March 4, 2021

GT Biopharma Adds University of Wisconsin--Madison Carbone Cancer Center as Second Site in Ongoing Phase 1/2 Clinical Trial of GTB-3550 TriKE™, a Novel NK Cell Therapeutic Cancer Treatment

BEVERLY HILLS, Calif., March 4, 2021 /PRNewswire/ -- GT Biopharma, Inc. (NASDAQ: GTBP), a clinical stage biopharmaceutical company focused on the development and commercialization of its disruptive, target-directed Natural Killer (NK) cell engager immunotherapy protein biologic platform technology: TriKE™ for cancer and infectious diseases, today announced the addition of a new clinical trial site for its ongoing GTB-3550 TriKE™ multicenter Phase I/II trial (ClinicalTrials.gov NCT03214666). The University of Wisconsin – Madison Carbone Cancer Center will serve as the second site for this program, with Kalyan Vara Ganesh Nadiminti M.D., UW Assistant Professor in Hematology, Oncology and Palliative Care, serving as lead investigator. Dr. Nadiminti will be working closely with Jeffery S. Miller, M.D., GT Biopharma's Consulting Chief Medical Officer and developer of TriKE™ and the trial design, and Erica Warlick, M.D., Principal Investigator, both of the University of Minnesota. UM's Masonic Cancer Center is the initial site of the GTB-3550 TriKE™ Phase 1/2 trial.

Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer, commented: "It is exciting to announce the addition of a second clinical trial site for our Phase I/II program of our novel GTB-3550 TriKE™ program. With this progress, we are closer to bringing our disruptive and target-directed NK cell engager approach to patients in need. We are grateful to the valiant patients and their families, as we continue to progress this initial indication trial of our first-in-class NK cell protein biologic cancer therapy."

GTB-3550 TriKE™ is being evaluated in patients age 18 and older with CD33+ malignancies (primary induction failure or relapsed acute myeloid leukemia [AML] with failure of one reinduction attempt, or high-risk myelodysplastic syndromes [MDS] progressed on two lines of therapy). The primary endpoint is to identify the maximum tolerated dose and safety of GTB-3550 TriKE™ therapy. Correlative objectives include the number, phenotype, activation status and function of NK cells and T cells. Interim results presented at the American Society of Hematology meeting on December 5, 2020 demonstrates GTB-3550 TriKE™ reduces bone marrow blast levels in AML and MDS patients with reported no toxicities, and improves NK cell function and proliferation.

About GTB-3550 TriKE™

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment AML. GTB-3550 is a single-chain, tri-specific scFv recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. The natural killer (NK) cell stimulating cytokine human IL-15 portion of the molecule provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We are evaluating GTB-3550 TriKE™ in a Phase I/II clinical trial for the treatment of acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and other CD33+ hematopoietic malignancies.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immunology therapeutic products based on our proprietary Trispecific Killer Engagers (TriKE™) target-directed Natural Killer (NK) cell engager platform. The TriKE™ NK protein biologic platform is designed to *harness and amplify* the body's native immune system for hope for patients with cancer and infectious diseases. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota, where Jeffery S. Miller, M.D., GT Biopharma's Consulting Chief Medical Officer, developed the TriKE™, to further develop and commercialize therapies using TriKE™ technology. For further information, please visit http://www.gtbiopharma.com.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the potential acquisition, the likelihood of closing the potential transaction, our clinical focus, and our current and proposed trials. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes", "hopes", "intends", "estimates", "expects", "projects", "plans", "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not a guarantee of performance, and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended December 31, 2019 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent Form 10Q Quarterly filings with the Securities and Exchange Commission, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our contemplated clinical trials, or to meet the FDA's requirements with respect to safety and efficacy, (iii) our ability to identify patients to enroll in our clinical trials in a timely fashion, (iv) our ability to achieve approval of a marketable product, (v) design, implementation and conduct of clinical trials, (vii) the results of our clinical trials, including the possibility of unfavorable clinical trial results,

(vii) the market for, and marketability of, any product that is approved, (viii) the existence or development of treatments that are viewed by medical professionals or patients as superior to our products, (ix) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, and social conditions, and (x) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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