January 15, 2026

GT Biopharma Announces IND Submission for GTB-5550 TriKE®, a B7-H3-targeted natural killer (NK) cell engager for B7-H3 expressing solid tumor cancers

GT Biopharma targets a portion of the estimated $362 billion global solid tumor market

Preliminary, unaudited cash balance of approximately $7 million as of December 31, 2025 anticipated to extend cash runway into Q3 2026

SAN FRANCISCO, CALIFORNIA, Jan. 15, 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 the submission of an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) in December 2025 for GTB-5550 TriKE, a B7-H3-targeted natural killer (NK) cell engager for the treatment of B7-H3 expressing solid tumor cancers.

"The IND for GTB-5550 represents another NK cell engager we plan to move into clinical development and a tremendous accomplishment for the company", said Michael Breen, Executive Chairman and Chief Executive Officer of GT Biopharma. "As we continue actively enrolling the Phase 1 trial with GTB-3650 in myeloid blood cancer, we expect the next data readout in 1H 2026 could provide potential evidence of clinical activity. Initiation of a Phase 1 basket trial with GTB-5550 for multiple solid tumors is planned for 2026. We look forward to applying the clinical learnings from the GTB-3650 study to help inform the GTB-5550 program, which targets a patient population with B7-H3 expressing solid tumors that is orders of magnitude larger than the myeloid blood cancer patient population." The global market for B7-H3 expressing solid tumor cancers accounts for a portion of the estimated $362 billion global solid tumor cancers market (according to Data Bridge Market Research). B7-H3 expressing solid tumor cancers are estimated to account for a significant portion of solid tumor cancers.

GTB-5550 is a camelid (cam) anti-CD16/WT IL-15/cam anti-B7-H3 tri-specific natural killer (TriKE) cell engager, with a single chain recombinant TriKE comprised of three components joined by flexible linkers: 1) a nanobody arm that engages the CD16 activating receptor (camelid anti-CD16) on natural killer (NK) cells; 2) a wildtype IL-15 (WT IL-15) linker arm to drive NK cell proliferation, priming, and survival; and 3) a nanobody arm that specifically engages B7-H3 (camelid anti-B7-H3) to target the antigen expressed on tumor cells.

Based on supportive preclinical data, the planned Phase 1 trial with GTB-5550 will be the first dual nanobody TriKE® tested with more patient-friendly subcutaneous dosing. The Phase 1a dose escalation portion of the trial will test up to 7 dose levels to identify the maximum tolerated dose (MTD). The Phase 1b dose expansion component of the trial will confirm the MTD identified in the Phase 1a trial across 7 distinct metastatic disease cohorts (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 tolerability assuming the toxicity rates are similar across the groups.

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. 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).

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.

Investor Relations Contact:

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

LinkedIn |Facebook |X |Instagram | YouTube

Source: GT Biopharma, Inc.