Bantam Pharmaceutical Accelerates BTM-3566 Clinical Program Expanding Phase 1 Trial into Canada

RESEARCH TRIANGLE PARK, NC, March 6, 2025 -- Bantam Pharmaceutical, a drug discovery and development company targeting selective modulation of mitochondrial dynamics in cancer, today announced it is proceeding with a Phase 1 clinical trial evaluating BTM-3566 in relapsed/refractory mature B-cell lymphomas, based on a recent Clinical Trial Application (CTA) cleared by Health Canada. This regulatory milestone enables Bantam to expand its ongoing clinical program and to activate multiple clinical trial sites in Canada early in the second quarter of 2025.

This clearance follows the recent activation of Bantam's first U.S. clinical trial site at The University of Texas MD Anderson Cancer Center for its BTM-3566 Phase 1 study. BTM-3566 is a first-in-class, small molecule cancer therapeutic which targets mitochondrial homeostasis via the ATF4-Integrated Stress Response (ISR) pathway to treat aggressive tumors.

"Activating clinical sites in Canada alongside our U.S. study sites is a key step in building a high-quality, efficient, and thoughtful clinical program," said Michael Stocum, President & CEO of Bantam Pharmaceutical. "This complementary approach accelerates the identification of clinically active doses for lymphoma patients while maintaining the scientific rigor needed to ensure a meaningful impact for those in need. We anticipate this expansion to enable us to achieve our clinical objectives sooner than originally projected."

The Phase 1 trial is designed to evaluate the safety, tolerability, and preliminary efficacy of BTM-3566 in patients with relapsed/refractory mature B-cell lymphomas. The Canadian trial will follow a similar overall design to the ongoing U.S. Phase 1 trial, a multicenter, open-label, and dose-escalation study assessing the safety, tolerability, pharmacokinetics, anti-tumor activity, and pharmacodynamic effects of BTM-3566. The dual country strategy was implemented to accelerate the development of BTM-3566 and will support future harmonization between the studies to generate a robust dataset and inform future development. Initial clinical data from the trial are expected in the second half of 2025.

For more information about the ongoing clinical trial, visit ClinicalTrials.gov and search NCT number NCT06792734.

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), 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). With its unique mechanism of action and strong preclinical data, Bantam also plans to expand clinical development into solid tumors, broadening its potential impact for patients with limited treatment options.

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/.

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