September 15, 2026

GT Biopharma Announces Potential New Indication for GTB-5550, a B7-H3-Targeted Natural Killer (NK) Cell Engager, for Multiple Myeloma

FDA clearance of a new IND for GTB-5550 in multiple myeloma (MM) under an investigator sponsored trial (IST) protocol

Initiation of Phase 1 trial in MM patients contingent upon timing and receipt of non-dilutive grant funding

Phase 1 dose escalation basket trial with GTB-5550 in solid tumor patients continues to actively enroll, with an update anticipated in Q4 2026

Unaudited proforma cash balance as of September 15, 2026 of approximately $11 million anticipated to provide sufficient cash runway into Q3 2027

SAN FRANCISCO, CALIFORNIA, Sept. 15, 2026 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the “Company”) (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary TriKE® natural killer (NK) cell engager platform, today announced IND clearance from the FDA for GTB-5550 in multiple myeloma.

“Today’s IND to expand the potential indications for GTB-5550 highlights the diverse utility of our Trike® platform,” said Michael Breen, Executive Chairman and Chief Executive Officer of GT Biopharma. “The company remains focused on its two ongoing Phase 1 trials with GTB-5550 and GTB-3650, both of which are actively enrolling, and we look forward to the potential initiation of a third Phase 1 trial, pending receipt of non-dilutive grant funding.”

“Targeting B7-H3 remains an active area for clinical development of new anti-cancer drugs, yet most competitive efforts are focused on solid tumors”, said Dr. Aimee Merino, MD, PhD, Assistant Professor of Medicine, Division of Hematology, Oncology and Transplantation, The University of Minnesota[1]. “Based on our findings of high levels of B7-H3 expression within the bone marrow of newly diagnosed multiple myeloma patients, we have begun a dedicated effort for this novel approach in later-line patients, which continues to be an area of unmet need. We have been encouraged with our preclinical findings in a bone chip model that show high levels of antitumor cell activity mediated by NK cells in the presence of GTB-5550.”

The Phase 1a/1b trial with GTB-5550 will be the first-in-human trial of a B7-H3-targeted TriKE® in multiple myeloma and will use more patient-friendly subcutaneous administration intended to extend the half-life relative to prior intravenous TriKE formulations. The Phase 1a dose escalation portion will enroll 4th line and later patients with multiple myeloma and evaluate up to 6 dose cohorts to identify the maximum tolerated dose (MTD). Following dose escalation, the Phase 1b expansion cohort will enroll a total of 25 patients treated at the MTD and further evaluate safety, tolerability, and preliminary anti-tumor activity.

In the Phase 1 trial, GTB-5550 will be administered by subcutaneous (SQ) injection in the abdominal area on 3 non-consecutive days per week during Week 1 and Week 2, followed by 2 weeks of no treatment. One treatment cycle is 4 weeks in duration, and this dosing schedule is repeated for each subsequent cycle. A minimum of 2 cycles is planned, and disease reassessment (monoclonal protein and free light chain analysis) is performed on Day 28 of each cycle. Patients with stable disease may continue for up to 4 cycles total, and those with a partial response or better may continue for up to 1 year. Patients are followed for 12 months from the first dose of GTB-5550 to determine progression-free survival (PFS) and overall survival (OS).

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE® NK cell engager platform. Our TriKE® platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit gtbiopharma.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

TriKE® is a registered trademark owned by GT Biopharma, Inc.

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[1] The University of Minnesota, pursuant to its license agreement with GT Biopharma, is entitled to receive royalties should commercial sales of product using the TriKE technology be realized, including GTB-3650 and GTB-5550. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Source: GT Biopharma, Inc.