August 13, 2021

GT Biopharma Provides Second Quarter 2021 Business Update

Announced Positive Interim Data Results Demonstrating Substantial Reduction in AML/MDS Cancer Cells and Bone Marrow Blast Levels from GTB-3550 TriKE® Phase I Clinical Trial

Entered Research Agreement with Dr. Jeffrey S. Miller of the University of Minnesota for Further Development of TriKE® Technology

Announced $16M Increase in Cash from Warrant Exercise Proceeds

Management to Host Conference Call Today at 8:30 a.m. EST

BEVERLY HILLS, Calif., Aug. 13, 2021 /PRNewswire/ -- GT Biopharma, Inc. ("GT Biopharma" or the "Company") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager (TriKE®) protein biologic technology platform, today provided a general business update of events in the second quarter ending June 30, 2021.

"I am pleased with the corporate and clinical development milestones that GT Biopharma continues to achieve throughout the first half of 2021," said Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "The Company continues to demonstrate that our proprietary TriKE® platform technology is both safe and efficacious, demonstrated through our recent positive, interim data announcement of our ongoing Phase

I/II dose expansion clinical trial of GTB-3550 TriKE®. The TriKE® platform is robust, focusing not only on hematologic cancers but also on solid tumor cancers such as lung, prostate, breast and ovarian cancers. The TriKE platform includes our B7H3, PD-L1 and HER2 TriKE® product candidates. Our breadth of indications and the utility of TriKE® as a therapeutic agent reduces the risk profile of our therapeutic platform and pipeline. Our collaborative efforts were strengthened through the Company's research agreement with Dr. Jeffrey S. Miller and the University of Minnesota, and signifies that we are continuing to hit important strides in the clinic. These positive milestones reinforce GT Biopharma's need to continue developing this first-in-human treatment for patients living with AML, MDS and other CD33+ hematologic cancers."

Clinical Highlights

- **Reported Positive, Interim Data Results from First-in-Human GTB-3550 TriKE® Phase I Clinical Trial for the Treatment of Refractory/Relapsed Acute Myeloid Leukemia (AML) and High-Risk Myelodysplastic Syndromes (MDS):** In June 2021, GT Biopharma and Dr. Jeffrey S. Miller presented positive, interim results from the Phase I dose-escalation portion of the Phase I/II dose expansion clinical trial of GTB-3550 TriKE® at the 2021 Raymond James Human Health Innovation Conference. Results demonstrated that 57% of patients achieved significant reduction in AML/MDS cancer cell burden, with one patient reaching up to 63.7% reduction in bone marrow blast levels. Across all patients, treatment of GTB-3550 TriKE® was well tolerated and no signs of cytokine release syndrome (CRS) were detected. This portion of the Phase I/II dose expansion trial is focused on determining the recommended Phase II dose, the maximum tolerated dose (MTD), optimal dose schedule, safety and tolerability of GTB-3550 TriKE® administration. The Phase I safety study is expected to complete later this fall and the Company has scheduled an interim data publication for September 16-21, 2021 at the European Society for Medical Oncology Conference to be held in Paris, France.

Corporate Highlights

- **Announced Strategic Research Agreement with Dr. Jeffrey S. Miller of the University of Minnesota:** In July 2021, GT Biopharma announced that it has entered a research agreement with Dr. Jeffrey S. Miller, associated with the University of Minnesota to further develop the Company's proprietary TriKE® technology. This agreement reinforces the clinical success that TriKE® continues to demonstrate in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).
- **Inclusion in the Russell 2000® Index:** In June 2021, GT Biopharma was added to the Russel 2000® Index, signifying corporate and clinical development milestones that the Company continues to achieve. This listing enhances GT Biopharma's visibility to a broader investment community, and increases long-term growth potential as the Company continues to achieve important clinical milestones associated with both their robust preclinical and clinical pipelines.
- **Announced $16M Cash Increase from Warrant Exercise Proceeds:** In July 2021, the Company announced a $16M increase in cash from exercised warrant proceeds that were a part of the recent $27M financing completed in February of this year. This capital will be used to further develop the TriKE® technology in both preclinical and

clinical pipelines.

Conference Call

The Company will host a conference call at 8:30 a.m. EST today to provide a general business update. To join the call U.S. callers should dial 1-877-870-4263 and international callers should dial 1-412-317-0790. All participants should ask to be connected to the GT Biopharma conference call.

A live webcast of the event will be available by visiting the "Presentations" page in the Investors section of GT Biopharma's website at www.gtbiopharma.com/news-media/presentations. A replay of the webcast will be archived for 30 days following the presentation.

About GTB-3550 TriKE®

GTB-3550 is the Company's first TriKE® product candidate being initially developed for the treatment of acute myeloid leukemia (AML), myelodysplastic syndromes (MDS) and other CD33+ hematologic cancers. 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 Interleukin 15 (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 intend to study GTB-3550 in CD33 positive leukemias such as AML, 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 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 (NK 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

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, 2020, in the section titled "Risk Factors" in Part I, Item 1A, filed with

the Securities and Exchange Commission (the "SEC") on April 16, 2021 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.

TriKE® is a registered trademark of GT Biopharma, Inc.

Contact:

Institutional Investors:
Brendan Payne
Stern Investor Relations, Inc.
brendan.payne@sternir.com
212-362-1200

Investor & Media Relations:
David Castaneda
David@gtbiopharma.com
414-351-9758

View original content to download multimedia:https://www.prnewswire.com/news-releases/gt-biopharma-provides-second-quarter-2021-business-update-301354858.html

SOURCE GT Biopharma, Inc.