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GT Biopharma Announces First Patient Dosed in Phase 1 Trial of GTB-5550, a B7-H3-Targeted Natural Killer (NK) Cell Engager for Solid Tumors

GTB-5550 is now the 3rd TriKE® to enter the clinic and an expansion into a broader solid tumor opportunity, with the Phase 1 trial likely to focus on prostate cancer patients during the dose escalation phase

Company anticipates providing updates in 2H 2026 as enrollment progresses through dose escalation cohorts

SAN FRANCISCO, CALIFORNIA, May 14, 2026 (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 the first patient was dosed in a Phase 1 dose escalation basket trial evaluating GTB-5550, its B7-H3-targeted natural killer (NK) cell engager for solid tumors expressing B7-H3.

"Dosing the first patient in our GTB-5550 Phase 1 trial is a pivotal milestone for GT Biopharma and represents the natural evolution of our TriKE® platform into the broader opportunity of treating patients with a variety of solid tumors. The ongoing Phase 1 progress with GTB-3650 in hematologic malignancies now gives us the confidence to advance the platform with GTB-5550 to target B7-H3, which is broadly expressed across many of the most common and difficult-to-treat solid tumor cancers. We look forward to providing updates on the trial's progress throughout the second half of 2026.", said Michael Breen, Executive Chairman and Chief Executive Officer of GT Biopharma.

The Phase 1 trial with GTB-5550 will be the first nanobody TriKE® tested with more patient-friendly subcutaneous dosing. The Phase 1a dose escalation portion of the trial will focus primarily on enrolling prostate cancer patients and evaluate up to 6 dose levels to identify the maximum tolerated dose (MTD). After the dose escalation phase, the Phase 1b expansion component will enroll patients with up to 7 different tumor types (castration-resistant prostate cancer, ovarian cancer, breast cancer, head and neck cancer, non-small cell lung cancer, pancreatic cancer, and bladder cancer) and further evaluate its safety, tolerability and preliminary anti-tumor activity.

"Patients with metastatic castration-resistant prostate cancer have B7-H3 expressed in over 90% of tumors and PSA can serve as an early biomarker of therapeutic activity. We look

forward to evaluating GTB-5550 across multiple solid tumor types as we continue dose escalation.", said Dr. Nicholas Zorko, MD, PhD, Assistant Professor of Medicine, Division of Hematology, Oncology and Transplantation, The University of Minnesota[1].

GTB-5550 will be administered by subcutaneous (SQ) injection in the abdominal area for 5 consecutive days during Week 1 and Week 2 followed by 2 weeks of no treatment. One treatment cycle is 4 weeks in duration. Subsequent cycles receive treatment three times weekly for 2 weeks followed by 2 weeks of no treatment. A minimum of 2 cycles is planned, and patient-appropriate disease reassessment is performed after 2 cycles and every 8-12 weeks thereafter. Treatment may continue until disease progression, unacceptable toxicity, patient refusal, or treatment is no longer in the best interest of the patient. Patients are followed for 12 months to determine progression free survival (PFS) and overall survival (OS). More details can be found on clinicaltrials.gov with the identifier: NCT07541573.

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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[1] The University of Minnesota, pursuant to its license agreement with GT Biopharma, is entitled to receive royalties should commercial sales of product using the TriKE technology be realized, including GTB-3650 and GTB-5550. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Source: GT Biopharma, Inc.