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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 Company is well on track with Phase 1 enrollment now that both patients in Cohort 3 have successfully initiated treatment with no evidence of dose-limiting toxicities or tolerability concerns to date

The first patient in Cohort 3 has shown promising evidence of immune activation consistent with levels of activity observed in patients from the previous two lower-dose cohorts; additional update anticipated by year-end

Upon successful completion of the Cohort 3 safety assessment, the trial will continue to dose escalate with initiation of Cohort 4 dosing planned by year-end 2025, and flexibility to dose up to 7 cohorts if necessary; additional data updates anticipated in Q1 2026

SAN FRANCISCO, CALIFORNIA, Oct. 08, 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 that enrollment in the dose escalation cohorts of the Phase 1 trial, evaluating GTB-3650 for the treatment of relapsed or refractory (r/r) CD33 expressing hematologic malignancies, is well on track.

Enrollment in Cohorts 1 and 2 were successfully completed; both patients in Cohort 3 have now initiated treatment with no evidence of dose-limiting toxicities or safety concerns to date. The level of immune activation observed from multiple biomarkers in the first patient of Cohort 3 is consistent with the evidence of heightened immune activity in the first four patients from Cohorts 1 and 2. Assuming Cohort 3 is completed with no new safety findings, the trial will continue to dose-escalate into the higher ranges of GTB-3650 anticipated to be necessary to translate heightened immune activation into clinically meaningful evidence of therapeutic activity. Initiation of dosing in Cohort 4 is planned by year-end 2025 and additional data updates are anticipated in Q1 2026.

The Phase 1 protocol allows evaluation of GTB-3650 in up to approximately 14 patients (two patients in each of seven cohorts), with doses ranging from 1.25ug/kg/day in Cohort 1 to 100ug/kg/day in Cohort 7. GTB-3650 will be 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.

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