/2 trials with chemotherapy: combination with radiation therapy and temozolomide (TMZ) in glioblastoma or combination with TMZ in advanced solid tumors</li> <li>Initiated China pivotal Phase 2 trial in patients with gBRCA+ ovarian cancer</li> <li>Expect to enter late-stage development globally</li> <li>Internal combination with tislelizumab: Preliminary anti-tumor activity observed in multiple solid tumors</li> </ul>
Clinical Data	<ul> <li>Phase 1/2 data demonstrated pamiparib was well-tolerated and showed promising anti-tumor activity in ovarian cancer</li> <li>— Low incidence of hematological toxicities (e.g. thrombocytopenia), no liver toxicity signal</li> </ul>
Expected 2018 Catalysts	<ul> <li>Present additional monotherapy and combination data</li> <li>Initiate global pivotal trial (1H)</li> </ul>



### Pamiparib Monotherapy Phase 1/2 Data Promising Activity and Generally Well-Tolerated to Date

#### Best Change from Baseline in Target Lesions in Epithelial Ovarian Cancer and Other Associated Tumors 100 BRCA+ 80 BRCA-WT BRCA Unknown 60 Platinum Resistant Best Response in Target Lesions (%) (0) (0) (0) 0 (0) Platinum Sensitive + Ongoing Patients + (80) (100) 40 mg 60 mg-P2 40 mg 80 mg 60 mg-P2 mg-P2 20 mg 80 mg 1 mg-P2 80 mg gm gm gm mg mg P1-Ę Ę b mg ĔĤ Ĕ ò, 200 20 20 С 80 8

#### P1, Phase 1; P2, Phase2.

Best Overall Response, n (%)	Total (N=39)
Overall Response rate per RECIST v1.1 (CR+PR)	13 (33.3%)
Complete Response (CR)	3 (7.7%)
Partial Response (PR)	10 (25.6%)
Stable Disease (SD)	21 (53.8%)
Clinical Benefit Rate (CR+PR+SD with ≥24 Weeks Duration)	18 (46.2%)

 Overall response rates by BRCA status were 43.5% (n=10/23; BRCA+), 15.4% (n=2/13; BRCA-WT), and 33.3% (n=1/3; BRCA unknown)

#### Summary of Adverse Events from Across the Phase 1/2 Trial

	Phase 1 (n=45)	Phase 1 (n=23)	Total (N=68)
Patient Reporting ≥1 TEAE	45 (100%)	22 (95.7%)	67 (98.5%)
Patients Reporting ≥1 Treatment-Related TEAE	34 (75.6%)	19 (82.6%)	53 (77.9%)
Patients Reporting ≥1 Serious TEAE	25 (55.6%)	6 (26.1%)	31 (45.6%)
Patients who Experienced ≥1 DLT	4 (8.9%)	NA	4 (5.9%)
TEAEs Leading to Discontinuation	4 (8.9%)	0	4 (5.9%)
TRAEs Occurring in ≥10% of All Patients (N=68)	Grade 1 or 2	Grade ≥3	Total
Nausea	36 (52.9%)	2 (2.9%)	38 (55.9%)
Vomiting	13 (9.1%)	1 (1.5%)	14 (20.6%)
Diarrhea	12 (17.6%)	2 (2.9%)	14 (20.6%)
Fatigue	25 (36.8%)	2 (2.9%)	27 (39.7%)
Anemia	10 (14.7%)	7 (10.3%)	17 (25.0%)
Neutropenia/Neutrophil Count Decrease	2 (92.9%)	6 (8.8%)	8 (11.8%)
Decreased Appetite	10 (14.7%)	0	10 (14.7%)

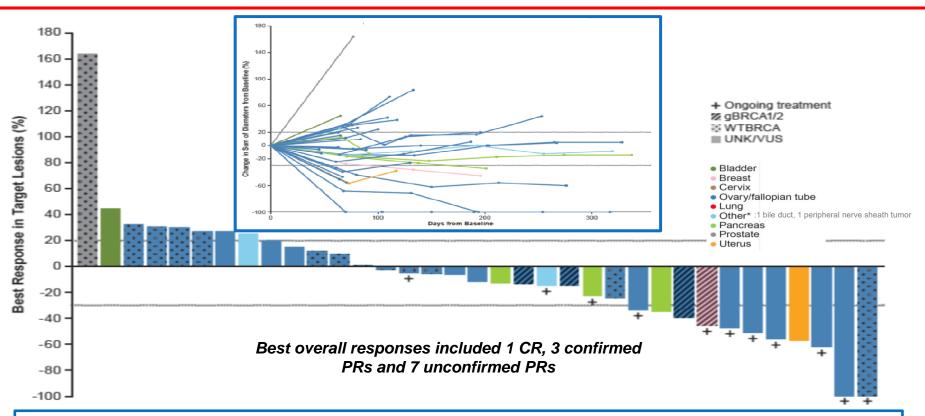
All date are presented as n (%).

**Abbreviations:** DLT, dose-limiting toxicity; NA, not applicable; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.



# **Tislelizumab/Pamiparib Combination Escalation Data**

Generally Well-Tolerated With Preliminary Anti-Tumor Activity In Multiple Tumor Types



- Ovarian or fallopian tube cancer pts (n=29) had best responses of CR (1), PR (2 confirmed, 5 unconfirmed), and SD (7). Breast cancer pts (n=2) had 1 confirmed PR. Pancreatic cancer pts (n=3) had best responses of PR (1 unconfirmed) and SD (2). Uterine cancer pt (n=1) had an unconfirmed PR. SD was observed in 1 of 3 pts with prostate cancer and the 1 pt with bile duct cancer. Additional tumor types enrolled included bladder, cervical, lung, and peripheral nerve sheath cancer (n=1 each)
- Gr. 3-4 AEs related to tislelizumab in >1 pt were AI hepatitis / hepatitis (12%) and ALT inc. (5%); related to pamiparib in >1 pt were anemia (14%), and ALT inc., AST inc., fatigue, and nausea (5% each)
- Liver-related AEs regardless of causality occurred in 12 pts (gr. 3-4 in 8 pts: 5 hepatitis, 3 inc. ALT and/or AST); all reversible with/without corticosteroids
- Treatment-related hepatic AEs have been reported in 1 of 300 patients treated with tislelizumab monotherapy and 0 of 65 patients treated with pamiparib monotherapy in separate ongoing trials

# Summary Financial Position And Near-Term Milestones

Cash, Cash Equivalents, and Short-term Investments (9/30/2017)

\$757M

Including \$142M held by the Guangzhou JV

(Unaudited)

Additional \$171M Celgene upfront payment received in 4Q17

Event	Expected Timing
Zanubrutinib (BTK Inhibitor)	
Present updated Phase I monotherapy or combination data at a medical conference	2018
Present China pivotal trial data	2018
Initiate head-to-head Phase 3 trial versus ibrutinib in R/R CLL	2018
NDA submission in China	2018
Completion of global WM registrational trial enrollment	Q3 2018
Tislelizumab (PD-1 Antibody)	
Present updated Phase I monotherapy or combination data at a medical conference	2018
Present China pivotal trial data	2018
NDA submission in China	2018
Initiate additional Phase 3 trials	2018
Pamiparib (PARP inhibitor)	
Present updated Phase 1 monotherapy or combination data at a medical conference	2018
Initiate global Phase 3 trial	1H 2018
In-licensed Products	
Vidaza launch in China	1Q 2018
Revlimid NDMM approval and launch in China	1Q 2018
Abraxane provincial reimbursement expansion	2018



# **Summary of BeiGene Product Portfolio**

	Commercial Rights	Current Phase						
Program ( <i>Target</i> )		Phase 1	Phase 2*	Pivotal Phase 2**	Phase 3		Lead Indications	
Zanubrutinib (BGB-3111, BTK)	Worldwide					•	WM, 1L CLL R/R MCL, R/R TN CLL, WM, R/R DLBCL (Phase 2)	
Zanubrutinib + Gazyva <sup>®</sup> ( <i>BTK</i> + <i>CD</i> 20)	Worldwide					•	R/R FL	
Tislelizumab (BGB-A317, PD-1)	Worldwide for hem malignancy, Asia ex-Japan for solid tumors <sup>1</sup>					•	2L NSCLC, 1L HCC 2L NSCLC, 1L HCC, R/R HL (Pivotal phase 2), 2L+ UC (Pivotal phase 2)	
Tislelizumab + Pamiparib (PD-1 + PARP)	Worldwide					•	Solid tumors	
Tislelizumab + Zanubrutinib (PD-1 + BTK)	Worldwide					•	B-cell malignancies	
Pamiparib (BGB-290, PARP)	Worldwide <sup>2</sup>					•	3L gBRCA+ ovarian cancer	
Pamiparib + Temozolomide (PARP + Chemo)	Worldwide <sup>2</sup>					•	Solid tumors	
Pamiparib+RT/Temozolomide (PARP + RT/Chemo)	Worldwide <sup>2</sup>					•	Glioblastoma	
Lifirafenib (BGB-283, RAF Dimer)	Worldwide <sup>2</sup>					•	B-Raf- or K-RAS/N-RAS-mutated solid tumors B-Raf- or K-RAS/N-RAS-mutated solid tumors	
BGB-A333 +/- Tislelizumab (PD-L1, PD-1)	Worldwide					•	Solid tumors	
Revlimid <sup>®</sup> (IMiD)	China		М	arketed		•	R/R MM (marketed), ND MM (NDA submitted), R/R NHL (Phase 3)	
Abraxane <sup>®</sup> (Albumin-bound paclitaxel)	China		М	arketed		•	Breast cancer	
Vidaza® (hypomethylating agent)	China		Αμ	proved		•	MDS (Approved), AML (Approved), CMMoL (Approved)	
CC-122 (CELMoD)	China					•	R/R DLBCL and NHL	

Abbreviations: WM=Waldenstrom's macroglobulinemia; CLL=chronic lymphocytic leukemia; MCL=mantle cell lymphocytic leukemia, FL=follicular lymphoma, NSCLC=non-small lung cancer, HCC=hepatocellular carcinoma, MM=multiple myeloma, HL=Hodgkin lymphoma, NHL=non-Hodgkin lymphoma, DLBCL=diffuse large B-cell lymphoma MDS=Myelodysplastic syndrome, AML=acute myeloid leukemia, UC=urothelial carcinoma, CMMoL=chronic myelomonocytic leukemia; 1L/2L/3L=first, second or third line, R/R=relapsed/refractory, ND=newly diagnosed

\*Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or 3 clinical trials. \*\*Confirmatory clinical trials post approval are required for accelerated approvals. <sup>1</sup> Celgene has the right to develop and China Global (ex-China)



BeiGene commercialize tislelizumab in solid tumors in the United States, European Union, Japan and the rest-of-world outside of Asia.<sup>2</sup> Limited collaboration with Merck KGaA.

# **Conclusion – BeiGene Company Highlights**

- 850+ person, global biotech company rooted in China with research, development, manufacturing, and commercial capabilities
- Ability to leverage regulatory changes in China as the country becomes an integral component of novel drug development and the oncology drug market continues to grow
- Plans to globally market potentially best-in-class BTK inhibitor zanubrutinib, with an expectation to file for marketing approval in China in 2018
- Collaborating with Celgene in the development and potential commercialization of PD-1 inhibitor tislelizumab globally and in China
- Continued development of proprietary pipeline assets
- Potential to further expand internal portfolio through future strategic relationships (as evidenced by the Celgene collaboration)

