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#### BeiGene, Ltd. 百濟神州有限公司

(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

#### OVERSEAS REGULATORY ANNOUNCEMENT - FORM 8-K

This announcement is issued pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Please refer to the attached for the document which has been published by BeiGene, Ltd. on the website of the U.S. Securities and Exchange Commission on August 8, 2019 (U.S. Eastern Time).

By order of the Board BeiGene, Ltd. Mr. John V. Oyler Chairman

Hong Kong, August 9, 2019

As at the date of this announcement, the Board of Directors of the Company comprises Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Mr. Timothy Chen, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Mr. Jing-Shyh (Sam) Su and Mr. Qingqing Yi as Independent Non-executive Directors.

### 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): August 8, 2019

#### BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

#### Cavman Islands

(State or Other Jurisdiction of Incorporation)

001-37686

98-1209416

(I.R.S. Employer Identification Number)

(Commission File Number)

c/o Mourant Governance 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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value \$0.0001 per share	BGNE	The NASDAQ Global Select Market
Ordinary Shares, par value \$0.0001 per share*	06160	The Stock Exchange of Hong Kong Limited

<sup>\*</sup>Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

#### Item 2.02. Results of Operations and Financial Condition.

On August 8, 2019, BeiGene, Ltd. (the "Company") announced its financial results for the three and six months ended June 30, 2019. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 7.01. Regulation FD Disclosure

On August 8, 2019, the Company posted an investor presentation to its website at <a href="http://ir.beigene.com">http://ir.beigene.com</a>. A copy of the investor presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein. The information in Item 7.01 of this Current Report on Form 8-K, including the presentation, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing or this Current Report.

#### Item 8.01. Other Events.

In its press release dated August 8, 2019, the Company also provided an update on second quarter 2019 and recent business highlights and expected milestones for the remainder of 2019 and 2020. The information in the press release set forth under the headings "Recent Business Highlights and Upcoming Milestones" and "Forward-Looking Statements" is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits.

Exhibit No.	Description						
99.1	Press release issued by BeiGene, Ltd. on August 8, 2019						
99.2	BeiGene Ltd. Investor Presentation dated August 8, 2019						
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL						

#### **Exhibit Index**

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#### **SIGNATURE**

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: August 8, 2019 By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel



#### BeiGene Reports Second Quarter 2019 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, August 8, 2019 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today reported recent business highlights, anticipated upcoming milestones, and financial results for the second quarter and first half of 2019.

"This quarter, our team continued to deliver across all functions, with the completion of enrollment in five Phase 3 or pivotal trials and the initiation of three new Phase 3 trials in oncology indications where we expect to have a profound impact on people fighting both hematologic and solid tumors. We believe that we are well-positioned to continue running our late-stage trials, including those for tislelizumab, for which we re-acquired full global rights from Celgene in advance of the closing of its pending acquisition by Bristol-Myers Squibb," said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. "We are progressing well with our U.S. and China product launch preparations, including our commercial and manufacturing build-outs, and we expect the remainder of 2019 and 2020 to be transformative for BeiGene, with readouts from up to 10 ongoing Phase 3 or potentially registration-enabling studies in addition to planned commercial launches of two of our internally developed products."

#### **Recent Business Highlights and Upcoming Milestones**

#### **Clinical Programs**

**Zanubrutinib,** an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects

- Completed enrollment in the global Phase 3 SEQUOIA trial (NCT03336333) comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naive (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL);
- Achieved first patient dosing in a Phase 1b trial (NCT02914938) conducted by MEI Pharma of zanubrutinib in combination with ME-401, an investigational selective oral phosphatidylinositol 3-kinase (PI3K) delta inhibitor;
- Presented data at the 15<sup>th</sup> International Conference on Malignant Lymphoma (ICML), including:
  - Clinical data from the pivotal Phase 2 trial (NCT03206918) in China in patients with relapsed/refractory (R/R)
     CLL or SLL;
  - Updated data from the pivotal Phase 2 trial (NCT03206970) in China in patients with R/R mantle cell lymphoma (MCL);
  - Updated data from the global Phase 1/2 trial (NCT02343120) in patients with different subtypes of B-cell malignancies, including MCL;
  - Updated data from the Phase 1b combination trial (NCT02569476) with GAZYVA® (obinutuzumab) in patients with R/R or TN CLL or SLL, and patients with R/R follicular lymphoma (FL).
- Presented data at the 24<sup>th</sup> Congress of European Hematology Association (EHA), including:
  - Clinical data from the nonrandomized cohort in patients with MYD88<sup>wt</sup> Waldenström's Macroglobulinemia (WM) from the Phase 3 ASPEN trial (NCT03053440). The randomized cohort of the study, in patients with MYD88<sup>mut</sup> WM, is ongoing;
  - Updated results from the ongoing Phase 1 trial (NCT02343120) of patients with WM;
  - Pooled safety data from six ongoing monotherapy studies in patients with B-cell malignancies; and
- Published in *Blood*, the Journal of the American Society of Hematology, an article on the Phase 1 trial of zanubrutinib in R/R B-cell malignancies, including CLL/SLL.

#### Expected Milestones for Zanubrutinib

Receive approvals in China for the treatment of patients with R/R MCL and R/R CLL/SLL in the first half of 2020.
 The Company expects manufacturing inspections to occur after the completion of the technical reviews. In addition, non-clinical and chemistry, manufacturing and controls (CMC) supplemental information was requested and has been provided;



- File an initial New Drug Application (NDA) in the U.S. in 2019 or early 2020;
- File a supplemental new drug application (sNDA) in China for WM in 2019;
- Announce top-line results from the Phase 3 ASPEN trial comparing zanubrutinib to ibrutinib in patients with WM in 2019;
- Announce top-line interim analysis from the SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with TN CLL or SLL as early as 2020; and
- Initiate a global Phase 3 clinical trial (NCT04002297) comparing zanubrutinib plus rituximab versus bendamustine plus rituximab in patients with previously untreated MCL who are ineligible for stem cell transplant in 2019.

**Tislelizumab**, an investigational humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to  $Fc\gamma R$  on macrophages

- Filed an sNDA in China for patients with previously treated locally-advanced or metastatic urothelial carcinoma (UC); the sNDA has been granted priority review status from the China National Medical Products Administration (NMPA);
- Regained full global rights from Celgene in advance of its pending acquisition by Bristol-Myers Squibb, and received
  a payment of \$150 million in connection with the termination;
- Completed enrollment in the Phase 3 trials in China of tislelizumab combined with chemotherapy in the front-line setting for patients with advanced squamous (NCT03594747) and non-squamous (NCT03663205) non-small cell lung cancer (NSCLC);
- Initiated the following trials:
  - A Phase 3 randomized trial (NCT04005716) in China of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer (SCLC);
  - A Phase 3 randomized trial (NCT03967977) in China of tislelizumab in combination with chemotherapy versus chemotherapy alone in patients with previously untreated locally advanced or metastatic UC; and
  - A Phase 3 randomized trial (NCT03957590) in China of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized esophageal squamous cell carcinoma (ESCC).
- Presented updated clinical results from the pivotal Phase 2 trial (NCT03209973) in China in patients with R/R classical Hodgkin lymphoma (cHL) at EHA; and
- Presented preliminary Phase 2 results from the Phase 1/2 trial (NCT03924986) in China in patients with nasopharyngeal cancer (NPC) at ASCO.

#### Expected Milestones for Tislelizumab

- Receive NDA approval in China for treatment of patients with R/R cHL in 2019;
- Announce top-line results from the global Phase 2 trial (NCT03419897) in second- or third-line patients with hepatocellular carcinoma (HCC) in 2019 or early 2020 and have regulatory discussions;
- Announce top-line results from the Phase 3 trial (NCT03594747) in first-line squamous NSCLC in China in 2019 or 2020;
- Announce top-line results from the Phase 3 trial (NCT03663205) in first-line non-squamous NSCLC in China in 2020; and
- Complete enrollment in the global first-line Phase 3 trial (NCT03412773) in HCC in 2019 and the global portion of the second-line Phase 3 trial (NCT03358875) in NSCLC in 2019 or early 2020.

#### Pamiparib, an investigational small molecule PARP inhibitor

• Completed enrollment in the Phase 3 randomized trial in China (NCT03519230) of pamiparib versus placebo as a potential maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer;



- Completed enrollment in the pivotal Phase 2 trial in China (NCT03333915) in third-line and above patients with ovarian cancer with germ-line BRCA mutation; and
- Published in *The Lancet Oncology* an article on the Phase 1A/B trial of pamiparib in combination with tislelizumab in patients with advanced solid tumors.

#### Expected Milestones for Pamiparib

- Announce top-line results from the pivotal Phase 2 trial in Chinese patients with previously treated ovarian cancer in 2020; and
- Announce top-line results from the Phase 3 trial in China of pamiparib versus placebo as a potential maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer in 2020.

Sitravatinib, an investigational tyrosine kinase inhibitor of receptor tyrosine kinases (RTKs), including TAM family receptors (TYRO3, Axl, MER), split family receptors (VEGFR2, KIT) and RET, licensed from Mirati Therapeutics in Asia (excluding Japan), Australia, and New Zealand

 Initiated a Phase 1/2 trial (NCT03941873) in China of sitravatinib in combination with tislelizumab in patients with unresectable locally advanced or metastatic HCC or gastroesophageal junction cancer.

BGB-A1217, an investigational TIGIT monoclonal antibody discovered by BeiGene scientists

Expected Milestones for BGB-A1217

 Initiate patient enrollment in a Phase 1a/1b trial in China and Australia investigating the safety, tolerability, pharmacokinetics and preliminary antitumor activity of BGB-A1217 in combination with tislelizumab in patients with advanced solid tumors in 2019.

#### **Manufacturing Facilities**

• Completed equipment installation and systems qualification of the Company's biologics manufacturing facility in Guangzhou, China. We expect manufacturing and validation of tislelizumab drug substance to begin later this year.

#### **Commercial Product Portfolio**

- Generated \$58.14 million in product revenue in the three months ended June 30, 2019, from sales in China of ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup>, which represents an 85.0% increase compared to the same period in 2018; and
- Announced that the China National Medical Products Administration (NMPA, formerly known as CFDA) accepted the supplemental import drug application for ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), in combination with gemcitabine, as a potential first-line treatment of patients with metastatic adenocarcinoma of the pancreas (mPC).

#### **Corporate Developments**

- Received approval from the Stock Exchange of Hong Kong Limited (HKEX) to transition into a general listing under Rule 8.05(3) by meeting its specified revenue and market capitalization thresholds. As a result of the approval, the "B" marker was removed from the Company's stock symbol in the HKEX, and the Company's ordinary shares may become eligible for listing in the Hang Seng indices;
- Along with SpringWorks Therapeutics, announced the formation of MapKure, LLC to develop BGB-3245, an
  investigational, selective next-generation RAF kinase inhibitor discovered by BeiGene scientists;
- Appointed Qingyi "Anita" Wu as Chief Commercial Officer, Greater China. Prior to joining BeiGene, Anita served as General Manager of the Specialty Care business unit at Sanofi China; and
- Appointed Yan "Lily" Liu as Vice President, Head of Marketing, Greater China. Lily was most recently Vice President, Head of the Specialty Care business unit at Takeda China.



#### **Second Quarter 2019 Financial Results**

**Cash, Cash Equivalents, Restricted Cash and Short-Term Investments** were \$1.56 billion as of June 30, 2019, compared to \$1.64 billion as of March 31, 2019 and \$1.81 billion as of December 31, 2018.

• The decrease of \$76.07 million in the second quarter of 2019 was primarily due to \$46.10 million of cash used in operating activities, \$21.45 million for investments in property, plant and equipment, and \$20 million for an upfront payment related to the BioAtla collaboration agreement.

**Revenue** for the quarter ended June 30, 2019 was \$243.35 million, compared to \$52.80 million in the same period in 2018. The increase is primarily attributable to the \$150 million payment received in connection with the termination of the tislelizumab collaboration agreement with Celgene, the recognition of previously deferred revenue from the collaboration as well as increased product revenue from sales of the in-licensed products from Celgene in China.

- Product revenue from sales of ABRAXANE®, REVLIMID® and VIDAZA® in China totaled \$58.14 million for the second quarter ended June 30, 2019, compared to \$31.43 million for the same period in 2018.
- Collaboration revenue totaled \$185.20 million for the second quarter ended June 30, 2019, compared to \$21.38 million for the same period in 2018. The increase is due primarily to the \$150 million payment in connection with the termination of our tislelizumab collaboration agreement with Celgene, as well as the recognition of previously deferred revenue from the collaboration.

**Expenses** for the second quarter ended June 30, 2016 were \$329.18 million, compared to \$215.85 million in the same period in 2018.

- Cost of sales for the second quarter ended June 30, 2019 were \$17.84 million, compared to \$6.26 million in the same period in 2018. Cost of sales related to the cost of acquiring ABRAXANE®, REVLIMID® and VIDAZA® for distribution in China.
- **R&D Expenses** for the second quarter ended June 30, 2019 were \$228.76 million, compared to \$164.25 million in the same period in 2018. The increase in R&D expenses was primarily attributable to increased spending on our ongoing and newly initiated late-stage pivotal clinical trials, preparation for regulatory submissions and commercial launch of our late-stage drug candidates, and manufacturing costs related to pre-commercial activities and supply. Additionally, we expensed \$20.0 million for the upfront payment related to the BioAtla collaboration agreement. Employee share-based compensation expense also contributed to the overall increase in R&D expenses, and was \$18.15 million for the second quarter ended June 30, 2019, compared to \$10.72 million for the same period in 2018, due to increased headcount.
- SG&A Expenses for the second quarter ended June 30, 2019 were \$82.25 million, compared to \$45.16 million in the same period in 2018. The increase in SG&A expenses was primarily attributable to increased headcount, including the expansion of our commercial team to support the distribution of our commercial products in China and the potential launches of our late-stage drug candidates, as well as higher professional service fees and costs to support our growing operations. The overall increase in SG&A expenses was also attributable to higher SG&A-related share-based compensation expense, which was \$14.45 million for the second quarter ended June 30, 2019, compared to \$7.92 million for the same period in 2018, due to increased headcount.
- **Net Loss** for the second quarter ended June 30, 2019 was \$85.57 million, or \$0.11 per share, or \$1.43 per American Depositary Share (ADS), compared to \$156.89 million, or \$0.22 per share, or \$2.92 per ADS in the same period in 2018.



#### **Financial Summary**

#### Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	As of		
	June 30,	De	ecember 31,
	2019		2018
	(unaudited)		(audited)
Assets:			
Cash, cash equivalents, restricted cash and short-term investments	\$ 1,561,479	\$	1,809,222
Accounts receivable	58,108		41,056
Working capital	1,484,001		1,697,390
Property and equipment, net	212,672		157,061
Total assets	2,150,318		2,249,684
Liabilities and equity:			
Accounts payable	148,536		113,283
Accrued expenses and other payables	103,061		100,414
Bank loan [1]	93,229		49,512
Shareholder loan [2]	154,321		148,888
Total liabilities	579,054		496,037
Noncontrolling interest	17,387		14,445
Total equity	\$ 1,571,264	\$	1,753,647

<sup>[1]</sup> The bank loan is attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd., which totaled \$84.49 million as of June 30, 2019, and the current portion of long-term debt for a term note secured by our Suzhou manufacturing facility.

<sup>[2]</sup> The shareholder loan is attributable to a RMB900 million convertible note obtained in 2017 from our joint venture partner for the construction and operation of our manufacturing facilities in Guangzhou.



#### Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

		Three Months Ended June 30,		Six Mont June		ths Ended e 30,		
		2019		2018		2019		2018
				(unau	dite	ed)		
Revenue:								
Product revenue, net	\$	58,142	\$	31,426	\$	- ,	\$	54,676
Collaboration revenue		185,204		21,378		205,616		30,672
Total revenues		243,346		52,804		321,179		85,348
Expenses:								
Cost of sales - products		(17,839)		(6,256)		(33,100)		(10,806)
Research and development		(228,760)		(164,251)		(407,111)		(273,951)
Selling, general and administrative		(82,248)		(45,160)		(139,893)		(74,075)
Amortization of intangible assets		(332)		(187)		(663)		(375)
Total expenses		(329,179)		(215,854)		(580,767)		(359,207)
Loss from operations		(85,833)		(163,050)		(259,588)		(273,859)
Interest income, net		2,886		1,892		7,363		3,444
Other (expense) income, net		(878)		75		850		804
Loss before income taxes		(83,825)		(161,083)		(251,375)		(269,611)
Income tax (expense) benefit		(2,129)		3,368		(2,648)		6,780
Net loss		(85,954)		(157,715)		(254,023)		(262,831)
Less: Net loss attributable to noncontrolling interest		(384)		(828)		(813)		(1,348)
Net loss attributable to BeiGene, Ltd.	\$	(85,570)	\$	(156,887)	\$	(253,210)	\$	(261,483)
	_		_		_		_	
Net loss per share attributable to BeiGene, Ltd., basic and diluted	\$	(0.11)	\$	(0.22)	\$	(0.33)	\$	(0.38)
Weighted-average shares outstanding, basic and diluted	Weighted-average shares outstanding, basic and diluted 777,50		-	598,506,891	_	776,137,299	-	584,586,086
			_		_		_	
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	\$	(1.43)	\$	(2.92)	\$	(4.24)	\$	(4.97)
Weighted-average ADSs outstanding, basic and diluted		59,808,392	_	53,731,299	_	59,702,869	_	52,660,468
			=		_		=	



#### About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 2,700 employees in China, the United States, Australia and Europe, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation<sup>i</sup>.

#### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the encouraging clinical data for BeiGene's product candidates and product revenue for its products; the conduct of late-stage clinical trials and expected data readouts; the potential commercial launches of BeiGene's product candidates; the advancement of and anticipated clinical development, regulatory milestones and commercialization of BeiGene's products and drug candidates; and BeiGene's plans and the expected milestones under the caption "Recent Business Highlights and Upcoming Milestones". 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-O, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

<b>Investor Contact</b>	Media Contact
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<sup>&</sup>lt;sup>i</sup> ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup>, and VIDAZA<sup>®</sup> are registered trademarks of Celgene Corporation.



## **Corporate Presentation**

August 8, 2019

#### **Disclosures**

- Certain statements contained in this presentation and in the 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 those regarding investigational drug candidates and clinical trials and the status and related results thereto, as well as those regarding continuing and further development and commercialization efforts and transactions with third parties. 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 forwardlooking 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, NMPA (formerly CFDA/CDA) and EMA, the possibility of having to conduct additional clinical trials and BeiGene's reliance on third parties to conduct drug development, manufacturing and other services. 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 (SEC). The reader should not place undue reliance on any forward-looking statements included in this presentation or in the accompanying oral 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.
- Some of the clinical data in this presentation relating to BeiGene's investigational drug candidates is from early
  phase, single-arm trials. When such data or data from later stage trials are presented in relation to other
  investigational or marketed drug products, the presentation and discussion are not based on head-to-head
  trials between BeiGene's investigational drug candidates and other products. BeiGene is still conducting
  clinical trials and, as additional patients are enrolled and evaluated, data on BeiGene's investigational drug
  candidates may change.
- This presentation and the accompanying oral presentation contains data and information obtained from thirdparty studies and internal company analysis of such data and information. BeiGene has not independently verified the data and information obtained from these sources. Forward-looking information obtained from these sources is subject to the same qualifications noted above.



#### **BeiGene At-A-Glance**

Fully-integrated global biotech **company** with internal capabilities in research, clinical development, commercialization and manufacturing

2,700+ employees 10 offices on 4 continents Trials in 34 countries and regions



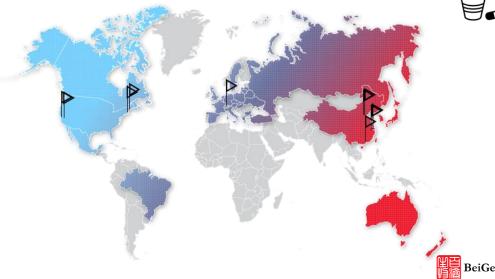
- ~300 research
- 1000+ global clinical
- 600+ commercial

Key catalysts in 2019 / 20 including expected product approvals and up to 10 Phase 3 or potentially registration-enabling trial readouts could further transform the company



#### Broad product portfolio and pipeline

- Three wholly owned late-stage candidates including two currently under regulatory review
- 26 Phase 3 or potentially registration-enabling trials ongoing, 60+ studies in total
- Balanced portfolio of 13 clinical or commercial stage assets including 6 internally developed and 7 in-licensed
- Growing **commercial business**, from \$15.6M in 4Q:17 to \$58.1M in 2Q:19 since transition to BeiGene



# Our Strategies -- Building a Leading Global Innovative Biotech Company From China

With the utmost commitment to patients, quality, and science



#### Realize two large near-term commercial opportunities

- Global opportunity for potentially best-in-class BTK inhibitor zanubrutinib
- · Opportunity for differentiated anti-PD-1 antibody tislelizumab in China and beyond



#### Strengthen key strategic capabilities

- · Global clinical development
- · Commercial platform



#### Capture opportunities created by regulatory reforms in China

- Accelerate global development through China-inclusive global trials
- Continue to expand our portfolio by leveraging our strong clinical capabilities



#### Pursue a new global model for growth by leveraging China's reimbursement expansion

- Expanded commercial base in China lowers per-patient R&D investment and allows greater access
- · Uniquely positioned due to strong China presence and global development



### **Our Leadership Team**

#### Attracting global talent to build a world-class team



**John V. Oyler**Founder, CEO, and Chairman
BioDuro, Galenea, Telephia,
Genta, McKinsey & Company



Xiaodong Wang, Ph.D.
Founder and Chairman SAB
NIBS: National Institute of Biological Sciences in
Beijing, UT Southwestern Medical Center,
Howard Hughes Medical Institute,
National Academy of Sciences



Xiaobin Wu, Ph.D. GM of China, President Pfizer Wyeth Bayer



**Howard Liang, Ph.D.** CFO and Chief Strategy Officer *Leerink Abbott* 



Eric Hedrick, M.D. Chief Advisor Genentech Pharmacyclics Epizyme



Jane Huang, M.D. Chief Medical Officer, Hematology Genentech Acerta



Yong Ben, M.D.
Chief Medical Officer,
Immuno-Oncology
BioAtla
AstraZeneca



Wendy Yan SVP, Global Head of Regulatory Affairs Bayer AstraZeneca



Lai Wang, Ph.D.
SVP, Head of Global Research,
Clinical Operation & Biometrics
and APAC Clinical Development
UT Southwestern Medical
Center



Anita Wu
Chief Commercial Officer, Greater China
Sanofi
AstraZeneca
Pfizer



Lily Liu
VP, Head of Marketing,
Greater China
Takeda
Pfizer



Josh Neiman
Head of U.S. Commercial
Flatiron Health
Onyx Pharmaceuticals
Genentech



Scott Samuels, Esq. SVP, General Counsel ARIAD Mintz Levin



**Todd Yancey, M.D.**SVP, Global Medical Affairs & New Market Development
BioMarin, Medivation
Clovis Oncology, Onyx



Guillaume Vignon, Ph.D. SVP, Business Development



### **BeiGene Product Portfolio and Pipeline**

Three marketed products in China, three late-stage assets, seven early-stage clinical assets



ASSETS	PROGRAMS	DOSE ESC.	DOSE EXPANSION		PIVOTAL		FILED	COMMERCIAL
ASSETS	FROGRAMS	PH1a	PH1b	PH2*	PH2**	PH3	FILED	RIGHTS
		R/R MCL, R/R CLL/SLI	L (NDAs accepted)					
zanubrutinib	monotherapy	R/R WM						
(BTK)	monotherapy	WM, 1L CLL/SLL, R/R	CLL/SLL					Global
(BTK)		R/R MZL						
	+ GAZYVA® (CD20)	R/R FL						
		R/R cHL, 2L+ UC (NDA	As accepted)					
	monotherapy	2L NSCLC, 1L HCC, 21	L ESCC					
	monotherapy	2L/3L HCC						
tislelizumab		R/R NK/T-cell lymphon						Global
(PD-1)	+ chemo	1L Sq. NSCLC, 1L Nor	-Sq. NSCLC, 1L NPC	, 1L SCLC				Giobai
tislelizumab (PD-1)	+ chemo	1L GC, 1L ESCC						
	+ pamiparib (PARP)	Solid tumors						
	+ zanubrutinib (BTK)	B-cell malignancies						
was not have no	1L platinum-sensitive 0	GC maintenance						
	monotherapy	2L platinum-sensitive OC maintenance						
pamiparib	pamiparib	3L gBRCA+ OC						Global
(PARP)		Solid tumors						Giobai
	+ TMZ (chemo)	Solid tumors						
	+ RT/TMZ (RT/chemo)	Glioblastoma						
lifirafenib (RAF Dimer)	monotherapy	B-Raf- or K-RAS/N-RA	S-mutated solid tumor					Global
initalenib (NAI Billiel)	monotherapy	B-Raf- or K-RAS/N-RA	S-mutated solid tumor	s				Global
BGB-A333 (PD-L1)	monotherapy & + tislelizumab	Solid tumors						Global
BGB-A425 (TIM-3)	monotherapy & + tislelizumab	Solid tumors						Global
REVLIMID®	(IMiD)	R/R MM (marketed), N	DMM (marketed), R/R	NHL (Ph3)				China
ABRAXANE®	(albumin-bound paclitaxel)	Breast cancer (markete		<u> </u>				China
VIDAZA®	(hypomethylating agent)	MDS, AML with 20-30%	% bone marrow blasts,	CMML (marketed)				China
sitravatinib	(multi-kinase inhibitor) <sup>1</sup>	NSCLC, RCC, OC, Me.	lanoma, HCC/GEJ					Asia ex-Japan, NZ, AU
ZW25	(bispecific HER2 antibody) <sup>2</sup>	Planned (in Ph2 ex-Ch.	ina by Zymeworks)					Asia ex-Japan, NZ, AU
ZW49	(bispecific anti-HER2 ADC) <sup>2</sup>	Planned (in Ph1 ex-Ch	ina by Zymeworks)					Asia ex-Japan, NZ, AU
avadomide	(CC-122, CELMoD)	Planned (in Ph1b ex-C	hina by Celgene)					China



### **Two Late-Stage Assets Represent Significant Commercial Opportunities**

#### zanubrutinib

Potentially Best-in-Class BTK Inhibitor

#### tislelizumab

PD-1 Inhibitor Targeting Asia-Prevalent Tumors

**CLASS REVENUE & FORECAST\*\*** 

 2018 Global: \$4.2 Bn 2025E Global: \$13.8 Bn 2025E China: \$1.3 Bn

 2018 Global<sup>^</sup>: \$15.5 Bn 2025E Global<sup>^</sup>: \$57.4 Bn 2025E China^: \$12.1 Bn

**KEY TARGET INDICATIONS** 

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Waldenstrom's Macroglobulinemia, Mantle Cell Lymphoma, Follicular Lymphoma, Marginal Zone Lymphoma Lung, liver, gastric, and esophageal cancers, classical Hodgkin's lymphoma, urothelial carcinoma, nasopharyngeal

**CLINICAL DATA\*** 

86-patient R/R MCL<sup>1</sup>

73-patient WM<sup>2</sup>

92% ORR, 82% MRR

91-patient R/R CLL/SLL3

85% ORR

70-patient China pivotal Ph2 R/R cHL4

104-patient China pivotal Ph2 2L+ UC<sup>5</sup>

23% ORR

 84% ORR • 59% CR

41% VGPR

• 63% CR

87% ORR

**FILING PROGRESS** 

- NDAs for R/R MCL and R/R CLL/SLL accepted by NMPA
- Priority review status granted to NDAs in R/R MCL and R/R CLL/SLL
- Fast Track in WM and Breakthrough Therapy in MCL by U.S. FDA

NDAs for cHL and UC in China accepted by NMPA

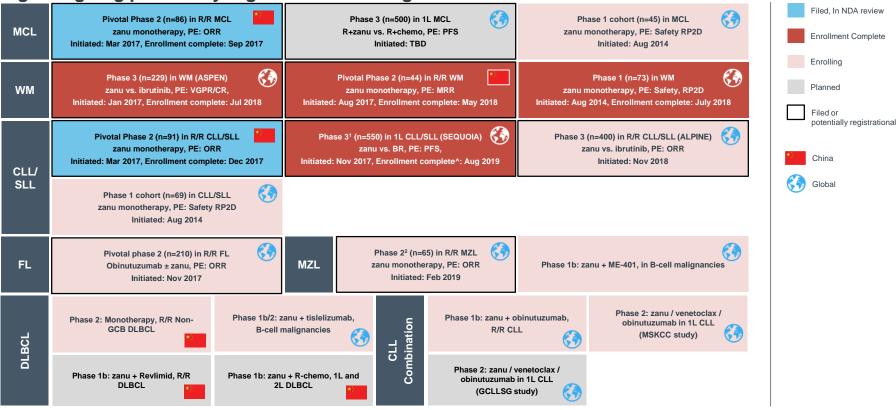
Priority review granted by NMPA

<sup>1.</sup> ICML 2019 Song et. al.; 2. EHA 2019 Trotman et. al.; 3. ICML 2019 Xu et. al.; 4. EHA 2019 Song et. al. 5. China pivotal Phase 2 trial, BeiGene press release May 30, 2019. \*All data are from independent review committee (IRC) assessment. \*\*Frost&Sullivan analysis; RMB:USD conversion: 6.5:1. ^For PD-1 & PD-L1 class; BTK: Bruton's Tyrosine Kinase; cHL: Classical Hodgkin's Lymphoma; CLL/SLL: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma; CR: Complete Response; FL: Follicular Lymphoma; f/u: Median follow up time; MCL: Mantle Cell Lymphoma; MZL: Marginal Zone Lymphoma; MRR: Major Response Rate; NDA: New Drug Application; NMPA: National Medical Products Administration; ORR: Overall Response Rate; PD-1: Programmed Cell Death-1; R/R: Relapsed/Refractory; UC: Urothelial Carcinoma; VGPR: Very Good Partial Response; WM: Waldenstrom's Macroglobulinemia; R/R: Relapsed / Refractory.



**Zanubrutinib Broad Clinical Development Program** 

**Eight ongoing potentially registration-enabling studies** 



ATime of the announcement of the enrollment completion; 1L: First Line; CLL/SLL: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma; CR: Complete Response; DLBCL: Diffuse Large B-Cell Lymphoma; FL: Follicular Lymphoma; GCB: Germinal Center B-cell-like; MCL: Mantle Cell Lymphoma; MRR: Major Response Rate; MZL: Marginal Zone Lymphoma; NHL: Non-Hodgkin's Lymphoma; ORR: Overall Response Rate; PCNSL: Primary Central Nervous System Lymphoma; PE: Primary endpoint; PFS: Progression-Free Survival; RP2D: Recommended Phase 2 Dose; R/R: Relapsed / Refractory; RT: Richter's Transformation; VGPR: Very Good Partial Response; WM: Waldenstrom's Macroglobulinemia. 1. Cohort 2 of 17p del patients completed enrollment. 2. global trial and potentially registration-enabling in certain countries.



### **Tislelizumab Broad Late-stage Development Program**

#### Fifteen ongoing potentially registration-enabling studies

				Filed, In NDA review
Lung	Phase 3 (n=800) in 2L NSCLC tislelizumab vs. docetaxel, PE: OS Initiated: Nov 2017	tislelizumab+ p	nase 3 (n=360) in 1L Stage IIIB or IV squamous NSCLC paclitaxel and carboplatin combo or nab-paclitaxel and carboplatin ombo vs. paclitaxel and carboplatin combo, PE: PFS nitiated: Aug 2018, Enrollment complete^: Aug 2019	Enrollment Complete
Lung	Phase 3 (n=320) in 1L Stage IIIB or IV non-squamous NSCLC tislelizumab+ chemo (platinum-pemetrexed) vs. chemo, PE: PFS Initiated: Jul 2018, Enrollment complete^: Aug 2019	Tislelizumab+ (	Phase 3 (n=364) in 1L SCLC chemo (Carboplatin /Cisplatin, Etoposide) vs. placebo + chemo, PE: PFS, OS Initiated: July 2019	Enrolling Planned
нсс	Phase 3 (n=640) in 1L HCC tislelizumab vs. sorafenib, PE: OS Initiated: Jan 2018		Phase 2 (n=225) in 2L/3L HCC tislelizumab monotherapy, PE: ORR by IRC Initiated: Apr 2018, Enrollment complete^: Feb 2019	Filed or potentially registrational
5000	Phase 3 (n=450) in 2L ESCC tislelizumab vs. single-agent chemo (paclitaxel, docetaxel, or irinotecan), PE: OS Initiated: Jan 2018	Phase 3 (n=480) in 1L advanced ESCC tislelizumab or placebo + platinum- and fluoropyrimidine-based chemo, Co-PE: PFS and OS Initiated: Dec 2018		China
ESCC	Phase 3 (n=316) in localized ESCC tislelizumab + chemoradiotherapy vs chemoradiotherapy, PE: OS Initiated: May 2019	GC	Phase 3 (n=720) in 1L advanced GC tislelizumab or placebo + platinum- and fluoropyrimidine-based chemo, Co-PE: PFS and OS Initiated: Dec 2018	
UC	Pivotal phase 2 (n=110) in 2L UC tislelizumab monotherapy, PE: ORR, Initiated: Jul 2017, Enrollment complete: Aug 2018, NDA accepted May 2019	tislelizumab +	Phase 3 (n=420) in 1L UC chemo (cisplatin + carboplatin + gemcitabine) vs placebo + chemo PE: OS Initiated: May 2019	
cHL	Pivotal phase 2 (n=70) in R/R cHL tislelizumab monotherapy, PE: ORR Initiated: Apr 2017, Enrollment complete: Nov 2017, NDA accepted in Aug 2018	R/R NK/T-cell lymphomas	Phase 2 (n=90) in 1L R/R Mature T- and NK- Neoplasms tislelizumab monotherapy, PE: ORR Initiated: Apr 2018	
MSI-H or dMMR solid tumors	Pivotal phase 2 (n=60) in MSI-H or dMMR solid tumors tislelizumab monotherapy, PE: ORR Initiated: Sep 2018	NPC	Phase 3 (n=256) in 1L tislelizumab + chemo (gemcitabine plus cisplatin) vs. placebo + chemo PE: PFS Initiated: Apr 2019	

<sup>^</sup>Time of the announcement of the enrollment completion; \*Tislelizumab dosage 200mg every three weeks, Q3W, Global Ph2 in R/R/ NK/T-cell lymphoma and Ph2 trial in MSI-H or dMMR solid tumors in China are potentially registrational-enabling trials. 1/2L: First/Second Line; cCRT: concurrent chemoradiotherapy; cHL: Classical Hodgkin's Lymphoma; ESCC: Esophageal Squamous-Cell Carcinoma; GC: Gastric Cancer; HCC: Hepatocellular Carcinoma; IRC: Independent Review Committee; ITT: Intent-to-freat; MSI-H or dMMR: Microsatellite Instability High or Deficient Mismatch Repair; NDA: New Drug Application; NK: Natural Killer; NSCLC: Non-Small Cell Lung Cancer; ORR: Overall response rate; OS: Overall survival; PE: Primary Endpoint; PFS: Progression-free survival; R/R: Relapsed / Refractory; UC: Urothelial Carcinoma;



### Other Clinical-Stage Drug Candidates and Internal Combinations

	ROBUST PIPELINE BEYOND BTK AND PD-1
pamiparib (PARP1&2 Inhibitor)	<ul> <li>Late stage studies in ovarian cancer in China</li> <li>Combination studies with temozolomide</li> </ul>
sitravatinib¹ (Multi-Kinase Inhibitor)	<ul> <li>Combination with tislelizumab initiated</li> <li>In-licensed from Mirati, rights in Asia ex-Japan, AU, NZ</li> </ul>
lifirafenib (Raf Dimer Inhibitor)	<ul> <li>Clinical activity observed in RAS-mutated cancers including NSCLC and endometrial cancer</li> <li>Global clinical trial collaboration with SpringWorks for combination with MEK inhibitor</li> </ul>
ZW25 <sup>2</sup> (Bispecific HER2 Antibody)	<ul> <li>In-licensed from Zymeworks, rights in Asia ex-Japan, AU, NZ</li> <li>Designed to provide dual HER2 signaling blockade by binding to epitopes for Herceptin and Perjeta</li> </ul>
ZW49² (Bispecific HER2 ADC)	<ul> <li>In-licensed from Zymeworks, rights in Asia ex-Japan, AU, NZ</li> <li>Designed to bind two non-overlapping epitopes of HER2 to maximize internalization and delivery of payload</li> </ul>
BGB-A333 (PD-L1 Antibody)	Ph1 trial testing the monotherapy and the combination with tislelizumab
BGB-A425 (TIM-3 Antibody)	Ph1 testing the combination with tislelizumab
avadomide (CELMoD [CC-122])	In-licensed from Celgene, rights in China

		Global		China
INDICATIONS	DOSE ESC.	DOSE	EXPAN	SION
INDICATIONS	PH1a	PH1b		PH2 <sup>*</sup>
HCC or GEJ	tislelizumab + sitra			
NSCLC, RCC, OC, melanoma	tislelizumab + sitra			
Solid tumors	lifirafenib + PD-03. inhibitor, SpringWo	<		
B-cell malignancies	Planned: zanubrut (PI3K delta inhibito Pharma)	01		
Solid tumors	tislelizumab + BGB-A333 (PD-L1)			
Solid tumors	tislelizumab + BGB-A425 (TIM-3)			
B-cell malignancies	tislelizumab + zanubrutinib			
Solid tumors	tislelizumab + pamiparib			

<sup>\*</sup>Some indications will not require a non-pivotal Ph2 clinical trial prior to beginning pivotal Ph2 or 3 clinical trials; confirmatory clinical trials post-approval are required for accelerated approvals.
\*\*Clinical trials in Asia Pacific regions; 1.Collaboration with Mirati Therapeutics, Inc., 2. Collaboration with Zymeworks; GEJ: gastroesophageal junction cancer.



### Leverage China to Pursue Global Excellence

#### BeiGene Is Becoming a Leader in China-Inclusive Global Clinical-Development



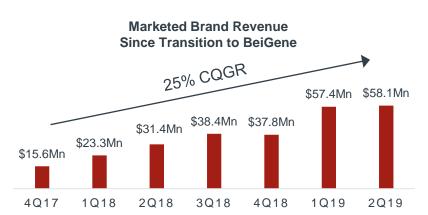
Countries with BeiGene clinical trial sites

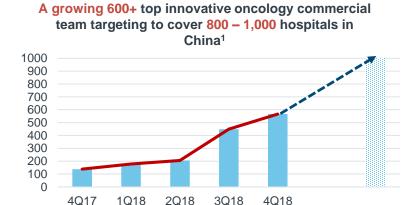
- In-house research capability with a team of approximately 300; all three late-stage clinical assets were discovered by BeiGene scientists with potentially differentiating profiles
- Additional new targets and potentially first-in-class candidates in earlier stages of development
- Clinical team of over 1,000, with over 50% in China and remainder in US, EU, AU; Largest oncology-focused clinical development team in China
- Initiated 6 China-inclusive global pivotal studies; 26 pivotal trials or potentially registration-enabling trials ongoing
- 60+ ongoing or planned clinical trials in China and globally with 7,000+ patients and healthy subjects enrolled
- Regulatory interactions and monitoring from 20+ countries



# Building Oncology-Focused Commercial Footprint in China and Establishing a Presence in the U.S.

Marketed product growth and commercial team expansion in China; Building a 100-200-person hematology commercial team in the U.S.













Xiaobin Wu, Ph.D. GM of China, President Pfizer Wyeth Bayer



Anita Wu Chief Commercial Officer, Greater China Sanofi AstraZeneca



Lily Liu VP, Head of Marketing, Greater China Takeda Pfizer



Josh Neiman Head, U.S. Commercial Flatiron Onyx Pharmaceuticals Genentech



### **Developing Strong Manufacturing Capabilities**



MULTI-FUNCTIONAL MANUFACTURING **FACILITY IN** SUZHOU, CHINA

- Manufacturing collaborations with leading high-quality manufacturers in biologics and small molecules
- Bl collaboration established in 2013; cell line and CMC process for tislelizumab developed by BI
- Commercial scale 2,000L at BI's Shanghai **expandable** facility



**BIOLOGICS** MANUFACTURING FACILITY IN GUANGZHOU (UNDER CONSTRUCTION)

- Aligned with the design criteria of US. EU and China
- Total area of 9,000 square meters
- Commercial-scale small molecule drug products facility, ~100M pills annual capacity
- Pilot-scale biologic facility at 500L scale



**EXPERIENCED** HIGH-QUALITY MANUFACTURING **PARTNERS** 

- Joint venture with **Guangzhou Development District**
- Investment of \$300+ million -- mostly from external funding but BeiGene retains majority equity ownership
- 100,000 square meter manufacturing site; 24,000-liter commercial-scale biologics manufacturing facility
- First phase of the manufacturing plant to be completed in 2019



William Novotny, Advisor, **Technical Operations** BMS. VP and Global Lead in Supply Chain Merck. AVP in Global Supply Chain Management and **Product Operations** 



Zhengming Du, Ph.D. Head of Chemistry Manufacturing & Control (CMC) Roche China. Head of Process and Synthesis.

Deputy Head of CMC



Jonathan Liu, Ph.D. SVP. Bio-Manufacturing J&J. Head of China Pharmaceutical 5 6 1 Development and Manufacturing Sciences



**Michael Garvey** VP, Head of Guangzhou **Biologics Manufacturing** Samsung Biologics, VP of Manufacturing



BeiGene

### China Is Becoming an Important Clinical Science Center, **Representing a Historic Opportunity**

BeiGene is well-positioned within this ecosystem

NMPA reforms expand China's role in global development	<ul> <li>NMPA reforms have removed delays, allowing China to participate in early drug development and to contribute significantly to global pivotal trials</li> <li>NMPA joined ICH in June 2017, setting international quality standards for China trials</li> </ul>
Bottlenecks today in China	<ul><li>Limited CRO capability</li><li>Highly limited talent pool</li><li>Data and trials management challenges</li></ul>

Effectively operating in China can significantly enhance global development

- Single biggest time and expense for drug development is trial enrollment
- Adding China significantly accelerates enrollment of global trials
  - China alone had 4.3 million new cancer patients in 2015, as large as the U.S. and EU combined

- Greater willingness to join clinical trials
- Having access to a large pool of patients can also reduce the average upfront cost in drug development

World-Class Clinical **Development Team** Positions BeiGene Well to **Capture This Opportunity** 

#### 1.000+ member clinical team

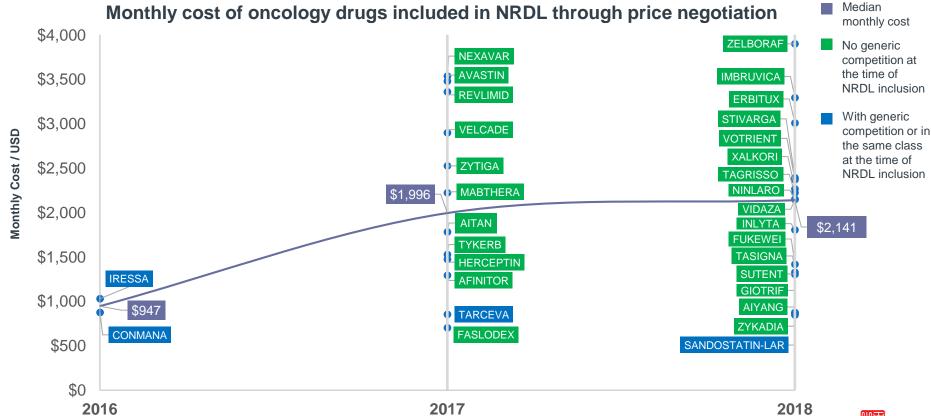
All data and clinical practices are designed to meet global ICH standards

Early mover in simultaneous Chinaglobal pivotal trial paradigm and has initiated six dual-purpose trials



### **Commercial Transformation in China Facilitates Access**

**Expanding national reimbursement, at reasonable prices** 



# China Enables a Model to Succeed in an Evolving Global Environment

BeiGene is uniquely positioned to leverage the large commercial base



Dramatic changes to biopharma industry occurring – China increasingly key focal point for future



Being able to effectively operate in clinical development in China attracts other U.S. biotech companies to partner with BeiGene, as part of their global development strategy



China enables an alternative model for growth, which is no longer reliant on U.S. pricing



The large commercial base in China allows more affordable pricing which in turn can be leveraged to provide greater access to high quality drugs globally



BeiGene will pursue true global model without sacrificing quality, innovation, or science





### **Established Collaborations Leverage China Capabilities and Expand Portfolio**



Agreement: July 2017 tislelizumab and Celgene commercial assets in China license to three marketed products in China

Obtained Celgene's commercial operations and

- In June 2019, BeiGene regained full global rights of tislelizumab in advance of the pending acquisition of Celgene / BMS and received \$150M from Celgene
- In-licensed sitravatinib in Asia (ex-JP) and
- Encouraging results -- 16 PRs and CRs (9 confirmed) in 56 patients -- reported by Mirati in an ongoing Ph2 trial in combination with nivolumab in NSCLC patients who have progressed on checkpoint inhibitor therapy<sup>1</sup>

AU/NZ





Agreement: Mar. 2019



Agreements: Sept. 2018, Jun. 2019 MEK inhibitor PD-0325901 and **BGB-3245** 

(MEK inhibitor synergistic with RAF inhibition in RAS-mutant solid tumors) development, manufacturing and commercialization of conditionally active anti-CTLA-4 antibody BA3071

Global collaboration for co-

- Global R&D collaboration to utilize Ambrx's Expanded Genetic Code technology
- Global clinical collaboration to evaluate in RAS-mutant advanced solid tumors in combination with BeiGene's RAF dimer inhibitor lifirafenib
- MapKure established to develop BGB-3245 RAF Kinase Inhibitor
- Global clinical collaboration to evaluate safety and efficacy in B-cell malignancies in combination with zanubrutinib
- MEI will amend its ongoing Phase 1b trial to include evaluation of ME-401 and zanubrutinib combination therapy in patients with B-cell malignancies



Agreement: Jan. 2018

sitravatinib

(multi-kinase inhibitor including

TAM receptors (TYRO3, Axl,

MER), split receptors (VEGFR2,

KIT) and RET)

Agreement: Nov. 2018 **ZW25** HER2-targeted bispecific antibody and ZW49 bispecific antibody drug conjugate (ADC); Azymetric<sup>™</sup> and EFECT<sup>™</sup> platforms

- In-licensed ZW25 and ZW49 in Asia (ex-JP) and AU/NZ; global research and license agreement for Azymetric<sup>TM</sup> and EFECT<sup>TM</sup> platforms
- Areas of high interest (breast and gastric cancers)
- Access to bispecific antibody discovery platform



Agreement: Oct. 2018 ME-401

(oral phosphatidylinositol 3kinase . PI3K. delta inhibitor)

17 1. ESMO 2018 Ticiana et al.

BeiGene

### **Financial Summary**

Selected Financials	Three Months Ended			ded	Six Months Ended				
Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)		June 30, 2019 (unaudited)		June 30, 2018 (unaudited)		June 30, 2019 (unaudited)		June 30, 2018 (unaudited)	
Total Revenue	\$	243,346	\$	52,804	\$	321,179	\$	85,348	
Product revenue, net		58,142		31,426		115,563		54,676	
Collaboration revenue		185,204		21,378		205,616		30,672	
Total Expenses		(329,179)		(215,854)		(580,767)		(359,207)	
Cost of sales – products		(17,839)		(6,256)		(33,100)		(10,806)	
Research and development		(228,760)		(164,251)		(407,111)		(273,951)	
Selling, general and administrative		(82,248)		(45,160)		(139,893)		(74,075)	
Net loss attributable to BeiGene, Ltd.	\$	(85,570)	\$	(156,887)	\$	(253,210)	\$	(261,483)	
Weighted-average ADSs outstanding, basic and diluted		59,808,392		53,731,299		59,702,869		52,660,468	
Net loss per ADS attributable to BeiGene, Ltd, basic and diluted	\$	(1.43)	\$	(2.92)	\$	(4.24)	\$	(4.97)	
Cash, cash equivalents, restricted cash and short-term investments	\$	1,561,479	\$	1,401,219	\$	1,561,479	\$	1,401,219	
Cash used in operations excluding business development		\$46,101*				\$218,076*			

BeiGene

<sup>\*</sup> Includes \$150,000 from Celgene in connection with termination of tislelizumab collaboration

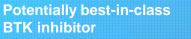
### **Upcoming Milestones and Catalysts**

Approval	proval in China for MCL and CLL e sNDA for WM in China DA filing in the U.S. p-line Phase 3 data of zanubrutinib vs. ibrutinib in WM, ASPEN tential top-line data in Phase 3 of zanubrutinib vs. bendamustine rituximab (BR) in 1L CLL, SEQUOIA dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	Timing  1 H20 2019 2019 carly 2020 2019 As early as 2020 2019
Submission Fill Submission NE Data To	de sNDA for WM in China  OA filing in the U.S.  p-line Phase 3 data of zanubrutinib vs. ibrutinib in WM, ASPEN  tential top-line data in Phase 3 of zanubrutinib vs. bendamustine rituximab (BR) in 1L CLL, SEQUOIA  dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	<ul><li>2019</li><li>2019 or early 2020</li><li>2019</li><li>As early as 2020</li></ul>
Submission • NE Data • To	DA filing in the U.S. p-line Phase 3 data of zanubrutinib vs. ibrutinib in WM, ASPEN tential top-line data in Phase 3 of zanubrutinib vs. bendamustine rituximab (BR) in 1L CLL, SEQUOIA dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	<ul><li>2019 or early 2020</li><li>2019</li><li>As early as 2020</li></ul>
Data • To	p-line Phase 3 data of zanubrutinib vs. ibrutinib in WM, ASPEN tential top-line data in Phase 3 of zanubrutinib vs. bendamustine rituximab (BR) in 1L CLL, SEQUOIA dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	<ul><li>2019</li><li>As early as 2020</li></ul>
	tential top-line data in Phase 3 of zanubrutinib vs. bendamustine rituximab (BR) in 1L CLL, SEQUOIA dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	As early as 2020
Data • Po	dated Phase 1 obinutuzumab combination data in NHL, updated CLL data from global Phase1 trial	· ·
	· · · · · · · · · · · · · · · · · · ·	■ 2019
Data • Up	tista glabal Dhaga 2 companing zapubrutinih u rituyimah ya handamustina u rituyimah in TNIMCI	2010
Initiate • Ini	tiate global Phase 3 comparing zanubrutinib + rituximab vs. bendamustine + rituximab in TN MCL	■ 2019
Tisle	elizumab (PD-1 Antibody)	
Approval • Ap	proval in China for cHL	■ 2019
Data + • Gle	obal top-line Phase 2 data in HCC and regulatory filing discussions	<ul><li>2019 or early 2020</li></ul>
Data • To	p-line Phase 3 data from China study in 1L Sq NSCLC	■ 2019 or 2020
Data • To	p-line Phase 3 data from China study in 1L Non-Sq NSCLC	■ 2020
Data • Ch	ina pivotal Phase 2 data in UC	■ 2019
Data • Ch	emotherapy combination data in esophageal and lung cancers from China Ph.2 trials; HCC cohort data from China Ph.1	<ul><li>2019 or early 2020</li></ul>
Enrollment • Co	mplete enrollment in Phase 3 global study in 1L HCC vs. sorafenib	■ 2019
Enrollment • Co	mplete enrollment in global portion of Phase 3 study in 2/3L Non-Sq NSCLC vs. docetaxel	<ul><li>2019 or early 2020</li></ul>
Initiate • Ini	tiate Phase 1/1b in China and Australia of A1217 (TIGIT) with tislelizumab in patients with advanced solid tumors	■ 2019
Pam	iparib (PARP inhibitor)	
Data • To	p-line data from China pivotal Phase 2 in 3L+ ovarian cancer	<b>2</b> 020
Data ■ To	p-line data from China Phase 3 comparing pamiparib vs. placebo as maintenance in platinum-sensitive OC	■ 2020
Data ■ Ov	rarian expansion cohort data including (including QD cohort) from global Ph.1 trial presented at a medical conference	■ 2019
	dated Ph.1 combination data with chemotherapy in solid tumors, and chemotherapy with or without radiation in GBM presented at additional conferences	■ 2019
Early	y-stage Assets	
Initiate • Ad	vance at least one additional preclinical compound from internal pipeline into clinic	■ 2019

### **Review of Product Candidates**



# Overview of Zanubrutinib (BGB-3111)





- Optimized pharmacologic properties relative to ibrutinib: superior bioavailability and higher selectivity
- Development hypothesis: more complete target inhibition, deeper responses, and favorable safety profile



- More than 1,450<sup>1</sup> patients enrolled across trials, including combinations
- Clinical experience to date supports best-in-class hypothesis
  - Strong suggestion of deeper responses in WM and MCL
  - · Favorable response rate, depth, and durability in CLL/SLL
  - High overall and complete response rates in FL with obinutuzumab combination
  - Low rate of toxicity/tolerability-related discontinuation



- Fast Track in WM and Breakthrough Therapy in MCL designations by FDA
- Global registrational trials: WM (H2H vs. ibrutinib, enrollment completed), 1L CLL/SLL (vs. BR), R/R CLL/SLL (vs. ibrutinib), FL (potential for global first-inclass BTK approval in FL); and R/R MZL (global pivotal phase 2 trial)
- China registration trials: accelerated approval trials for MCL (filed), CLL/SLL (filed), and WM (enrollment completed)



- Submitted NDAs in China for MCL and CLL/SLL (acceptance announced on August 26, 2018 and October 24, 2018; priority review granted to NDA in MCL announced on November 15, 2018, in CLL/SLL in January 14, 2019)
- Presented MYD88<sup>WT</sup> cohort from Ph3 WM trial and update Phase 1 WM data at FHA
- Presented updated Ph2 data in MCL at 15-ICML
- Presented updated Ph2 data in CLL at 15-ICML



### **Zanubrutinib Clinical Program**

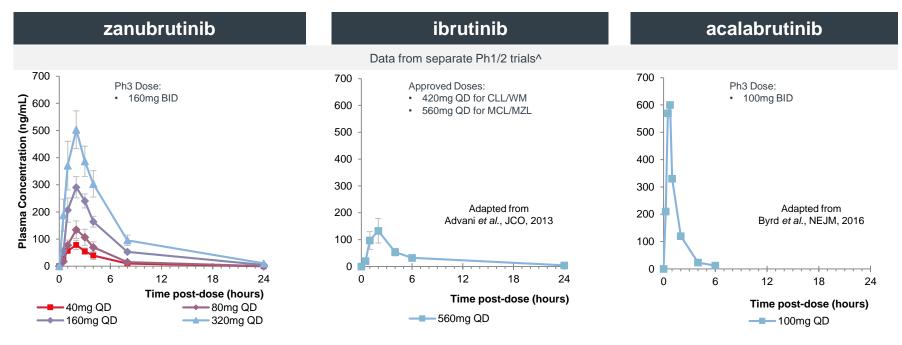
					Global	China	
PROGRAM (TARGET)	DOSE ESCALATION	DOSE EX	PANSION	PIVOTAL		F!! FD	
PROGRAW (TARGET)	PH1a	PH1b	PH2*	PH2**	PH3	FILED	
	R/R CLL/SLL (NDA Accepted)						
	R/R MCL (NDA accepted)						
	WM: zanubrutinib vs. ibrutinib, ASPEN						
	TN CLL/SLL: zanubrutinib vs. BR, SEQUO						
zanubrutinib	R/R CLL/SLL: zanubrutinib vs. ibrutinib, ALPINE						
(BGB-3111, BTK)	Planned: 1L MCL: zanubrutinib + R vs. BR						
	R/R MZL⁴						
	R/R WM						
	R/R DLBCL						
	B-cell malignancies						
+ GAZYVA® (CD20)	R/R FL: zanubrutinib + GAZYVA® vs. GAZ	YVA®					
T GAZT VA" (CD20)	B-cell malignancies						
+ GAZYVA® + venetoclax (CD20 + BCL2)	TN CLL/SLL						
+ tislelizumab (PD-1)	Hematological tumors						
+ ME-401 (PI3K delta)	R/R CLL/SLL or B-cell malignancies						

More than 1,450 patients<sup>3</sup> treated with zanubrutinib across program, including combination trials.

<sup>1.</sup> Some indications will not require a non-pivotal Ph2 clinical trial prior to beginning pivotal Ph2 or Ph3 clinical trials. 2. Confirmatory clinical trials post approval are required for accelerated approvals. 3. as of August 7, 2019. 4. global study and potentially registration-enabling in certain countries; DLBCL: Diffuse Large B-cell Lymphoma



### **Zanubrutinib – Pharmacokinetics Profile**



- Cmax 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: 1.11 (zanubrutinib) and 3.42-7.23 (acalabrutinib)



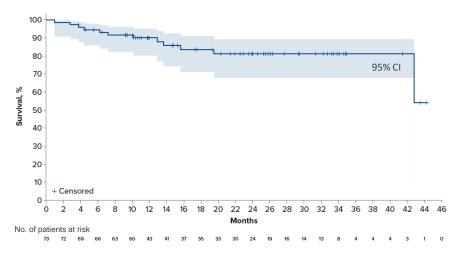
### **Zanubrutinib Efficacy in WM**

#### Favorable response depth and durability

#### **Overall Response Rate (ORR)**

Best Response in WM	zanubrutinib					
	Overall	TN	RR			
Evaluable for efficacy, n	73	24	49			
Median Follow-up	23.9 mo	12.3 mo	24.8 mo			
Response Criteria	Mod. 6 <sup>th</sup> IWWM (IgM decreases only, and not extramedullary disease)					
Median Prior Lines of Therapy		0	2 (1-8)			
ORR	92%	96%	90%			
MRR	82%	87%	78%			
CR/VGPR <sup>1</sup>	42%	29%	49%			
PR	40%	58%	31%			

#### **Progression Free Survival (PFS)**



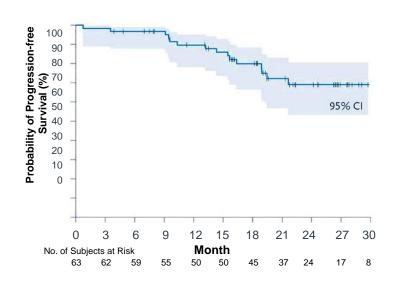


# **Ibrutinib Efficacy in WM**

#### **Overall Response Rate (ORR)**

Best Response in WM	ibrutinib		
Enrolled, n	63		
Median Time-on-Treatment	19.1 months		
Response Criteria	Modified 3 <sup>rd</sup> IWWM (IgM only)		
Median Prior Lines of Tx	2 (1-9)		
ORR, n (%)	57 (90%)		
MRR	46 (73%)		
VGPR	10 (16%)		
Median IgM Reduction (g/L)	35.2 to 8.8 (75%)		
Median Hb Change (g/dl)	10.5 to 13.8		

#### **Progression Free Survival (PFS)**





# Zanubrutinib MYD88<sup>WT</sup> Data from Phase 3 Cohort 2 and Phase 1 Suggest Activity in Difficult-to-Treat WM Patients

Best response, n (%)	Phase 3 cohort 2 <sup>1</sup> (n=26)	Phase 1² (n=8)		
		EHA 2019		
ORR	21 (80.8)	7(87.5)		
MRR	14 (53.8)	5(62.5)		
CR / VGPR	6 (23.1) <sup>a,b</sup>	2(25.0)		
PR	8 (30.8)	3(37.5)		
MR	7 (26.9)	2(25.0)		
SD	4 (15.4)	1(12.5)		
PD	1 (3.8)	0		
Study follow-up time, median (range)				
Months	12.2 (2.3 - 21.7)	24.3 (4.1-45.7)*		

Phase 1 safety summary for full WM n=77 cohort. Patients with an event n (%): Patients with ≥1 AE grade ≥3 40 (51.9); Patients with ≥1 serious AE 36¹ (46.8); AE leading to treatment discontinuation 8² (10.4); Fatal AE 5c (6.5). ¹Includes serious AEs possibly related to zanubrutinib (n=6): hemothorax+pleural effusion+anemia (n=1), atrial fibrillation (n=1), colitis (n=1), febrile neutropenia (n=1), pneumonia (n=1), and cellulitis (n=1); septic arthritis relatedness was unknown. ²Abdominal sepsis (fatal), septic arthritis (fatal), worsening bronchiectasis (fatal), gastric adenocarcinoma (fatal), prostate adenocarcinoma, metastatic neuroendocrine carcinoma, acute myeloid leukemia, and breast cancer (each n=1).

<sup>&</sup>lt;sup>a</sup>One patient achieved IgM complete response (normalized IgM and negative immunofixation since Cycle 11, with bulky extramedullary disease improving).

<sup>b</sup>Including the patient who had CXCR4 frameshift mutation. 1 Dimopoulos et. al. EHA 2019, Data cut: Feb 28, 2019, Safety summary below; 2 Tam et al, EHA 2019; \* Follow up for full WM cohort.



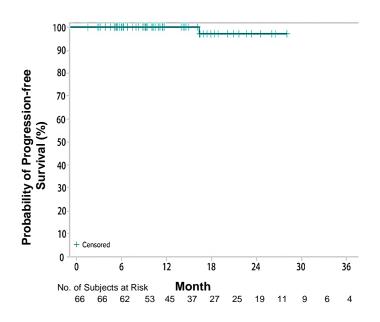
# Zanubrutinib Efficacy in CLL/SLL

#### Frequent and durable responses

#### **Overall Response Rate (ORR)**

zanubrutinib	TN CLL	R/R CLL	Total CLL
n	16	50	66
Median follow- up (mo)	7.6	14.0	10.5
Best Response			
ORR	16 (100%)	46 (92%)	62 (94%)
CR	1 (6%)	1 (2%)	2 (3%)
PR	13 (81%)	41 (82%)	54 (82%)
PR-L	2 (13%)	4 (8%)	6 (9%)
SD	0	3 (6%)	3 (5%)
Non-evaluable*	0	1 (2%)	1 (2%)

#### **Progression Free Survival (PFS)**





<sup>\*</sup>Discontinuation prior to first assessment Source: Seymour et al. 14-ICML 2017 (abstract 237) poster

## **Ibrutinib Efficacy in CLL/SLL**

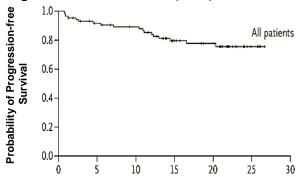
#### Overall Response Rate (Relapsed / Refractory)

n	85
Median FU (mo)	20.9
Best Response ORR CR PR PR-L SD PD	75 (88%) 2 (2%) 58 (68%) 15 (18%) NR NR

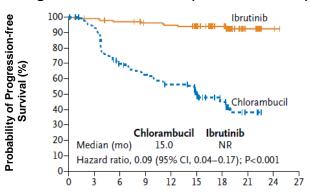
#### Overall Response Rate (Treatment-Naïve)

n	136
Median FU (mo)	18.4
Best Response	
ORR	117 (86%)
CR	5 (4%)
PR	107 (79%)
PR-L	5 (4%)
SD	NR
PD	NR

#### **Progression Free Survival (Relapsed / Refractory)**



#### **Progression Free Survival (Treatment-Naïve)**





## **Ibrutinib**

#### Discontinuation for toxicity or progression in CLL/SLL

	Treatment-Naïve (n=80)	Relapsed/Refractory (n=536)	Total (n=616)
Median Follow-Up	14.5	months	
Total Treatment Discontinuation	19 (24%)	231 (43%)	250 (41%)
Toxicity/Tolerability	12 (15%)	117 (22%)	129 (21%)
CLL/SLL Progression	3 (4%)	49 (9%)	52 (8%)
Transformation (RT or HD)	0 (0%)	10 (2%)	10 (2%)
Death Unrelated to Treatment	1 (1%)	28 (5%)	29 (5%)
Physician or Patient Decision	2 (2%)	15 (3%)	17 (3%)
Transplant	0 (0%)	8 (1.5%)	8 (1%)
Financial Concerns	0 (0%)	1 (0.2%)	1 (0.2%)
Secondary Malignancy	1 (1%)	2 (0.5%)	3 (0.5%)

Source: Mato ASH 2016

Note: at med follow-up 24.5 mos, 22% discontinuation rate with acalabrutinib in R/R CLL; 9% AE-related, 8% PD-related. Byrd ASH 2017.



## Zanubrutinib

#### Discontinuation for toxicity or progression in CLL/SLL is uncommon

	Treatment-Naïve (n=18)	Relapsed/Refractory (n=51)	Total (n=69)
Median Follow-Up	10.3		
Total Treatment D/C	0 (0%)	2 (4%)	2 (3%)
Toxicity/Tolerability	0 (0%)	1 (2%)	1 (1%)
CLL/SLL Progression	0 (0%)	0 (0%)	0 (0%)
Transformation (RT or HD)	0 (0%)	1 (2%)	1 (1%)



#### Zanubrutinib

#### Safety and tolerability summary; Over 600-patient experience

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

AE of Interest (All Causes) <sup>1</sup>	Zanubrutinib <sup>1</sup> (Including Patients Enrolled in Combo Studies		
Patient Number	N=641		
Mean Exposure Time	7.7 mo		
Atrial Fibrillation	1.7%		
Major Hemorrhage	1.9%		

AE of Interest (All Causes) <sup>2</sup>	Zanubrutinib (Single Agent Only)
Patient Number	N=682
Median Exposure Time	13.4 mo
Atrial Fibrillation (Gr ≥3)	1.9% (0.6%)
Major Hemorrhage*	2.5% (2.1%)
Diarrhea (Gr ≥3)	19.4% (0.9%)

- Very low rates of headache and hypertension (6.7% and 6.3%)
- Concomitant use of anti-coagulants was allowed in these zanubrutinib trials
- Low rate of treatment discontinuation for drug-related adverse events



# **Zanubrutinib Responses Across Additional B-Cell Malignancies**

	MZL	MCL	MCL	FL	FL	DLBCL
Source	ASH 2017 <sup>1</sup>	ICML 2019 <sup>3</sup>	China pivotal data ASH2018 <sup>2</sup>	ASH 2017 <sup>1</sup>	CSCO 2018 <sup>4</sup>	ASH 2017 <sup>1</sup>
n	9	48	85	17	26	26
Follow-up (med)	7.0 mo	16.7 mo	35.9 wk	7.8 mo	9.5 mo	4.2 mo
Prior Lines (med)	2 (1-8)	1 (1-4)	2 (1-4)	2 (1-8)	3 (1-9)	2 (1-10)
ORR	78%	85%	84%	41%	42%	31%
CR	0	29%*	59%**	18%	8%	15%
VGPR						
PR/PR-L	78%	56%	25%	24%	35%	15%
MR						

- Despite relatively early follow-up, responses were observed in multiple B-cell malignancies
- Consistency across tumor types suggests that zanubrutinib is a highly active BTK inhibitor



# Zanubrutinib Plus Obinutuzumab Combination in Follicular Lymphoma

39%

CR

	Data from separate trials					
FL	Zanubrutinib + Obinutuzumab	Zanubrutinib	Ibrutinib	Obinutuzumab	Idelalisib	
Source	ICML 2019 <sup>1</sup>	ASH 2017 <sup>2</sup>	ASH 2016 <sup>3</sup>	JCO 2013 <sup>4</sup>	NEJM 2014 <sup>5</sup>	
n	36	17	110	34	72	
Population	prior alkylator and CD20, mixed rituximab-sensitive and -refractory	median 2 prior lines of therapy, range 1-8	prior alkylator and CD20, last response <12 months	mixed rituximab-sensitive and -refractory	alkylator and rituximab- refractory relapse	
Follow-up (med)	20.1 mo	7.8 mo	27.7 mo	33.7 mo	NR	
ORR	72%	41%	21%	50%	54%	

11%

**18%**<sup>6</sup>

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

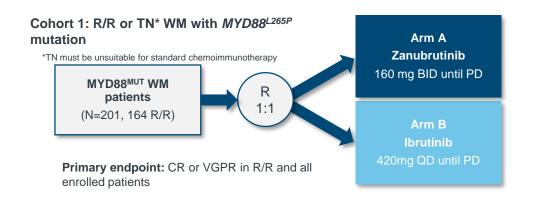
18%



6%

# Ongoing Global Phase 3 Studies ASPEN

#### Zanubrutinib vs. Ibrutinib in WM



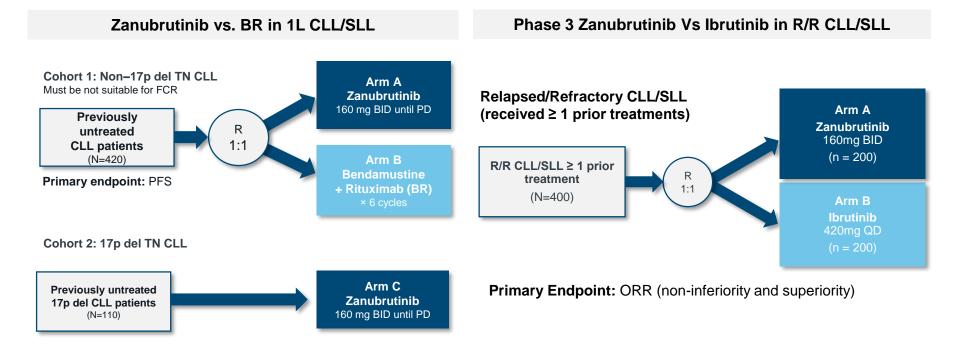
#### Cohort 2: WM with wild type MYD88

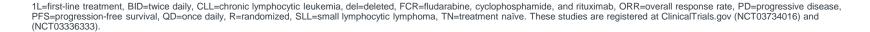




# **Ongoing Global Phase 3 Studies**

#### SEQUOIA and ALPINE



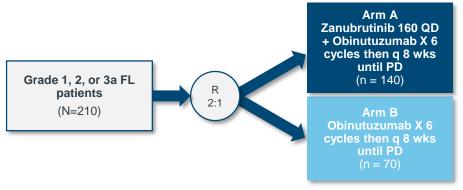




# **Ongoing Pivotal Study**

#### Phase 2 Zanubrutinib + Obinutuzumab vs Obinutuzumab in R/R FL

#### Relapsed/Refractory FL (received ≥2 prior treatments\*)



**Primary Endpoint: ORR** 



# Zanubrutinib Potentially Addresses Areas of Need for Patients Treated with BTK Inhibitors

#### **Efficacy**

- Complete and sustained target inhibition may result in better response quality
  - · We are testing this hypothesis in Phase 3 head-to-head trials against ibrutinib in WM and CLL

#### **Tolerability**

- In "real-world" ibrutinib use in CLL, not only acute/ serious toxicities (atrial fibrillation, serious bleeding), but cumulative tolerability issues (myalgia, arthralgia, hypertension) are frequently treatment-limiting
- Zanubrutinib to date has been associated with low rates of toxicity-related discontinuations and cumulative "off-target" toxicities<sup>1</sup>

#### **Drug-Drug Interactions**

- Based on drug interaction studies, co-administration with strong CYP3A inhibitors is permitted
  - · Includes important agents in management of leukemia/lymphoma patients, such as azole anti-fungals
- Co-administration of proton pump inhibitor (PPIs) or other Acid-Reducing Agents (ARA) does not affect zanubrutinib exposure based on PK models
- Patients have been allowed to receive anticoagulants and and aspirin on zanubrutinib single arm trials



# Overview of Tislelizumab (BGB-A317)

**Broad integrated global and China development program** 



- Tislelizumab is a PD-1 checkpoint inhibitor with distinct molecular structure and an engineered Fc region; believed to minimize potentially negative interactions with other immune cells<sup>1</sup>
  - · Pivotal data in lead indication: 87% ORR (63% CR) in R/R cHL
- Broad development in Asia-prevalent cancers
  - 14 ongoing and soon-to-start Ph. 3 or potentially registration-enabling trials: 4 in lung cancer, 2 in liver cancer, 3 in esophageal cancer, 1 in gastric cancer, 2 in bladder cancer, 1 in nasopharyngeal cancer, and 1 in MSI-H or dMMR solid tumors
  - Aimed to support broad label and label-based reimbursement
- · Strong manufacturing capabilities with emphasis on quality
  - · Manufacturing process and initial capacity developed by Boehringer Ingelheim
  - BeiGene's state-of-the-art 24,000L facility in Guangzhou expected to become operational in 2019



- Clinical experience in more than 2,950 patients<sup>2</sup> enrolled over 3 years has demonstrated encouraging clinical activity and generally well-tolerated safety profile
- Broad development program designed to capture worldwide commercial opportunities
  - Two China accelerated approval trials : cHL (priority) and urothelial cancer (priority)
  - Initiated global Ph2 trials in NK/T cell lymphomas and 2L/3L HCC, China pivotal Ph2 in MSI-H or dMMR solid tumors, 5 global Ph3 trials in 1L GC, 1L and 2L ESCC, 1L HCC and 2L NSCLC; 6 Ph3 trials in 1L non-sq and sq NSCLC, 1L SCLC, 1L UC, localized ESCC and 1L NPC in China
  - Combinations ongoing with BeiGene's PARP, BTK, PD-L1 and TIM3 inhibitors
  - Additional Ph3 trials planned



**PLAN** 

**DEVELOPMENT** 

- Submitted first NDA in China for cHL (priority review granted November 15, 2018) and sNDA for UC (priority review announced July 8, 2019)
- Presented data on long term exposure and structure/mechanism at AACR 2019
- Presented data on use in NPC at ASCO 2019
- Presented China cHL pivotal trial data at EHA 2019



### **Tislelizumab Clinical Program**

#### **Broad development for Asia-prevalent cancers**

		DOOF FOOM ATION				PNOTAL	
PROGRAM (TARGET) TUMO	TUMOR	DOSE ESCALATION	DOSE EX	DOSE EXPANSION		PIVOTAL	
		PH1a	PH1b	PH2*	PH2**	PH3	FILED
	Hama	R/R cHL (NDA accepted)					
	Heme	R/R NK/T-cell lymphoma					
	Bladder	2L+ UC (NDA accepted)					
	Diduuei	1L UC					
		2L NSCLC					
	Lung	1L non-squamous NSCLC					
	Lung	1L squamous NSCLC					
tislelizumab		1L SCLC					
(PD-1)	Liver	1L HCC					
(1 D-1)		2L/3L HCC <sup>2</sup>					
		2L ESCC					
	Esophageal	1L ESCC					
		Localized ESCC					
	Gastric	1L GC					
		1L NPC					
		MSI-H or dMMR solid tumors					
		Solid tumors					
+ pamiparib (PARP)		Solid tumors					
+ zanubrutinib(BTK)		Hematologic tumors					
sitravatinib(multi-kinase)		NSCLC, RCC, OC, melanoma^					
- sitravatinib(multi-kinase)		HCC, GC^					
+ A333(PD-L1)		Solid tumors					
+ A425(TIM3)		Solid tumors					

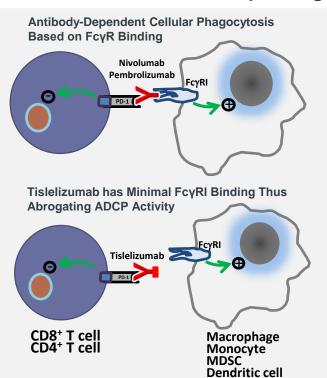
- More than 2,950 patients<sup>1</sup> enrolled over 3 years across tislelizumab program, including combination trials
- Broad development global program with additional Ph3/potential registration-enabling trials planned in lung, gastric, liver, and esophageal cancers



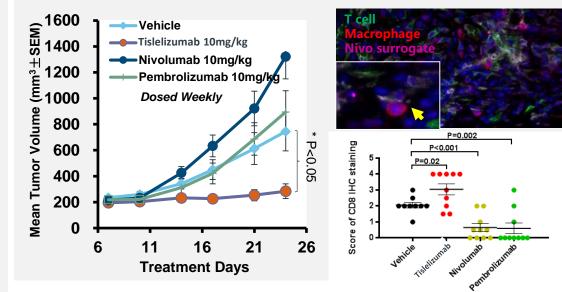
<sup>\*</sup>Some indications will not require a non-pivotal Ph2 clinical trial prior to beginning pivotal Ph2 or 3 clinical trials. \*\*Confirmatory clinical trials post-approval are required for accelerated approvals. ATrials conducted in the APAC region. 1. as of June 2019. 2. global study and potentially registration-enabling in certain countries

# Tislelizumab's Lack of FcγR Binding Is Designed to Prevent Macrophage-Mediated T-Cell Clearance

We believe the different FcyR design may have meaningful differences in the clinic



Tislelizumab Differential Preclinical Efficacy in in vivo Mouse Tumor Model



- Tislelizumab was specifically engineered to minimize binding to FcγR on macrophages, thereby abrogating antibody-dependent cellular phagocytosis (ADCP), a potential mechanism of T-cell clearance
- Hypothesis supported by literature: Dahan et al. reported that FcγR engagement compromises the
  anti-tumor activity of anti-PD-1 Abs; Arlauckas et al. showed in a mouse model that anti-PD-1 Abs could
  be transferred from PD-1+ T cells to macrophages in FcvR-dependent manner

FcyRI=Fc gamma receptor-1, MDSC=myeloid-derived suppressor cell; Source: Dahan et al., Cancer Cell, 2015; Arlauckas et al., Sci. Transl. Med., 2017

BeiGene

#### Tislelizumab China cHL Pivotal Trial Data

# Deep and frequent responses observed in both transplant-ineligible patients and patients who failed transplant

	(11 -0)
Baseline Characteristics	Total (N=70)
Age (years), median (range)	32.5 (18, 69)
Age group <65 / 65-74 years, n (%)	66 (94.3) / 4 (5.7)
Sex, male / female, n (%)	40 (57.1) / 30 (42.9)
Time since first diagnosis of cHL (months), median (range)	25.33 (4.6, 262.3)
Stage IV at study entry, n (%)	42 (60.0)
Bulky disease*, n (%)	8 (11.4)
Bone marrow involvement, n (%)	22 (31.4)
B-symptom(s), n (%)	26 (37.1)
Ineligible for prior ASCT <sup>†</sup> , n (%)	
Failure to achieve an objective response to salvage chemotherapy	53 (75.7)
Inadequate stem cell collection or unable to collect stem cells	2 (2.9)
Co-morbidities	2 (2.9)
Prior lines of systemic therapy, median (range)	3 (2-11)
Type of prior therapy, n (%)	
Chemotherapy	70 (100.0)
Radiotherapy	21 (30.0)
ASCT	13 (18.6)
Immunotherapy <sup>‡</sup>	15 (21.4)
Brentuximab vedotin	4 (5.7)

IRC Dataset	cHL
Enrolled Patients	N=70
Median Follow-up	13.9 months
Prior Lines, Median (range)	3 (2-11)
ORR	87.1%
CR	62.9%
PR	24.3%



<sup>--</sup> Majority of transplant-ineligible patients had failed to respond to salvage chemotherapy

## **Summary of Tislelizumab Adverse Events**

#### cHL pivotal trial

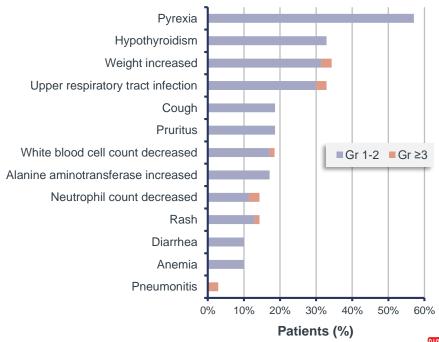
# Summary of Treatment-Emergent Adverse Events

Event, n (%)	N=70
Grade ≥3 TEAE	21 (30)
Serious TEAE	12* (17.1)
TEAE leading to treatment discontinuation	4 <sup>†</sup> (5.7)
TEAE leading to death	0 (0.0)
Immune-related (ir) TEAEs (by aggregate categories)	gory)
≥1 irTEAE	27 (36.8)
Thyroid disorder	16 (22.9)
Pneumonitis	5 (7.1)
Skin adverse reactions	6 (8.6)
Myositis/rhabdomyolysis/cardiomyopathy <sup>‡</sup>	1 (1.4)
Nephritis and renal dysfunction	1 (1.4)
Other immune-related reactions (lipase increased	1 (1.4)

Source: Song et al., EHA 2019

Data cut: Nov 26, 2018; TEAE, treatment-emergent adverse events by individual preferred term.

# TEAEs in ≥10% of Patients and Grade ≥3 TEAEs in ≥2 Patients Regardless of Causality



<sup>\*</sup>SAEs in 11 of the 12 patients determined to be possibly related to tislelizumab

<sup>†</sup>Pneumonitis (n=2), focal segmental glomerulosclerosis (n=1), organizing pneumonia (n=1)

<sup>‡</sup>Blood creatine phosphokinase increased

#### Tislelizumab China UC Pivotal Trial Data

#### **Activity in previously treated patients**

	uc
Enrolled Patients/evaluable	N=113/104
Median Follow-up	8 months
ORR	23.1%
CR	7.7%
PR	15.4%

- IRC assessed
- Frequency and severity of adverse events were generally consistent with the previously reported Phase 1/2 safety and tolerability data for tislelizumab, or, in the case of certain immune-related adverse events, consistent with previous reports of other PD-1 antibodies. Full results of the study are planned to be presented at an upcoming medical conference.



# **Tislelizumab Response Data in Disease-Specific Cohorts**

Tumor Type	Gastric Cancer	Esophageal Cancer	Head & Neck SCC	Ovarian Cancer	Hepatocellular Carcinoma	Urothelial Cancer	NSCLC	MSI-H / dMMR	NPC
Source	ESMO-IO 2018 <sup>1</sup>	ESMO-IO 2018 <sup>1</sup>	ESMO 2017 <sup>2</sup>	ESMO 2017 <sup>3</sup>	ESMO-IO 2018 <sup>1</sup>	ESMO-IO 2018 <sup>4</sup>	ESMO-IO 2018 <sup>1</sup>	CSCO 2018 <sup>5</sup>	ASCO 2019 <sup>6</sup>
Median Treatment Duration			104 days (30-339)	71 days (29-540)		4.1 mo (0.7-26.3)		2.2 mo (0.69-11.1)	7.5 mo (2.1-15.8)
Median Follow-up Time	4.9 mo (0.9-25.4)	5.2 mo (0.2-22.7)			10.8 mo (0.7-31.6)		11.2 mo (0.5-25.9)	4.4 mo (0.1-10.7)	11.7 mo (4.9-15.7)
Median Duration of Response	8.5 mo	NR			15.7 mo	18.7 mo (6.2-18.7)	NR		8.3 mo
Evaluable Patients	N=54	N=54	N=17	N=50	N=49	N=17	N=46	N=14	N=21
CR (Confirmed)		1				1			
PR	7	5	3	2	6	4	6	4	9
SD	9	14	6	20	19	3	23	4	9
Patients Remaining on Treatment*	3	3	3	6	5	2	7	9	9

• Objective responses observed with limited follow-up in multiple disease-specific cohorts. NR = Not reached

Sources:1. Ph1A/1B data as of August 31, 2018, presented at the ESMO Immuno-Oncology 2018 Congress (Sanjeev et al); 2. Ph1 data as of June 8, 2017, presented at the ESMO 2017 Congress (Meniawy et al, Abstract 389P); 3. Ph1 data as of June 8, 2017, presented at the ESMO Immuno-Oncology 2018 Congress (Shahneen et al); 5. Ph1 data as of May 11, 2018, presented at CSCO 2018; 6. Ph1/2 as of December 1, 2018, presented at ASCO 2019 (Wang et al); \*At time of data cutoff.



### **Tislelizumab Phase 1 Common AEs in ≥ 10% of Patients**

System Organ Class Preferred Term	Phase 1a N=116 n (%)	Phase 1b N=335 n (%)	Total N=451 n (%)
Patients with at least one TEAE	114 (25.3)	322 (71.4)	436 (96.7)
Fatigue	47 (10.4)	78 (17.3)	125 (27.7)
Nausea	41 (9.1)	68 (15.1)	109 (24.2)
Decreased appetite	19 (4.2)	71 (15.7)	90 (20.0)
Diarrhea	32 (7.1)	49 (10.9)	81 (18.0)
Constipation	26 (5.8)	50 (11.1)	76 (16.9)
Abdominal pain	26 (5.8)	38 (8.4)	64 (14.2)
Vomiting	20 (4.4)	43 (9.5)	63 (14.0)
Back pain	22 (4.9)	40 (8.9)	62 (13.7)
Cough	15 (3.3)	45 (10.0)	60 (13.3)
Rash	23 (5.1)	37 (8.2)	60 (13.3)
Dyspnea	12 (2.7)	33 (7.3)	45 (10.0)



# **Tislelizumab Chemotherapy Combination Data in Lung Cancers**

Responses	Non-Sq Tislelizumab + pemetrexed + platinum (n=16)	Sq Tislelizumab + paclitaxel + platinum (n=15)	Sq Tislelizumab + gemcitabine + platinum (n=6)	SCLC Tislelizumab + etoposide + platinum (n=17)	Total (N=54)
BOR, n (%)					
CR	0	0	0	0	0
PR	5 (31.3)	12 (80.0)	4 (66.7)	8 (47.1)	29 (53.7)
UPR	4 (25.0)	0	0	6 (35.5)	10 (18.5)
SD	5 (31.3)	2 (13.3)	1 (16.7)	1 (5.9)	9 (16.7)
PD	2 (12.5)	0	0	1 (5.9)	3 (5.6)
Missing	0	1 (6.7)	1 (16.7)	1 (5.9)	3 (5.6)
ORR %	56.3	80.0	66.7	82.3	72.2
ORR confirmed %	31.3	80.0	66.7	47.1	53.7

Abbreviations: BOR, best overall response; CR, complete response; Sq, squamous; PD, progressive disease; PR, partial response; SCLC, small cell lung cancer; SD, stable disease; UPR, unconfirmed partial response. Source: CSCO 2018 Wang et al Abstract 450

AEs were considered manageable and reversible, with chemotherapy dose modifications or tislelizumab dose holds, except for one fatal event of myocarditis/myositis (onset of AEs on Day 10 and died on Day 19 of treatment administration). Five patients (9.3%) experienced at least one grade 23 AE (polymyositis, dyspnea, rhabdomyolysis, myocarditis/myositis, and myasthenia gravis) that were considered to be possibly related to tislelizumab. Immune-related AEs (irAEs) occurred in 13 patients (24%) and included hypothyroidism (n=3), decreased tri-iodothyronine (n=2), hyperthyroidism (n=2), previa (n=2), and rash (n=2).



# Overview of Pamiparib (BGB-290) Selective Inhibitor of

PARP1 and PARP2



 Highly selective PARP1 and PARP2 inhibitor with potential brain penetration and strong PARP trapping activity in preclinical studies



CLINICAL DATA

- Ph1/2 data demonstrated pamiparib was generally well-tolerated with promising anti-tumor activity in ovarian cancer
  - Low incidence of hematological toxicities (e.g. thrombocytopenia), no liver toxicity



- Two ongoing global Ph1b/2 trials with chemotherapy: combination with radiation therapy and temozolomide (TMZ) in glioblastoma or combination with TMZ in advanced solid tumors
- Enrollment complete in China pivotal Ph2 trial in patients with gBRCA+ ovarian cancer
- Enrollment complete in Ph3 trial in China as maintenance therapy in patients with platinum-sensitive recurrent ovarian cancer
- Enrolling patients for a global Ph3 trial in gastric cancer as maintenance therapy
- Internal combination with tislelizumab: preliminary anti-tumor activity observed in multiple solid tumors



- Presented updated Ph1 data in ovarian cancer at AACR 2018
- Presented updated Ph1/2 combination data in solid tumours at ESMO 2018
- Presented updated Ph1/2 combination data in GBM at SNO 2018

# **Pamiparib Clinical Program**

RROCRAM (TARCET)	DOSE ESCALATION	DOSE EXPANSION		PIVOTAL	
PROGRAM (TARGET)	PH1a	PH1b	PH2*	PH2**	PH3
	3L gBRCA+ OC				
pamiparib	2L plat-sensitive OC maintenance				
(BGB-290, PARP)	1L plat-sensitive GC maintenance				
	Solid tumors				
+ TMZ (Chemo)	Solid tumors				
+ RT/TMZ (RT/Chemo)	Solid tumors				
+ tislelizumab (PD-1)	Solid tumors				

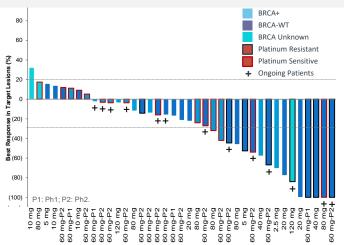
- Two ongoing global Ph1b/2 trials with chemotherapy: combination with radiation therapy and temozolomide (TMZ) in glioblastoma or combination with TMZ in advanced solid tumors
- Internal combination with tislelizumab: preliminary anti-tumor activity observed in multiple solid tumors



# Pamiparib Monotherapy Phase 1/2 Data

#### Promising activity and generally well-tolerated

#### Best Change from Baseline in Target Lesions in Epithelial Ovarian Cancer and Other Associated Tumors



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 Ph1/2 Trial

	Ph1 (n=45)	Ph1 (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			

All date are presented as n (%).

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



Source: Ph1/2 data as of June 1, 2017, presented at the ESMO 2017 meeting (Lickliter et al)

## **Tislelizumab/Pamiparib Combination Escalation Data**

#### Generally well-tolerated with preliminary anti-tumor activity in multiple tumor types

- Ovarian or fallopian tube cancer patients
   (n=29) had best responses of CR (1), PR (2
   confirmed, 5 unconfirmed), and SD (7). Breast
   cancer patients (n=2) had 1 confirmed PR.
   Pancreatic cancer patients (n=3) had best
   responses of PR (1 unconfirmed) and SD (2).
   Uterine cancer patient (n=1) had an
   unconfirmed PR. SD was observed in 1 of 3
   patients with prostate cancer and the 1 patient
   with bile duct cancer. Additional tumor types
   enrolled included bladder, cervical, lung, and
   peripheral nerve sheath cancer (n=1 each)
- Grade 3-4 AEs related to tislelizumab in >1
   patients were AI hepatitis/hepatitis (12%) and
   ALT inc. (5%); related to pamiparib in >1
   patients were anemia (14%), and ALT inc.,
   AST inc., fatigue, and nausea (5% each)
- Liver-related AEs regardless of causality occurred in 12 patients (gr. 3-4 in 8 patients: 5 hepatitis, 3 including 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

