BeiGene Reports First Quarter 2024 Financial Results and Business Updates

- *Total revenues of $752 million in the first quarter, including product revenue of $747 million, an 82% increase from the prior-year period*
- *BRUKINSA revenue of $489 million, driven by growth in the U.S. and Europe of 153% and 243%, respectively, from the prior-year period; with recent fifth FDA approval, BRUKINSA now has the broadest label in the BTKi class*
- *Rapidly advancing late-stage hematology pipeline; sonrotoclax in development both as a monotherapy and in combination with backbone therapy BRUKINSA; pivotal program initiated for BTK CDAC*
- *Progressing potentially differentiated solid tumor programs with ADC, degrader platforms and targeted therapies in priority cancer types*
- *Significantly improved operating leverage and progress on path to sustainable profitability*

SAN MATEO, Calif. – (BUSINESS WIRE) – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global oncology company, today announced results from the first quarter 2024 and business highlights.

"We are pleased to present another quarter of strong financial results. Supported by our tremendous global growth in revenue, we have now ascended into the top 15 of global oncology innovators based on total oncology sales. We also continue to make significant improvement in our operating leverage as we progress to sustainable profitability," said John V. Oyler, Co-Founder, Chairman and CEO at BeiGene. "We strengthened our hematology leadership with BRUKINSA, now the BTK inhibitor with the broadest label in the class, as we advance our innovative pipeline of therapies for hematologic malignancies. With TEVIMBRA now approved for use in the U.S. and Europe, we look forward to rapidly advancing our deep pipeline of solid tumor therapies to match our leadership in hematology and continue to solidify our reputation as a global oncology innovator."

Financial Highlights

(Amounts in thousands of U.S. dollars)

(in thousands, except percentages)	Three Months Ended March 31, 2024	2023	% Change
Net product revenues	$ 746,918	$ 410,291	82 %
Net revenue from collaborations	$ 4,734	$ 37,510	(87)%
Total Revenue	$ 751,652	$ 447,801	68 %
GAAP loss from operations	$ (261,348)	$ (371,258)	(30)%
Adjusted loss from operations*	$ (147,341)	$ (275,859)	(47)%

* For an explanation of our use of non-GAAP financial measures refer to the "Use of Non-GAAP Financial Measures" section later in this press release and for a reconciliation of each non-GAAP financial measure to the most comparable GAAP measures, see the table at the end of this press release.

Key Business Updates

BRUKINSA® (zanubrutinib)

- U.S. sales of BRUKINSA totaled $351 million in the first quarter of 2024, representing growth of 153% over the prior-year period, as BRUKINSA gained share in treatment-naïve (TN) chronic lymphocytic leukemia (CLL), and emerged as the BTKi class leader in new-patient share in relapsed or refractory (R/R) CLL; BRUKINSA sales in Europe totaled $67 million in the first quarter of 2024, representing growth of

243%, driven by continued gains in market share and additional reimbursements including France, which implemented reimbursement for BRUKINSA within CLL, Waldenström's macroglobulinemia (WM) and marginal zone lymphoma for the first time;

- Presented a new matching adjusted indirect comparison of the efficacy of BRUKINSA versus acalabrutinib in R/R CLL based on data from the Phase 3 ALPINE and Phase 3 ASCEND trials demonstrating a progression-free survival and Complete Response (CR) advantage for BRUKINSA versus acalabrutinib, as well as potentially improved overall survival; and

- Received U.S. Food and Drug Administration (FDA) approval for the treatment of adult patients with R/R follicular lymphoma, in combination with the anti-CD20 monoclonal antibody obinutuzumab, after two or more lines of systemic therapy.

TEVIMBRA® (tislelizumab)

- Sales of tislelizumab totaled $145 million in the first quarter of 2024, representing growth of 26% compared to the prior-year period;

- Announced European Commission approval as a treatment for non-small cell lung cancer (NSCLC) across three indications, including first- and second-line use;

- Received FDA approval for the treatment of second-line esophageal squamous cell carcinoma (ESCC) after prior chemotherapy;

- Received FDA acceptance of BLA for the treatment of first-line gastric or gastroesophageal junction cancers; and

- The pending FDA approval for tislelizumab in first-line unresectable, recurrent, locally advanced, or metastatic ESCC with a target PDUFA action date of July 2024 may be deferred on account of a potential delay in scheduling clinical site inspections.

Key Pipeline Highlights

Hematology

Sonrotoclax (BCL2 inhibitor)

- Received FDA fast track designation for R/R mantle cell lymphoma (MCL); and

- Continued enrollment in R/R MCL and WM with registrational intent as well as Phase 3 in TN CLL in combination with BRUKINSA; more than 850 patients enrolled to date across the program.

BGB-16673 (BTK CDAC)

- Initiated expansion cohorts in R/R MCL (potential registrational intent) and R/R CLL; more than 220 patients enrolled to date across the program; and

- Expect to initiate Phase 3 clinical trial in R/R CLL by the end of 2024.

Solid Tumors

Lung Cancer

- Enrolled last subject in a Phase 3 clinical trial for ociperlimab (anti-TIGIT) for first-line PD-L1 high NSCLC;
- Multiple tislelizumab lung cancer combination cohorts with BGB-A445 (anti-OX40), LBL-007 (anti-LAG3) and BGB-15025 (HPK1 inhibitor) expected to read out in 2024; and
- Pan-KRAS and MTA-cooperative PRMT5 inhibitors and EGFR CDAC on track to enter the clinic in the second half of 2024.

Breast Cancer

- *BGB-43395 (CDK4 inhibitor):* Initiated fourth dose level of monotherapy, which is in the efficacious dose range with no dose limiting toxicities observed; and initiated dosing of combination with fulvestrant just over four months from first monotherapy dose.
- *BG-68501 (CDK2 inhibitor):* Initiated second dose level of monotherapy in first-in-human study, with clinical pharmacokinetics as expected and no dose limiting toxicities observed.
- *BG-C9074 (B7H4 ADC):* First patient dosed in Australia in global first-in-human Phase 1 study.

Gastrointestinal Cancers

- Multiple tislelizumab combination cohorts with LBL-007 (anti-LAG3) and BGB-A445 (anti-OX40) reading out in 2024;
- Plan to submit a BLA with the NMPA for zanidatamab for the treatment of second-line biliary tract cancer; and
- CEA-ADC and FGFR2b-ADC on track to enter the clinic in the second half of 2024.

Other Business Highlights

- The U.S. Patent and Trademark Office (USPTO) granted the Company's petition for post-grant review of the Pharmacyclics' patent asserted against the Company in a patent infringement suit, stating that the Company has shown that it is more likely than not that the patent is invalid; The USPTO is expected to issue a final decision on the validity of the patent within 12 months;
- Published the 2023 Responsible Business & Sustainability Report which details the Company's commitment to providing equitable benefit to patients, business and society; and
- Anticipate opening of state-of-the-art biologics manufacturing facility and clinical R&D center at the Princeton West Innovation Campus in Hopewell, New Jersey, in July.

First Quarter 2024 Financial Highlights

Revenue for the three months ended March 31, 2024, was $752 million, compared to $448 million in the same period of 2023, driven primarily by growth in BRUKINSA product sales in the U.S. and Europe of 153% and 243% respectively.

Product Revenue for the three months ended March 31, 2024, was $747 million, compared to $410 million in the same period of 2023, representing an increase of 82%. The increase in product revenue was attributable to increased sales of our internally developed products, BRUKINSA and tislelizumab. For the three months ended March 31, 2024, the U.S. was the Company's largest market, with product revenue of $351 million, compared to $139 million in the prior year period.

Gross Margin as a percentage of global product revenue for the first quarter of 2024 was 83%, compared to 80% in the prior-year period. The gross margin percentage increased primarily due to proportionally higher sales mix of global BRUKINSA compared to other products in the portfolio.

Operating Expenses

	GAAP			Non-GAAP		
(in thousands, except percentages)	Q1 2024	Q1 2023	% Change	Q1 2024	Q1 2023	% Change
Research and development	$ 460,638	$ 408,584	13 %	$ 405,440	$ 361,696	12 %
Selling, general and administrative	$ 427,427	$ 328,499	30 %	$ 372,146	$ 283,154	31 %
Amortization	$ —	$ 187	(100)%	$ —	$ —	NM
Total operating expenses	$ 888,065	$ 737,270	20 %	$ 777,586	$ 644,850	21 %

Research and Development (R&D) Expenses increased for the first quarter of 2024 compared to the prior-year period on both a GAAP and adjusted basis primarily due to advancing preclinical programs into the clinic and early clinical programs into late stage. Upfront fees and milestone payments related to in-process R&D for in-licensed assets totaled $35 million in the first quarter of 2024, compared to nil in the prior-year period.

Selling, General and Administrative (SG&A) Expenses increased for the first quarter of 2024 compared to the prior-year period on both a GAAP and adjusted basis due to continued investment in the global commercial launch of BRUKINSA, primarily in the U.S. and Europe. SG&A expenses as a percentage of product sales were 57% for the first quarter of 2024 compared to 80% in the prior year period.

Loss from Operations in the first quarter of 2024 decreased 30% on a GAAP basis and 47% on an adjusted basis compared to the prior-year period. The decrease is driven by significantly improved operating leverage associated with substantial revenue growth and expense discipline as we make significant progress on the path to sustainable profitability.

GAAP Net Loss improved for the quarter ended March 31, 2024, compared to the prior-year period, as our product revenue growth and management of expenses is driving increased operating leverage.

For the quarter ended March 31, 2024, net loss per share were $(0.19) and $(2.41) per American Depositary Share (ADS), compared to $(0.26) per share and $(3.34) per ADS in the prior year period.

Cash Used in Operations for the quarter ended March 31, 2024, totaled $309 million compared to $564 million in the prior-year period, driven by improved operating leverage.

For further details on BeiGene's First Quarter 2024 Financial Statements, please see BeiGene's Quarterly Report on Form 10-Q for the first quarter of 2024 filed with the U.S. Securities and Exchange Commission.

About BeiGene

BeiGene is a global oncology company that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 10,000 colleagues spans five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on LinkedIn, X (formerly known as Twitter) and Facebook.

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 BeiGene's ability to advance its pipeline of therapies for hematologic malignancies and rapidly advance its pipeline of solid tumor therapies to solidify its reputation as a global oncology innovator; BeiGene's anticipated clinical activities and read outs; the opening date of BeiGene's biologics manufacturing facility and clinical R&D center in Hopewell, New Jersey; BeiGene's progress towards sustainable profitability; and BeiGene's plans, commitments, aspirations and goals under the caption "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products; BeiGene's ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, 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.

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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	
	2024	2023
	(Unaudited)	
Revenues		
Product revenue, net	$ 746,918	$ 410,291
Collaboration revenue	4,734	37,510
Total revenues	751,652	447,801
Cost of sales - products	124,935	81,789
Gross profit	626,717	366,012
Operating expenses:		
Research and development	460,638	408,584
Selling, general and administrative	427,427	328,499
Amortization of intangible assets	—	187
Total operating expenses	888,065	737,270
Loss from operations	(261,348)	(371,258)
Interest income, net	16,160	16,016
Other income (expense), net	1,762	18,303
Loss before income taxes	(243,426)	(336,939)
Income tax expense	7,724	11,492
Net loss	(251,150)	(348,431)
Net loss per share, basic and diluted	$ (0.19)	$ (0.26)
Weighted-average shares outstanding—basic and diluted	1,355,547,626	1,354,164,760
Net loss per ADS, basic and diluted	$ (2.41)	$ (3.34)
Weighted-average ADSs outstanding—basic and diluted	104,272,894	104,166,520

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

(Amounts in thousands of U.S. Dollars)

	As of	
	March 31, 2024	**December 31, 2023**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 2,807,436	$ 3,188,584
Accounts receivable, net	435,294	358,027
Inventories	447,345	416,122
Property, plant and equipment, net	1,417,992	1,324,154
Total assets	5,667,681	5,805,275
Liabilities and equity:		
Accounts payable	356,575	315,111
Accrued expenses and other payables	569,438	693,731
R&D cost share liability	225,530	238,666
Debt	1,025,992	885,984
Total liabilities	2,307,320	2,267,948
Total equity	$ 3,360,361	$ 3,537,327

Note Regarding Use of Non-GAAP Financial Measures

BeiGene provides certain non-GAAP financial measures, including Adjusted Operating Expenses and Adjusted Operating Loss and certain other non-GAAP income statement line items, each of which include adjustments to GAAP figures. These non-GAAP financial measures are intended to provide additional information on BeiGene's operating performance. Adjustments to BeiGene's GAAP figures exclude, as applicable, non-cash items such as share-based compensation, depreciation and amortization. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. BeiGene maintains an established non-GAAP policy that guides the determination of what costs will be excluded in non-GAAP financial measures and the related protocols, controls and approval with respect to the use of such measures. BeiGene believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of BeiGene's operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of the Company's historical and expected financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators BeiGene's management uses for planning and forecasting purposes and measuring the Company's performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by the Company may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

RECONCILIATION OF SELECTED GAAP MEASURES TO NON-GAAP MEASURES

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Reconciliation of GAAP to adjusted cost of sales - products:		
GAAP cost of sales - products	$ 124,935	$ 81,789
Less: Depreciation	2,345	2,180
Less: Amortization of intangibles	1,183	799
Adjusted cost of sales - products	$ 121,407	$ 78,810
Reconciliation of GAAP to adjusted research and development:		
GAAP research and development	$ 460,638	$ 408,584
Less: Share-based compensation expenses	38,045	34,028
Less: Depreciation	17,153	12,860
Adjusted research and development	$ 405,440	$ 361,696
Reconciliation of GAAP to adjusted selling, general and administrative:		
GAAP selling, general and administrative	$ 427,427	$ 328,499
Less: Share-based compensation expenses	50,669	41,360
Less: Depreciation	4,612	3,985
Adjusted selling, general and administrative	$ 372,146	$ 283,154
Reconciliation of GAAP to adjusted operating expenses		
GAAP operating expenses	$ 888,065	$ 737,270
Less: Share-based compensation expenses	88,714	75,388
Less: Depreciation	21,765	16,845
Less: Amortization of intangibles	—	187
Adjusted operating expenses	$ 777,586	$ 644,850
Reconciliation of GAAP to adjusted loss from operations:		
GAAP loss from operations	$ (261,348)	$ (371,258)
Plus: Share-based compensation expenses	88,714	75,388
Plus: Depreciation	24,110	19,025
Plus: Amortization of intangibles	1,183	986
Adjusted loss from operations	$ (147,341)	$ (275,859)