August 14, 2025

GT Biopharma Reports Second Quarter 2025 Financial Results

- *GTB-3650 TriKE® Phase 1 trial has successfully completed Cohort 1 and Cohort 2 dosing, treating a total of four patients; following Cohort 2's formal safety review, it has advanced into Cohort 3 and initiated dosing of the fifth patient in the study; initial Phase 1 data expected later in 2025*

- *GTB-5550 TriKE® IND submission for treatment of B7H3 positive solid tumors expected in Q4 2025; recent peer-reviewed publication highlights the pre-clinical anti-tumor activity of GTB-5550 against head and neck cancer*

- *Cash of approximately $5.3 million as of June 30, 2025, anticipated to be sufficient to fund operations into Q1 2026*

SAN FRANCISCO, CALIFORNIA, Aug. 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 second quarter 2025 financial results for the period ended June 30, 2025.

"We are pleased with the enrollment momentum in our Phase 1 clinical trial evaluating GTB-3650 in cancer patients, which continues to advance on schedule," said Michael Breen, Executive Chairman and Chief Executive Office of GT Biopharma. "Moving into the third dose cohort after a successful safety review and encouraging early evidence of immunological activity, mark important steps forward in the development of GTB-3650. We look forward to sharing more data later this year to reinforce the ability of our TriKE constructs to activate endogenous NK cells, and the potential for broader utility with other targets to treat solid tumors (GTB-5550) and autoimmune indications (GTB-7550)."

The Phase 1 dose escalation study is evaluating GTB-3650 in 12 patients (six cohorts) with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). 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 will assess safety, pharmacokinetics, pharmacodynamics, in vivo expansion of endogenous patient NK cells and clinical activity. GT Biopharma plans on releasing more detailed results later in 2025 following enrollment and completion of additional dose cohorts.

Second Quarter 2025 Financial Summary

Cash Position: The Company had cash and cash equivalents of approximately $5.3 million as of June 30, 2025, anticipated to be sufficient to fund operations into Q1 2026.

Research and Development (R&D) Expenses: R&D expenses for the second quarter ended June 30, 2025 were approximately $400,000 compared to $1.8 million for the same comparable quarter of 2024, the $1.4 million decrease was primarily due to a reduction in production and scientific research costs. Research and development expenses relate to our continued licensing, development and production of our most advanced TriKE® product candidates GTB-3650 and GTB-5550 along with the progression on other promising candidates. In late June 2024, we received clearance from the FDA with respect to our IND Application in relation to our next generation GTB-3650 camelid nanobody product. Study enrollment began in early 2025 and we have advanced into the clinic, enrolling patients, and performing tests for data collection throughout the year. Following our May 2025 financing we have restarted the final phase of product development of GTB-5550 and anticipate submission of an IND application for GTB-5550 in fourth quarter of 2025.

Selling, General and Administrative (SG&A) Expenses (Excluding Stock Compensation): SG&A expenses for the second quarter ended June 30, 2025 were approximately $1.1 million compared to $2.0 million for the same comparable quarter of 2024, the $900,000 decrease was primarily due to a significant decrease in legal fees and other cost reduction measures.

Net Loss: The Company reported a net loss of approximately $1.4 million for the second quarter ended June 30, 2025 compared to a net loss of $3.7 million for the same comparable quarter in 2024, the $2.3 million decrease consisted primarily of significant decreases in R&D and SG&A 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 "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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