BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

VOLUNTARY ANNOUNCEMENT — UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS

BRUKINSA® Receives Positive Recommendation from NICE in U.K. for Adult Patients with Chronic Lymphocytic Leukemia

On October 20, 2023, BeiGene, Ltd. ("**BeiGene**" or the "**Company**") announced the National Institute for Health and Care Excellence (NICE) of the United Kingdom (U.K.) has issued a final draft guidance (FDG) recommending BRUKINSA® (zanubrutinib) for the treatment of eligible adult patients with:

- Untreated chronic lymphocytic leukemia (CLL) if there is a 17p deletion or TP53 mutation (high risk) or
- Untreated CLL without a 17p deletion or TP53 mutation, and fludarabine-cyclophosphamide-rituximab (FCR) or bendamustine plus rituximab (BR) is unsuitable and
- Relapsed or refractory CLL

"We are delighted that NICE has recognized the clinical and economic benefit of BRUKINSA for patients with CLL," said Dr. Robert Mulrooney, General Manager, U.K. & Ireland at BeiGene. "This follows the previous approval of BRUKINSA by NICE in July 2022 as the only cost-effective treatment for patients with Waldenstrom's macroglobulinemia. Although we are a relatively new player in the U.K. market, we are rapidly establishing ourselves as a company that can make innovative cancer medicines accessible and affordable for U.K. patients."

As stated in the FDG, for the untreated CLL population that is high-risk or for whom FCR or BR is unsuitable and for the relapsed/refractory CLL population, zanubrutinib had lower incremental costs and more incremental quality adjusted life years compared with other BTK inhibitors. The committee considered that zanubrutinib is a cost-effective use of NHS resources in CLL.

"This decision represents a significant milestone for patients in England and Wales with CLL, the most common form of leukemia in adults," said Nick York, Patient Advocacy Healthcare Liaison Officer, U.K. Leukemia Care. "Despite continued treatment advances, many patients with CLL will relapse and need additional treatment options. Furthermore, a proportion of patients have a disease which is refractory to initial treatment."

BRUKINSA is the third BTKi for CLL to be recommended by NICE for routine commissioning.

"Zanubrutinib has demonstrated superior efficacy and a favorable safety profile in two global Phase 3 trials, SEQUOIA and ALPINE, in adult patients with CLL," said Dr. Talha Munir, consultant hematologist at Leeds Teaching Hospitals NHS Trust, Leeds, U.K.[i,ii] "The positive recommendation from NICE will allow patients with CLL in England and Wales to access this important new treatment option."

In addition, on October 9, 2023, BRUKINSA received approval by the Scottish Medicines Consortium for the treatment of adult patients with CLL in whom chemo-immunotherapy is unsuitable.

BRUKINSA is approved in more than 65 countries, including the U.S., China, EU, Great Britain, Canada, Australia, South Korea, and Switzerland, in selected indications and under development for additional indications globally. The global BRUKINSA development program includes more than 5,000 subjects enrolled to date in 29 countries and regions.

About Chronic Lymphocytic Leukemia (CLL)

A life-threatening cancer of adults, CLL is a type of mature B-cell malignancy in which abnormal leukemic B lymphocytes (a type of white blood cells) arise from the bone marrow and flood peripheral blood, bone marrow, and lymphoid tissues.[iii,iv] CLL is the most common type of leukemia in adults, accounting for about one-quarter of new cases of leukemia.[iv,v] Approximately 3,800 people in the U.K. are diagnosed with CLL every year.[vi,vii]

About BRUKINSA® (zanubrutinib)

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

References

i. Brown JR, Eichhorst B, Hillmen P, et al. Zanubrutinib or Ibrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia. *N Engl J Med*. 2023;388(4):319-332. doi:10.1056/NEJMoa2211582.

ii. Tam CS, Brown JR, Kahl BS, et al. Zanubrutinib versus bendamustine and rituximab in untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (SEQUOIA): a randomised, controlled, phase 3 trial. Lancet Oncol. 2022;23(8):1031-1043. doi: 10.1016/S1470-2045(22)00293-5.

iii. National Cancer Institute. Chronic Lymphocytic Leukemia Treatment (PDQ®)–Patient Version. Accessed October 2023. https://www.cancer.gov/types/leukemia/hp/cll-treatment-pdq.

iv. American Cancer Society. What is Chronic Lymphocytic Leukemia? Updated May 10, 2018. Accessed October 2023. https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/about/what-is-cll.html.

v. American Cancer Society. Key Statistics for Chronic Lymphocytic Leukemia. Updated January 12, 2023. Accessed October 2023. https://www.cancer.org/cancer/types/chronic-lymphocytic-leukemia/about/key-statistics.html.

vi. Cancer Research UK. Chronic Lymphocytic Leukaemia (CLL) Incidence Statistics. Accessed October 2023. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/leukaemia-cll/incidence.

vii. Leukaemia UK. Chronic Lymphocytic Leukaemia. Accessed October 2023. https://www.leukaemiauk.org.uk/about-leukaemia/types-of-leukaemia/chronic-lymphocytic-leukaemia-cll/.

About BeiGene

BeiGene is a global biotechnology company that is discovering and developing innovative oncology treatments that are more accessible and affordable 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, with administrative offices in Basel; Beijing; and Cambridge, U.S. To learn more about BeiGene, please visit www.beigene.com and follow us on LinkedIn and X (formerly known as Twitter) at @BeiGeneGlobal.

Forward-Looking Statements

This announcement 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 clinical and economic benefit of BRUKINSA for patients, particularly those with CLL or Waldenstrom's macroglobulinemia; BeiGene's ability to make innovative cancer medicines accessible and affordable for U.K. patients; the future development, regulatory filing, approval and commercialization of BRUKINSA; and BeiGene's plans, commitments, aspirations, and goals under the heading "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 and its 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 and The Stock Exchange of Hong Kong Limited. All information in this announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

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

Hong Kong, October 20, 2023

As of the date of this announcement, the Board of Directors of the Company consists of Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi as Independent Non-executive Directors.