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GT Biopharma Announces FDA Clearance of Investigational New Drug (IND) Application for GTB-5550 TriKE®, a B7-H3-Targeted Natural Killer (NK) Cell Engager for Solid Tumors Expressing B7-H3

GTB-5550 Phase 1 dose escalation basket trial expected to initiate mid-2026

Phase 1 protocol allows multiple solid tumor types known to express B7-H3

Unaudited proforma cash balance as of January 31, 2026 of approximately $9 million anticipated to extend cash runway through Q4 2026

SAN FRANCISCO, CALIFORNIA, Feb. 03, 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 FDA clearance of its IND application for GTB-5550, allowing the company to proceed with a Phase 1 clinical trial, which is anticipated to initiate in mid-2026.

"FDA clearance of our third TriKE® IND, GTB-5550, represents a defining moment for GT Biopharma as we bring another NK cell engager into the clinic", said Michael Breen, Executive Chairman and Chief Executive Officer of GT Biopharma. "We expect to commence enrollment of the Phase 1 basket trial in mid-2026. While the phase I trial is open to patients with common solid tumors that express B7-H3, in the dose-escalation component we will prioritize enrollment for advanced prostate, ovarian, and pancreatic cancer patients who have failed standard therapies. Based on the encouraging trends we have seen from our ongoing Phase 1 trial with GTB-3650 in AML patients, we are even more enthusiastic about the potential benefits of GTB-5550 treatment in patients with solid tumors known to express B7-H3."

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.

“This clearance is an important step toward developing new immune-based therapies for patients with advanced prostate cancer and other solid tumor types”, said Dr. Emmanuel Antonarakis, MD, Associate Director, Translational Research at the University of Minnesota Masonic Cancer Center[1]. “Given the high expression of B7-H3 in over 90% of metastatic castration-resistant prostate cancers and the unmet need in the patient population, I look forward to evaluating GTB-5550’s TriKE® approach in the upcoming Phase 1 trial. As part of our team, I am excited that Dr. Nicholas Zorko will be leading this clinical trial. He is emerging as a national leader in early phase immune engager clinical trials across oncology.”

The 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 6 dose levels to identify the maximum tolerated dose (MTD). After the dose escalation phase , the Phase 1b expansion component of the trial will then confirm the MTD identified in the Phase 1a trial in up to 7 different possible 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 safety, tolerability and preliminary anti-tumor activity.

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.

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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.