Bantam Pharmaceutical Announces First Patient Treated in BTM-3566 Phase 1 Clinical Trial at Princess Margaret Cancer Centre in Toronto

RESEARCH TRIANGLE PARK, NC, December 10, 2025 -- Bantam Pharmaceutical, a clinical-stage company pioneering mitochondrial biology to develop first-in-class medicines for treating aggressive cancers, today announced that the first patient was treated at The Princess Margaret Cancer Centre in Toronto, Canada in its Phase 1 clinical trial studying BTM-3566.

This milestone is an important step as the company begins testing the safety, tolerability, and early signs of effectiveness of BTM-3566 in patients. BTM-3566 is a new type of medicine that targets aggressive cancers by modulating a stress pathway inside cells which may help patients whose cancer has worsened after other treatments.

This first-in-class small molecule works by activating the OMA1-ATF4 integrated stress response (ISR) pathway - a newly described mechanism that governs mitochondrial functions and how cells respond to stress. Instead of targeting an individual protein and its cancer-driver mutations, BTM-3566 specifically uses the machinery of the cancer cell to trigger cell death, making it an ideal treatment option for patients whose cancers no longer respond to standard therapies.

"Enrolling the first patient in our Phase 1 trial is a pivotal milestone in our clinical development efforts," said Michael Stocum, President & CEO of Bantam Pharmaceutical. "Princess Margaret Cancer Centre is an esteemed institution, and we are proud to collaborate with their expert investigators to advance this study for patients with limited treatment options."

Bantam's Phase 1 program is active in both the U.S. and Canada to study BTM-3566 in lymphomas and solid tumors. The lymphoma cohort includes patients with relapsed/refractory mature B-cell lymphomas. The solid tumor cohort includes a broad range of cancers such as head and neck, lung, gastroesophageal/gastrointestinal, colorectal, sarcomas, uterine, renal and bladder, among others.

"Princess Margaret Cancer Centre is excited to be the first institution to enroll a patient in Bantam's study of this novel therapeutic approach for those who no longer respond to standard treatments," said Dr. Albiruni Razak, Medical Oncology Lead, Sarcoma at the Princess Margaret Cancer Centre.

Bantam expects to have early information from the first patient available during J.P. Morgan Week in January 2026, along with a full summary of all non-clinical monotherapy and combination data underpinning its regulatory filings in the US and Canada.

For information about the ongoing U.S. trials, visit ClinicalTrials.gov and search NCT06792734 and NCT07266285. For information about the ongoing Canadian trial, visit ISRCTN.com and search ISRCTN15438979.

About BTM-3566

BTM-3566 is a first-in-class small molecule targeting aggressive cancers by activating the OMA1-ATF4 ISR pathway—a newly described mechanism that governs mitochondrial homeostasis and cell survival under stress. Unlike many therapies that target specific tumor mutations, this approach triggers intrinsic apoptotic pathways by modulating mitochondrial function, making it an ideal treatment option when patients progress.

In pre-clinical studies, BTM-3566 demonstrated potent anti-cancer activity, showing complete regressions in patient-derived xenograft (PDX) models of aggressive B-cell lymphomas, including double- and triple-hit DLBCL and in MCL PDX models from patient tumors that progressed on rituximab, BTK inhibitors and CAR-T therapies. BTM-3566 exhibits activity in solid tumors, including tumor regressions in multiple PDX models, where low FAM210B RNA expression is a potential biomarker for patient selection. BTM-3566 also exhibits strong synergy in combination with other drugs, including BH3 mimetics, hypomethylating agents and rituximab, enabling both monotherapy and combination development strategies.

About Bantam Pharmaceutical

Bantam Pharmaceutical is a clinical-stage company pioneering mitochondrial biology to develop first-in-class small molecule therapeutics for treating aggressive cancers after standard-of-care (SoC) therapies fail. The company currently holds active Investigational New Drug (IND) applications in the U.S. and a Clinical Trial Application (CTA) in Canada for its lead candidate, BTM-3566, targeting B-cell malignancies and select solid tumors. Learn more at https://bantampharma.com/.

Media Contact

Pam O'Connor
Corporate Communications, Bantam Pharmaceutical
poconnor@bantampharma.com
919-621-1230
www.bantampharma.com