Bantam Pharmaceutical to Present at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting

RESEARCH TRIANGLE PARK, NC, May 22, 2025 -- Bantam Pharmaceutical, a drug discovery and development company targeting selective modulation of mitochondrial dynamics in cancer, today announced that its Trial in Progress abstract has been accepted for presentation at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting, which is being held May 30 – June 3, 2025 at the McCormick Place Convention Center in Chicago, Illinois. The poster will highlight the company's ongoing Phase 1 trial evaluating its lead product candidate, BTM-3566, in patients with relapsed/refractory mature B-cell lymphomas. BTM-3566 is a first-in-class, small molecule cancer therapeutic which targets difficult-to-treat, aggressive tumors by activating OMA1-ATF4 Integrated Stress Response (ISR), a newly described mitochondrial homeostasis pathway.

The Phase 1 multicenter, prospective, dose-escalation study is focused on enrolling patients in the United States and Canada, with the first U.S. site activated at The University of Texas MD Anderson Cancer Center.

"Patients with relapsed or refractory B-cell lymphomas continue to face significant clinical challenges, particularly those who have progressed following cell therapy or targeted agents," said Dr. Michael Wang, global principal investigator and professor of lymphoma & myeloma at The University of Texas MD Anderson Cancer Center. "The opportunity to investigate BTM-3566 and its novel mechanism of action is especially compelling given its preclinical activity across diverse hematologic tumor models, including those with high-risk features. Advancing BTM-3566 into the clinic represents an important step toward expanding therapeutic options for patients who urgently need more effective treatments."

In the U.S., the study follows a standard 3+3 dose escalation design beginning at 0.3 mg/kg, while the Canadian sub-protocol initiates at 0.9 mg/kg using a single-patient cohort with accelerated dose titration. In both regions, patients receive BTM-3566 orally on Days 1 through 7 of a 14-day cycle. The complementary-dual-country approach accelerates the identification of clinically active doses for lymphoma patients while preserving the scientific rigor required to ensure meaningful clinical impact. It is expected to support future harmonization of U.S. and Canadian data to generate a robust, integrated dataset and inform development strategy.

Primary endpoints are safety and tolerability. Secondary and exploratory endpoints include objective response rate (ORR) by revised Lugano criteria, duration of response (DoR), progression-free survival (PFS), and pharmacokinetic and pharmacodynamic assessments. Initial clinical data from the trial are expected in the second half of 2025.

While the current trial is focused on treating lymphomas through activating the OMA1-ATF4 ISR, the mechanism represents a broader therapeutic opportunity. Recent preclinical findings have shown that BTM-3566 drives significant regressions in biomarker-selected solid tumors – particularly in difficult-to-treat tumor types. Additionally, combination data demonstrate synergy with standard-of-care agents in acute myeloid leukemia, underscoring the broad potential of this mechanism across both hematological and solid tumors. The company intends to advance these findings clinically as product development progresses.

Poster Presentation Details

Title: A phase 1 trial of BTM-3566 in relapsed/refractory mature B cell lymphomas
Presenter: Michael Wang, MD, Department of Lymphoma & Myeloma, MD Anderson Cancer Center
Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
Date/Time: Sunday, June 1st at 10 a.m. to 1 p.m. ET
Abstract Number: TPS7097

Additional meeting information can be found on the ASCO website, https://asco.org. The poster presentation will be made available under the News & Resources section of the company's website shortly after the event.

About BTM-3566

BTM-3566 is a novel, orally available small molecule designed to target a wide range of cancers, including both hematologic and solid tumors. Its initial clinical focus is on mature B-cell lymphomas, such as mantle cell lymphoma (MCL), diffuse large B-cell lymphoma (DLBCL), Burkitt's lymphoma, and follicular lymphoma (FL). In preclinical studies, BTM-3566 demonstrated potent anti-cancer activity, driving significant tumor regression – and in many cases, complete tumor elimination – in models resistant to standard treatments, including CAR-T cell therapy. BTM-3566 works by disrupting the mitochondrial function in tumor cells, triggering their natural cell death process (apoptosis). Notably, its anti-tumor activity is independent of tumor genotype, addressing a critical need for therapies capable of delivering robust and durable responses across genetically diverse cancers. With its unique mechanism of action and strong preclinical data, Bantam also plans to expand clinical development, broadening its potential impact for patients with limited treatment options.

Currently, Bantam is conducting ongoing Phase 1 clinical trials in both the U.S. and Canada evaluating BTM-3566 in relapsed/refractory mature B-cell lymphomas. For more information about the U.S. trial, visit ClinicalTrials.gov and search NCT06792734. For more information about the Canadian trial, visit ISRCTN.com and search ISRCTN15438979.

About Bantam Pharmaceutical

Bantam Pharmaceutical is a drug discovery and development company leveraging the power of mitochondrial dynamics to address critical unmet needs in oncology. Using its unique expertise in mitochondrial cellular biology, Bantam is advancing novel, first-in-class oral small molecule therapeutics for difficult-to-treat hematological and solid tumors. The company currently holds an active Investigational New Drug (IND) application in the U.S. and a Clinical Trial Application (CTA) in Canada for its lead candidate, BTM-3566, targeting B-cell malignancies, with plans to expand clinical development into solid tumors. Learn more at https://bantampharma.com/.

Media Contact

Jennifer Almond
Corporate Communications
Bantam Pharmaceutical

jalmond@bantampharma.com
www.bantampharma.com