November 14, 2025

GT Biopharma Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Phase 1 trial evaluating GTB-3650 TriKE® for relapsed or refractory (r/r) CD33 expressing hematologic malignancies continues to actively enroll with the next update anticipated in Q1 2026

GTB-5550 TriKE® IND submission for B7H3-expressing solid tumors expected in late December 2025 or January 2026

SAN FRANCISCO, CALIFORNIA, Nov. 14, 2025 (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 natural killer (NK) cell engager TriKE® platform, today announced third quarter 2025 financial results for the period ended September 30, 2025.

The Company's Phase 1 dose escalation study is evaluating GTB-3650 in a total of 14 patients (two patients per cohort) with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia and high-risk myelodysplastic syndrome. GTB-3650 is dosed in two-week blocks, two weeks on and two weeks off, for up to four months based on clinical benefit. The trial aims to assess the safety, pharmacokinetics, pharmacodynamics, in vivo expansion of endogenous patient NK cells and clinical activity. The Company plans to provide the next update on the trial in the first quarter of 2026 following completion of additional dose cohorts.

"We are highly encouraged by the continued progress of our Phase 1 clinical trial evaluating GTB-3650 in cancer patients, which has now advanced to Cohort 4 at a dose level of 10 µg/kg/day," said Michael Breen, Executive Chairman and Chief Executive Officer. "We look forward to assessing higher doses, as we are now approaching the efficacy range predicted by preclinical in vivo leukemia models, and we plan to share the next trial update in the first quarter of 2026. The excellent safety profile observed with GTB-3650 and the immune activation potential of bringing IL-15 to the immune synapse suggests a potential competitive advantage for GTB-5550 compared to other modalities like bispecific antibodies, cell therapies, and antibody drug conjugates also targeting solid tumors expressing B7H3, which is quicky emerging as a compelling novel immune checkpoint target."

Third Quarter 2025 Financial Summary

Cash Position: The Company had cash and cash equivalents of approximately $2.6 million

as of September 30, 2025, which is anticipated to be sufficient to fund the Company's operations into the first quarter of 2026.

Research and Development (R&D) Expenses: R&D expenses for the third quarter ended September 30, 2025 were approximately $0.6 million compared to $1.3 million for the same comparable quarter of 2024. The $0.7 million decrease was primarily due to a reduction in production and material costs. R&D expenses primarily relate to the Company's continued licensing, development and production of its most advanced TriKE® product candidates GTB-3650 and GTB-5550 along with the progression on other promising product candidates. In late June 2024, the Company received clearance from the Food and Drug Administration with respect to the Company's Investigational New Drug ("IND") application in relation to the Company's next generation GTB-3650 camelid nanobody product. Study enrollment began in early 2025 and the Company has advanced into the clinic, enrolling patients, and performing tests for data collection throughout the year. Following the financing completed in May 2025, the Company has restarted the final phase of product development of GTB-5550 and anticipates submission of an IND application for GTB-5550 in late December 2025 or in January 2026.

Selling, General and Administrative (SG&A) Expenses (Excluding Stock Compensation): SG&A expenses for the third quarter ended September 30, 2025 were relatively flat compared to the same comparable quarter of 2024, amounting to approximately $2.4 million compared to $2.3 million, respectively.

Net Loss: The Company reported a net loss of approximately $3.1 million for the third quarter ended September 30, 2025 compared to a net loss of $3.4 million for the same comparable quarter in 2024. The $0.3 million decrease consisted primarily of significant decreases in R&D expenses (as described above).

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 "aims," "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 the use of 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 (i) the Company's ability to continue as a going concern; (ii) the risk that if the Company experiences delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and the Company's receipt of necessary regulatory approvals could be delayed or prevented; (iii) the risk that the Company will need additional capital to conduct its operations and develop its products, and the Company's ability to obtain the necessary funding is uncertain; (iv) the risk that the Company's common stock may be delisted in the future if the Company is unable to maintain compliance with continued listing requirements; (v) the risk that the Company's products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit the company's ability to general revenues from therapeutic products and (vi) those other 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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Source: GT Biopharma, Inc.