May 17, 2021

GT Biopharma Reports First Quarter 2021 Results

Announced Encouraging Interim Results Demonstrating a 63.7% Reduction in Bone Marrow Blast Levels from its GTB-3550 TriKE™ Phase I/II clinical trial for the Treatment of MDS and AML

Announced Revised Design of the GTB-3550 Phase 2 Trial Towards Enhanced Efficacy Measures Having Observed Indications of Anti-Tumor Activity and Towards the Goal of Seeking Accelerated FDA Approval

Current cash balance as of May 14th, $35,000,000.00: Closed a $28.7M public offering with Uplisting to Nasdaq Capital Market

Appointed Gregory Berk, M.D. to the Position of Chief Medical Officer and Jeffery Miller, M.D. to the Position of Consulting Chief Scientific Officer

BEVERLY HILLS, Calif., May 17, 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 reported financial results for the first quarter ended March 31, 2021 and provided a general business update.

"In the first quarter of 2021, and in the weeks since, we were very pleased to report exciting and encouraging data from our ongoing Phase I/II clinical trial of GTB-3550 in MDS and AML," said Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "Both from efficacy and safety perspectives, our GTB-3350 TriKE™ program appears to be delivering the TriKE's unique therapeutic potential which has been well tolerated in all of our patients. Our differentiated approach stimulating NK cell activity, reinforces our rationale to proceed with additional programs in solid tumor and hematologic cancers. In addition, with our $28.7M financing completed and a key strategic manufacturing partnership in place, we are well equipped and positioned to capitalize on the potential we are already seeing from these innovative new therapies. We again thank the patients and their families for their contribution, as we advance towards the prospect of an off-the-shelf monotherapy cancer therapeutic that can be therapeutically effective without supplemental engineered NK cells or the need for any combination drugs."

Clinical Highlights

- **Updated Interim Results from First-in-Human GTB-3550 TriKE™ Phase I/II Clinical Trial for the Treatment of High-Risk Myelodysplastic Syndromes (MDS) and Refractory/Relapsed Acute Myeloid Leukemia (AML):** In March and April 2021, GT Biopharma announced updated interim results from the Phase I dose-escalation portion of the Phase I/II expansion clinical trial of GTB-3550 TriKE™ from 9 patients with MDS and AML. Results demonstrated up to 63.7% reduction in bone marrow blast levels, restoration of endogenous NK cell function, proliferation and immune surveillance. All patients treated displayed no signs of any grade of cytokine release syndrome (CRS) across all dose cohorts. GTB-3550 TriKE™ is currently being administered to patients at doses significantly higher than the reported maximum tolerated dose (MTD) for continuous infusion of recombinant human interleukin-15 (IL-15).
- **Enrollment in Phase I Portion of GTB-3550 TriKE™ Phase I/II Clinical Trial in MDS and AML Continues:** In April 2021, GT Biopharma announced the enrollment of patient 10 in its GTB-3550 TriKE™ Phase I/II Clinical Trial in high-risk MDS and AML patients. The patient was dosed at 100mcg/kg/day.
- **Additional New Findings Supporting GTB-3550 TriKE™ Monotherapy:** In April 2021, GT Biopharma announced additional interim results demonstrating that GTB-3550 TriKE™ monotherapy is able to rescue the patient's otherwise exhausted/inhibited/non-functional endogenous NK cell population, and target direct killing of the patient's AML and MDS cancer cells without the need for the co-administration addition of supplemental progenitor-derived or autologous/allogenic engineered NK cells.
- **Announced Preliminary Phase II Clinical Trial Design:** In May 2021, GT Biopharma announced updates to the Phase 2 design of the ongoing Phase I/II clinical trial of GTB-3550 TriKE™ monotherapy. The Phase II portion intends to enroll patients with CD33 expression ≥50% in independent cohorts (higher-risk MDS and AML); treat patients with two cycles of GTB-3550 therapy with a rest period between cycles as opposed to the single-cycle used during Phase 1; enroll patients with fewer prior treatment lines; and, (evaluate the potential use of minimal residual disease (MRD) based endpoints that may allow for accelerated approval.

Corporate Highlights

- **Closed $28.7 Million Public Offering and Successful Nasdaq Listing:** In February 2021, GT Biopharma announced the closing of an underwritten public offering extending GT Biopharma's cash runway through 2022. The Company also retired over $32 million in debt and consolidated capital structure to 28,637,000 shares issued and outstanding.
- **Strengthened Leadership Team with Key Appointments:** In April 2021, GT Biopharma announced the appointment of Gregory Berk, M.D., as Chief Medical Officer and the transition of Jeffrey S. Miller, M.D., from Consulting Chief Medical Officer to Consulting Chief Scientific Officer. Additionally, in January 2021, GT Biopharma announced the appointments of Michael Breen and Rajesh Shrotriya, M.D., as independent directors to the Company's Board of Directors.
- **Expanded GMP Manufacturing Agreement with Cytovance Biologics:** In February 2021, GT Biopharma announced that it signed an expanded GMP manufacturing agreement with Cytovance Biologics for the manufacturing of all TriKE™ product candidates.

First Quarter 2021 Financial Results:

- **Cash Position:** As of March 31, 2021, cash, cash equivalents and investments were $27.6 million, compared to $5.3 million as of December 31, 2020. The increase in cash, cash equivalents and investments was primarily due to the completed public offering of 4,945,000 shares of common stock for net proceeds of $24,679,000 after deducting underwriting discounts, commissions and other direct offering expenses. As of May 14th, current cash position of $35,000,000.
- **Research and Development Expenses:** Research and development expenses were $1.6 million for the first quarter of 2021, compared to $.3 million for the same period in 2020. The increase in research and development expenses for the first quarter 2021 was primarily due to the issuance of 189,753 shares of common stock as payment of a fee valued at $1,355,000. We anticipate our direct clinical costs to increase in the remainder of 2021 upon the continuation of a phase one/two clinical trial of our most advanced TriKE product candidate, GTB-3550.
- **General Administrative Expenses:** General administrative expenses were $27.3 million for first quarter 2021, compared to $.7 million for the same period in 2020. The increase in selling, general and administrative expenses is primarily attributable the increase in stock-based compensation. In the period ended March 31, 2021 we incurred $21,535,000 of stock-based compensation, we incurred no such expenses during 2020.
- **Net Loss:** Net loss was $29.7million for the first quarter of 2021, resulting in basic and diluted net loss per share of $1.83. Net loss was $1.7 million for the same period in 2020, resulting in basic and diluted net loss per share of $0.41.

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 intend to study GTB-3550 in CD33 positive

leukemias such as 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 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.

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:http://www.prnewswire.com/news-releases/gt-biopharma-reports-first-quarter-2021-results-301293000.html

SOURCE GT Biopharma, Inc.