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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 Medicines Announces Positive Phase 3 Results for BRUKINSA in Frontline Mantle Cell Lymphoma

On June 30, 2026, BeOne Medicines Ltd. (“**BeOne**”, “**BeOne Medicines**” or the “**Company**”) announced positive topline results from the Phase 3 MANGROVE study (BGB-3111-306; NCT04002297) evaluating foundational BTK inhibitor BRUKINSA® (zanubrutinib) plus rituximab versus bendamustine plus rituximab (BR) in adult patients with previously untreated mantle cell lymphoma (MCL). MANGROVE is the first Phase 3, global, randomized trial to evaluate a BTK inhibitor-based chemotherapy-free regimen against standard chemoimmunotherapy in this setting. This pivotal Phase 3 trial builds on the established clinical evidence for BRUKINSA in MCL.

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

“For patients with newly diagnosed MCL, chemotherapy is currently the default. MANGROVE demonstrates for the first time that BRUKINSA plus rituximab, a chemotherapy-free regimen, can deliver unprecedented improvements in progression-free survival, potentially redefining the treatment paradigm globally. We believe it would be very meaningful for patients to be free from the burden of frequent infusions. This is what it means to state that BRUKINSA is foundational: another study where it anchors frontline therapy and extends its leadership across B-cell malignancies.”

Topline results with practice-changing potential

For this prespecified interim analysis, MANGROVE met its primary endpoint of progression-free survival (PFS), demonstrating a highly statistically significant and clinically meaningful improvement for BRUKINSA plus rituximab versus BR, as assessed by an independent review committee (IRC). This is the first Phase 3 study of its kind to employ a chemotherapy-free, rituximab maintenance-free approach in first-line MCL, sparing patients approximately two years of infusions. This BRUKINSA-based, chemotherapy-free regimen led to a 43% reduction in the risk of progression or death (HR=0.57; [95% CI, 0.43, 0.76]; $p<0.0001$). The safety profile of BRUKINSA plus rituximab was consistent with the known safety profile of both medicines, with no new safety signals identified. Overall survival (OS), a key secondary endpoint, was immature at the time of this analysis; however, a strong trend in favor of BRUKINSA plus rituximab was observed. OS will be tested as part of the final analysis.

Full results from MANGROVE will be shared at an upcoming medical meeting. The Company is in discussions with global regulatory authorities with planned submissions in 2H 2026.

Why a chemotherapy-free approach is needed in MCL

Mantle cell lymphoma is a rare and typically aggressive (fast-growing) type of B-cell non-Hodgkin lymphoma.¹ It predominantly affects older adults, who often have comorbidities that can influence treatment decisions and how well they can tolerate therapies.² Frontline care has long relied on chemoimmunotherapy such as BR.³

Chemoimmunotherapy carries well-documented burdens, including myelosuppression, prolonged immune suppression and heightened infection risk, and cumulative toxicity that can be especially difficult for older patients.⁴

Efforts to improve frontline outcomes in MCL with BTK inhibitors have largely focused on adding them to chemotherapy rather than replacing it.⁵ MANGROVE takes a different approach, by evaluating whether a chemotherapy-free regimen of BRUKINSA plus rituximab can deliver durable disease control while sparing patients the burden of upfront chemotherapy. This approach seeks to advance longstanding efficacy and tolerability limitations of first-line care.

About MANGROVE

MANGROVE is a global, randomized, open-label Phase 3 trial evaluating BRUKINSA plus rituximab versus bendamustine plus rituximab in adult patients with previously untreated mantle cell lymphoma. The trial enrolled 510 patients across 176 sites worldwide.

In the experimental arm, patients received BRUKINSA at 160 mg orally twice daily plus rituximab during the initial treatment period, followed by BRUKINSA monotherapy until disease progression or intolerance. In the control arm, patients received bendamustine plus rituximab for six cycles. The primary endpoint is PFS assessed by IRC. Overall survival is a key secondary endpoint for the study. Other secondary endpoints include investigator-assessed PFS, overall response rate (ORR), duration of response (DOR), patient-reported outcomes, and safety.

About BRUKINSA® (zanubrutinib)

BRUKINSA is a next-generation Bruton tyrosine kinase (BTK) inhibitor designed to deliver complete and sustained BTK inhibition, enabled by optimized pharmacokinetics, including bioavailability, half-life, and selectivity, resulting in consistent target coverage in disease-relevant tissues.

BRUKINSA is the foundational BTK inhibitor and the first and only to demonstrate progression-free survival superiority over another BTK inhibitor in a Phase 3 study, setting a new benchmark for efficacy in the class. With the broadest label globally, it is also the only BTK inhibitor that offers the convenience of once- or twice-daily dosing to support individualized treatment.

The global BRUKINSA clinical development program spans more than 8,000 patients across over 45 trials in 30+ countries and regions. Approved in more than 80 markets, BRUKINSA has been used to treat over 290,000 patients worldwide, reflecting its rapidly expanding role as a standard of care across B-cell malignancies.

Select Important Safety Information for BRUKINSA

Serious adverse reactions, including fatal events, have occurred with BRUKINSA, including hemorrhage, infections, cytopenias, second primary malignancies, cardiac arrhythmias, and hepatotoxicity (including drug-induced liver injury).

In the pooled safety population (N=1729), the most common adverse reactions ($\geq 30\%$), including laboratory abnormalities, in patients who received BRUKINSA were neutrophil count decreased (51%), platelet count decreased (41%), upper respiratory tract infection (38%), hemorrhage (32%), and musculoskeletal pain (31%).

Please see full U.S. Prescribing Information including U.S. Patient Information.

References

1. National Cancer Institute. *Mantle cell lymphoma*. NCI Dictionary of Cancer Terms. Accessed June 16, 2026. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mantle-cell-lymphoma>.
2. National Cancer Institute. *Mantle Cell Lymphoma Treatment (PDQ®)–Health Professional Version*. Accessed June 16, 2026.
3. Tix T, Kumar A, Eyre TA, Dreyling M. Modern management of mantle cell lymphoma. *J Clin Oncol*. 2026;46:e517468.
4. Blayney DW, Schwartzberg L. Chemotherapy induced neutropenia and emerging agents for prevention and treatment: a review. *Cancer Treat Rev*. 2022;109:102427.
5. Noor WD, Cheah CY. Recent advances and future directions in newly diagnosed mantle cell lymphoma. *Expert Opin Pharmacother*. 2025;26(13):1415-1432.

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 BRUKINSA plus rituximab as a chemotherapy-free regimen in adult patients with previously untreated MCL; the foundational potential of BRUKINSA to anchor frontline therapy on its own and extend its leadership across B-cell malignancies; the timing of clinical and regulatory developments and data readouts; and BeOne's plans, commitments, aspirations, and goals under the heading "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, June 30, 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. Felix J. Baker and Dr. Xiaodong Wang as Non-executive Directors, and Dr. Olivier Brandicourt, Dr. Margaret Han Dugan, Mr. Anthony C. Hooper, Ms. Elizabeth F. Mooney, Dr. Alessandro Riva, Dr. Charles L. Sawyers and Ms. Shalini Sharp as Independent Non-executive Directors