GT Biopharma Advances GTB-3650 Phase 1 Trial to Cohort 2 Following Successful Initial Human Dosing and evidence of Early Immune Activation Signals

Following the formal safety review of Cohort 1, no safety or tolerability issues were observed, allowing the company to move forward with Cohort 2.

The company plans on releasing more detailed results from Phase 1 later in 2025 following completion of additional dose cohorts.

SAN FRANCISCO, CALIFORNIA, May 19, 2025 -- 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 successful completion of dosing in Cohort 1 and subsequent initiation of dosing in Cohort 2 of its Phase 1 dose escalation trial evaluating GTB-3650 for the treatment of relapsed or refractory (r/r) CD33 expressing hematologic malignancies.

GT Biopharma's second-generation TriKE, GTB-3650, is currently being evaluated in a Phase 1 dose escalation trial for the treatment of relapsed or refractory (r/r) CD33 expressing hematologic malignancies. Cohort 1 has been successfully completed with patients having undergone the first and second dosing cycles. Following the formal safety review, no safety or tolerability issues were observed, allowing the company to move forward with Cohort 2, with the first patient now having been treated with the first dose cycle.

Based on multiple assays of various blood biomarkers, both patients in Cohort 1 have shown early evidence of increased immunologic activity, supporting GTB-3650's ability to activate endogenous NK cells and induce NK cell expansion. The company plans on releasing more detailed results later in 2025 following enrollment and completion of additional dose cohorts.

The trial plans to evaluate GTB-3650 in up to approximately 14 patients (seven cohorts) and GTB-3650 will be 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. More details can be found on clinicaltrials.gov with the identifier: *NCT06594445*.

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.

Investor Relations Contact:

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
212-915-2577