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GT Biopharma Provides Enrollment Update on GTB-3650 Phase 1 Trial in Patients with Relapsed or Refractory (r/r) CD33 Expressing Hematologic Malignancies

The formal safety review of Cohort 3 (5ug/kg/day) has been successfully completed with no safety or tolerability issues observed, allowing advancement into Cohort 4 with a dose of 10 ug/kg/day

Actively screening patients for Cohort 4; anticipate initiation of dosing in the coming weeks

Cohort 4 dose is potentially more reflective of the clinical efficacy threshold given positive trend in observations on multiple immunological biomarkers from the previous six patients in Cohorts 1 through 3, the absence of dose limiting toxicities, and the associated lower dose levels

Next update expected in Q1 2026, as well as continued dose escalation (up to 100ug/kg/day) in 3 additional cohorts if necessary

SAN FRANCISCO, CALIFORNIA, Oct. 23, 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 TriKE® natural killer (NK) cell engager platform, today announced successful completion of the Cohort 3 formal safety review with no safety or tolerability issues observed and advancement into Cohort 4 of its Phase 1 dose escalation trial evaluating GTB-3650 for the treatment of relapsed or refractory (r/r) CD33 expressing hematologic malignancies.

The six patients in Cohorts 1 through 3 have been successfully treated with GTB-3650 and the formal safety review of Cohort 3 showed no safety or tolerability issues observed. This has allowed progression to actively screening patients for Cohort 4. With a dose of 10 ug/kg/day, Cohort 4 is more reflective of the potential efficacy threshold. The Phase 1 trial protocol allows for three additional cohorts with much higher dose levels ranging from 25 ug/kg/day with Cohort 5, 50 ug/kg/day with Cohort 6 and 100 ug/kg/day for Cohort 7, if necessary. The company anticipates providing its next update on the trial in Q1 2026.

The Phase 1 trial will evaluate of GTB-3650 in up to approximately 14 patients (two patients in each of seven cohorts), with doses ranging from 1.25 ug/kg/day in Cohort 1 to 100 ug/kg/day in Cohort 7. GTB-3650 is dosed in two-week blocks, two weeks on and two weeks

off (defining a treatment cycle), 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.

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

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