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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 Announces Positive Topline Results for Sonrotoclax in Relapsed or Refractory Mantle Cell Lymphoma (MCL)

On August 29, 2025, BeOne Medicines Ltd. ("**BeOne**", "**BeOne Medicines**" or the "**Company**") announced positive topline results from a Phase 1/2 study (BGB-11417-201) of sonrotoclax, a next-generation and potentially best-in-class investigational BCL2 inhibitor, in adult patients with relapsed/refractory (R/R) mantle cell lymphoma (MCL), following treatment with a Bruton's tyrosine kinase inhibitor (BTKi) and anti-CD20 therapy. BeOne plans to present the full data at an upcoming medical meeting.

"For people with relapsed or refractory mantle cell lymphoma, the disease is aggressive, the treatment landscape fragmented, and the outcomes unacceptably poor. These topline results for sonrotoclax underscore its potential to deliver meaningful and durable responses and offer the first BCL2 inhibitor for patients with R/R MCL, if approved," said Lai Wang, PhD, Global Head of R&D, BeOne Medicines. "These data add to the remarkable progress we've seen over the past five years in treating B-cell malignancies, and I'm proud that BeOne has played an impactful role in that transformation with our leading BTK inhibitor."

The BGB-11417-201 (NCT05471843) study is a global, multicenter, single-arm, open-label, Phase 1/2 study, which enrolled 125 adult patients with R/R MCL post-treatment with anti-CD20 therapy and a BTK inhibitor. In Part 1, 22 patients received daily treatment with either 160 mg or 320 mg of sonrotoclax to assess the safety and tolerability of sonrotoclax and identify the recommended dose for Part 2. In Part 2, 103 patients were enrolled to receive the recommended daily dose of sonrotoclax (320 mg), following ramp-up, to assess the efficacy and safety of sonrotoclax.

The study met its primary endpoint of overall response rate (ORR) as assessed by an independent review committee (IRC), demonstrating that treatment with sonrotoclax elicited clinically meaningful responses in this heavily pretreated population. The study also showed promising results across several secondary efficacy endpoints, including complete response (CR) rate, duration of response (DOR) and progression-free survival (PFS). The safety profile was generally well-tolerated, and the toxicities were manageable. These findings represent another important milestone in BeOne's hematology franchise, which now includes three foundational medicines designed to address the ongoing and evolving needs of patients across B-cell malignancies.

BeOne plans to submit these data to the U.S. Food and Drug Administration (FDA) and other global regulatory bodies for the potential approval of sonrotoclax in R/R MCL. New drug applications for sonrotoclax for the treatment of R/R MCL and R/R CLL/SLL have also been accepted and are under review by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) for potential accelerated approval. The Phase 3 confirmatory CELESTIAL-RR MCL study (BGB-11417-302; NCT06742996) is underway, with the first patient enrolled earlier this year. The U.S. FDA previously granted sonrotoclax Orphan Drug Designation for the treatment of patients with MCL.

About Mantle Cell Lymphoma

Mantle cell lymphoma (MCL) is a rare subtype of aggressive B-cell non-Hodgkin lymphoma (NHL)[1] that develops in B-cells located in the mantle zone of the lymph nodes. MCL accounts for approximately 5% of all NHL cases globally[2], affecting an estimated 28,000 people[3]. MCL is often diagnosed at advanced stages[4] and nearly all MCL patients will eventually develop refractory or relapsed (R/R) disease.[5] The five-year survival rate for MCL is approximately 50%, reflecting the urgent need for new therapeutic options.[6]

About Sonrotoclax (BGB-11417)

Sonrotoclax is a next-generation and potential best-in-class investigational inhibitor of B-cell lymphoma 2 (BCL2), which is one of several proteins that help cancer cells survive. It is part of a group of drugs called BH3 mimetics, which mimic natural cell death signals. Studies in the lab and during early drug development have shown that sonrotoclax is a highly potent and specific inhibitor of BCL2 with a short half-life and no drug accumulation. Sonrotoclax has shown promising clinical activity across a range of B-cell malignancies, and nearly 2,000 patients have been enrolled to date across the broad global development program. The U.S. Food and Drug Administration (FDA) granted sonrotoclax Fast Track Designation for the treatment of adult patients with mantle cell lymphoma (MCL) and Waldenström macroglobulinemia (WM).

References

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About BeOne

BeOne Medicines is a global oncology company domiciled in Switzerland that is discovering and developing innovative treatments that are more affordable and accessible to 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. With a growing global team of more than 11,000 colleagues spanning six continents, the Company is committed to radically improving access to medicines for far more patients who need them.

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; BeOne's plans to present the full data at an upcoming medical meeting; 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 quarterly report on Form 10-Q, 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, August 29, 2025

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.