BeOne Medicines Ltd.
百濟神州有限公司
(a corporation incorporated under the laws of Switzerland)
(Stock Code: 06160)

VOLUNTARY ANNOUNCEMENT — UPDATE REGARDING RECENT BUSINESS DEVELOPMENTS

BeOne Medicines' BEQALZI™ (sonrotoclax) Approved by U.S. FDA as First and Only BCL2 Inhibitor for R/R Mantle Cell Lymphoma

On May 13, 2026 (U.S. Eastern Time), BeOne Medicines Ltd. ("**BeOne**", "**BeOne Medicines**" or the "**Company**") announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to BEQALZI™ (bee-KAHL-zee; sonrotoclax), a foundational, next-generation BCL2 inhibitor, for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL), after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor. BEQALZI was designed to enhance BCL2 inhibition – with greater potency, selectivity, and a pharmacologic profile with potential to improve efficacy, tolerability, and convenience over others in the class.

Michael Wang, M.D., Global Principal Investigator, the Puddin Clarke Endowed Professor, Department of Lymphoma and Myeloma, The University of Texas MD Anderson Cancer Center, said:

"The data supporting the approval of sonrotoclax in the U.S. confirm its role as a foundational therapy for mantle cell lymphoma in the post-BTK inhibitor setting, and demonstrate that it can deliver robust disease control when treatment choices are limited and outcomes are poor. From a clinical perspective, this provides physicians with an important new option grounded in both efficacy and tolerability, fundamentally changing how we think about sequencing therapy in this disease."

Data supporting approval

The accelerated approval of BEQALZI is supported by efficacy and safety data from the Phase 1/2 study, BGB-11417-201 (NCT05471843), which was presented at the 67th American Society of Hematology (ASH) Annual Meeting & Exposition. The study included an independent review of efficacy data and demonstrated:

- Overall response rate (ORR): 52% (95% CI, 42-62)
- Complete response (CR) rate: 16% (95% CI, 9.1-24.0)
- Median time to response (TTR): 1.9 months
- Median duration of response (DOR): 15.8 months (95% CI, 7.4 months-NE) at a median response follow-up of 11.9 months (has yet to reach full maturity)
- Safety: treatment with sonrotoclax monotherapy was generally well tolerated

Continued approval for this indication is contingent upon confirmation of clinical benefit in the confirmatory CELESTIAL-RRMCL trial (NCT06742996), which is underway. The U.S. FDA granted Breakthrough Therapy Designation (BTD) for sonrotoclax in this indication, as well as Fast Track Designation and Orphan Drug Designation.

Amit Agarwal, M.D., Ph.D., Chief Medical Officer, Hematology, BeOne Medicines, said:

"BeOne is leading the advancement and enhancement of BCL2 inhibition to revolutionize how we treat patients living with B cell malignancies. Today's approval of BEQALZI represents critical progress for patients with mantle cell lymphoma and reinforces our strategy of building foundational medicines designed to raise the standard of care in B-cell malignancies."

A new BCL2 option for a challenging R/R MCL post-BTK inhibitor setting

MCL is a rare and often aggressive subtype of non-Hodgkin lymphoma. In the United States, approximately 3,300 new cases of MCL are diagnosed each year.[1] While many patients respond to initial therapy, relapse is common, and outcomes after progression can be poor, particularly after prior treatment with a BTK inhibitor. The accelerated approval of BEQALZI introduces a new targeted mechanism to the MCL treatment landscape and reinforces the importance of expanding therapeutic choices for patients as the disease evolves.

Meghan Gutierrez, Chief Executive Officer, Lymphoma Research Foundation, said:

"For people living with relapsed or refractory mantle cell lymphoma, each progression can bring uncertainty and questions regarding remaining treatment options. The FDA approval of sonrotoclax represents significant progress for the U.S. mantle cell lymphoma community, offering renewed hope for patients and families who have exhausted other available therapies. Advances like this underscore why continued research and innovation in this disease remain so critical."

Additional regulatory and development updates

BEQALZI is also approved in China for the treatment of R/R MCL, as well as adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have previously received at least one systemic therapy, including a BTK inhibitor. Data from the Phase 1/2 study of sonrotoclax in R/R MCL is also under review by the European Medicines Agency and other regulatory agencies.

The U.S. FDA also granted sonrotoclax Fast Track Designation for Waldenström macroglobulinemia (WM), as well as Orphan Drug Designation for the treatment of adult patients with WM, multiple myeloma, acute myeloid leukemia, and myelodysplastic syndrome.

Additionally, sonrotoclax is currently being studied in combination with other therapeutics, including zanubrutinib, as a potential treatment for CLL, with updated data expected to be presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

About BEQALZI™ (sonrotoclax)

BEQALZI™ (sonrotoclax) is a foundational, next-generation and potentially best-in-class B-cell lymphoma 2 (BCL2) inhibitor with a unique pharmacokinetic and pharmacodynamic profile. Preclinical and clinical studies in early drug development have shown that sonrotoclax is a highly potent and specific BCL2 inhibitor with a short half-life and no drug accumulation. Sonrotoclax has shown promising clinical activity across a range of B-cell malignancies, including chronic lymphocytic leukemia (CLL), and is in development as a monotherapy and in combination with other therapeutics, including zanubrutinib. To date, more than 2,200 patients have been enrolled across the broad sonrotoclax global development program.

INDICATION

BEQALZI™ (sonrotoclax) is a BCL-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

BEQALZI is contraindicated with strong CYP3A inhibitors at initiation and during the ramp-up phase due to the potential for an increased risk of tumor lysis syndrome (TLS).

WARNINGS & PRECAUTIONS

- **Tumor Lysis Syndrome (TLS):** BEQALZI can cause rapid tumor reduction and changes in blood chemistries consistent with TLS, which may be serious or life-threatening and require prompt management. TLS may occur as early as 4 hours after the first dose, with dose increases, or upon reinitiation following treatment interruption. Laboratory or clinical TLS occurred in 7% of patients who followed the recommended dose ramp-up. Assess all patients for TLS risk and initiate prophylaxis, including adequate hydration and antihyperuricemics. For patients at high risk of TLS, consider hospitalization with intravenous hydration and employ frequent monitoring. Monitor blood chemistries closely and manage abnormalities promptly. Interrupt BEQALZI for TLS; upon reinitiation, follow dose modification guidance in the Prescribing Information.

- **Serious Infections:** BEQALZI can cause fatal or serious infections. Serious infections occurred in 14% of patients; Grade 3-4 occurred in 17% (fatal: 2.6%). The most common Grade 3 or greater infection was pneumonia (10%). Monitor for signs and symptoms of infection and treat appropriately. Consider prophylactic antimicrobials and immunoglobulins. Interrupt, reduce dose, or permanently discontinue BEQALZI based on severity.

- **Neutropenia:** BEQALZI can cause serious or severe cytopenias, including neutropenia. Grade 3 or 4 decreases in neutrophils occurred in 18% of patients (Grade 4: 6%); febrile neutropenia occurred in 1.7% of all patients. Monitor complete blood counts throughout treatment. Interrupt treatment, reduce the dose, or permanently discontinue BEQALZI based on severity.

- **Embryo-Fetal Toxicity:** BEQALZI can cause fetal harm when administered to pregnant women. Advise patients of the potential risk to a fetus. Verify pregnancy status prior to initiation. Advise females to use effective contraception and males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥15%) are pneumonia (16%) and fatigue (16%). The most common Grade 3-4 laboratory abnormalities (≥15%) are decreases in lymphocytes (29%) and neutrophils (18%).

DRUG INTERACTIONS

- **Strong or Moderate CYP3A Inhibitors:** Concomitant use increases BEQALZI exposure. Avoid use of strong CYP3A inhibitors during BEQALZI initiation and ramp-up. Avoid use of moderate CYP3A inhibitors at the 1 mg and 2 mg doses; for all other doses, reduce the BEQALZI dose with concomitant use. See approved labeling for dose modifications.

- **Strong or Moderate CYP3A Inducers:** Concomitant use decreases BEQALZI exposure. Avoid use.

SPECIAL POPULATIONS

Lactation: Advise women not to breastfeed during treatment with BEQALZI and for 1 week after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact BeOne Medicines at 1-877-828-5596 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full U.S. Prescribing Information.

About BeOne

BeOne Medicines is a global oncology company that is discovering and developing innovative treatments for cancer patients worldwide. With a portfolio spanning hematology and solid tumors, BeOne is expediting development of its diverse pipeline of novel therapeutics through its internal capabilities and collaborations. The Company has a growing global team spanning six continents who are driven by scientific excellence and exceptional speed to reach more patients than ever before.

To learn more about BeOne, please visit www.beonemedicines.com and follow us on LinkedIn, X, Facebook and Instagram.

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 potential benefits of sonrotoclax; BeOne's expectations regarding sonrotoclax's clinical development, regulatory milestones, submissions and approvals; and BeOne's plans, commitments, aspirations and goals under the caption "About BeOne." Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeOne'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; BeOne's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeOne's ability to obtain and maintain

protection of intellectual property for its medicines and technology; BeOne's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeOne's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products; BeOne'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 BeOne's most recent periodic report, as well as discussions of potential risks, uncertainties, and other important factors in BeOne'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 BeOne undertakes no duty to update such information unless required by law.

By order of the Board
BeOne Medicines Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, May 14, 2026

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. Olivier Brandicourt, Dr. Margaret Han Dugan, Mr. Michael Goller, Mr. Anthony C. Hooper, Mr. Ranjeev Krishana, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders, Ms. Shalini Sharp and Mr. Qingqing Yi as Independent Non-executive Directors.