April 19, 2021

GT Biopharma Reports Fourth Quarter and Year End 2020 Results and Business Update

Posted Significant FDA Clinical Trial Results for GTB-3550 TriKE™ in AML and MDS Patients

Established GMP Manufacturing Partnership with Cytovance

Initiated Manufacturing of Additional Solid Tumor TriKE™ for Programs in Lung, Breast, Ovarian and Gastrointestinal Cancers, in preparation for FDA Clinical Trials

Brought in Accomplished Board of Directors

Successful NASDAQ Listing and Financing of $28.7 Million Public Offering Covering Two Years of Capital Requirements, Now Leaving the Company with Over $30 Million in the Bank

BEVERLY HILLS, Calif., April 19, 2021 /PRNewswire/ -- GT Biopharma, Inc. (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, reported financial results for the fourth quarter and year ended December 31, 2020.

"2020 was a year of robust clinical progress and milestone achievements for GT Biopharma, which allowed us to accomplish a major corporate milestone in listing GT Biopharma on NASDAQ at the beginning of 2021. The emerging data from our GTB-3550 TriKE™ program in hematological malignancies, MDS and AML, are encouraging in both safety and efficacy profiles. The ongoing data profile has demonstrated significant differences from all other NK cell therapies and NK engager companies, making TriKE™ a monotherapy, off-the-shelf platform therapeutic. TriKE™ exerts its therapeutic effect without the need for outside assistance in the form of combination therapies or the addition of supplemental progenitor-derived or autologous/allogenic NK cells. As a result, TriKE™ therapy cost to patients will be far superior, significantly more economic than progenitor-derived or autologous/allogenic NK cell therapy companies' offerings. Additionally, the results generated from the GTB-3550 TriKE™ clinical trial reinforces its versatility, providing a clear rationale to proceed with additional programs in solid tumor and hematologic cancers. As a result, in 2020 we formed a strong GMP manufacturing partnership with Cytovance Biologics to bring our TriKE™ product candidates forward for evaluation in the clinic," said Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "In the first quarter of 2021, we have achieved numerous clinical and operational milestones, which included garnering the attention of institutional investors and analyst research coverage as a result of our successful NASDAQ listing and public offering. We transferred all TriKE™ GMP manufacturing to Cytovance, as we progress our solid tumor TriKE™ product candidates. Additionally, the interim results from our ongoing Phase I/II clinical trial of GTB-3550 TriKE™ showed a 63.7% reduction in bone marrow blast (cancer cell killing) levels in patient 9; up from 61% in patient 7 at a lower dose for patients with MDS and AML. We also added the University of Wisconsin-Madison as a second clinical trial site. There will be more trials sites added, as we will soon proceed to the Phase II portion of our ongoing GTB-3550 TriKE™ clinical trial. We look forward to building on this momentum throughout the year, particularly as we continue to dose escalate our GTB-3550 TriKE™ in these incredibly difficult-to-treat relapsed/refractory AML and high-risk MDS patient populations. We thank the patients and their families for their contribution, as we progress this novel, off-the-shelf monotherapy cancer therapeutic that uniquely works without outside supplemental engineered NK cells or the need for any combination drugs."

Corporate Highlights

- **Strengthened Leadership Team with Key Appointments to Executive**

Management, Board of Directors, and Scientific and Medical Advisory Board: In November 2020, GT Biopharma announced the appointment of Michael Handelman, CPA as Chief Financial Officer. Mr. Handelman was the former CFO of Iovance Biotherapeutics. Throughout 2020, GT Biopharma announced multiple appointments to its two boards. Bruce J. Wendel was named Vice Chairman and Independent Director of the Board of Directors, and Greg Berk, M.D., Michael Breen and Rajesh Shrotriya, M.D. were appointed as independent directors. Samir Taneja, M.D. and Philip Werthman, M.D., M.M.H. were appointed to the Company's Scientific and Medical Advisory Board.

- **Established and Expanded TriKE™ Partnership with Cytovance Biologics:** In October 2020, GT Biopharma announced a partnership agreement with Cytovance Biologics for the exclusive GMP manufacturing of three TriKE™ product candidates. Under the terms of the agreement, Cytovance will manufacture TriKE™ product candidates in accordance with its proprietary Keystone® bacterial or mammalian expression systems. Subject to certain milestones by Cytovance, GT Biopharma has the option to pay Cytovance up to a total of $6 million. In December 2020, GT Biopharma issued $1 million to Cytovance as a first milestone payment. GT Biopharma's agreement with Cytovance was further expanded in February 2021 for the manufacturing of all TriKE™ products.

Subsequent Event:

- **Closed $28.7 Million Public Offering and Successful Listing on NASDAQ:** In February 2021, GT Biopharma announced the successful completion of its NASDAQ up list, in addition to the simultaneous closing of its public offering, in which it raised $28.7 million. Further, the Company retired over $32 million in debt and consolidated its capital structure.

Clinical Highlights

- **Presented Interim Results for GTB-3550 TriKE™ for the Treatment of High-Risk MDS and Refractory/Relapsed AML at the 62nd American Society of Hematology (ASH) Annual Meeting:**

    - In December 2020, GT Biopharma presented promising proof-of-principle interim results from its lead product candidate, GTB-3550 TriKE™, at ASH in an oral presentation. As of the data cut-off date, six out of seven enrolled patients were evaluable and displayed no signs of clinical immune activation or serious adverse events across all dose cohorts. Data demonstrated that the first patient from the 5 mcg/kg/day cohort achieved stable disease after one course of GTB-3550 TriKE™ therapy and the first patient from the 25 mcg/kg/day cohort achieved AML blast level decrease from 18% to 12% by morphological analysis after one course of GTB-3550 TriKE™ therapy. Correlative studies also have shown reproducible NK cell activity across all evaluable patients with NK cell activation increasing during early treatment. Of note, NK cell proliferation started at day 3, is maximal at day 8 and maintained above baseline at days 15 and 22.

    - Additional clinical data from a patient with HR-MDS were presented,

demonstrating that GTB-3550 TriKE™ safely activated and harnessed native NK cell's cancer killing ability in a target-directed fashion with no adverse events or dose limiting toxicities. Successful bone marrow blast level reduction from 12% prior to treatment to 4.6% post-treatment was determined by morphological assessment. The patient also achieved stable hematologic parameters, including normal platelet counts throughout therapy.

- **Expanded Clinical Programs with HER2 TriKE™ for the Treatment of Breast and Gastrointestinal Cancers:** In December 2020, GT Biopharma announced the initiation of clinical development for TriKE™ therapy for the treatment of HER2+, HER3+ and HER2+/HER3+ heterodimer complex breast cancer and gastrointestinal cancers.

- **Published Results on B7H3-Targeted TriKE™ Potential to Enhance NK-Cell Immunotherapy in Solid Tumors:** In October 2020, GT Biopharma announced the publication of results conducted by researchers at the University of Minnesota and Massachusetts General Hospital/Harvard Medical School in the journal, *Cancers,* in an article entitled "*NK-Cell-Mediated Targeting of Various Solid Tumors Using B7-H3 Tri-Specific Killer Engager In Vitro and In Vivo."* Results indicated that a B7H3-targeted TriKE™ has the potential to enhance NK cell immunotherapy in solid tumor settings, particularly where B7H3 is highly expressed on solid tumor surfaces.

Subsequent Events:

- **Updated Interim Results from GTB-3550 TriKE™ Clinical Program for the Treatment of MDS and AML:** In March 2021, GT Biopharma announced updated interim results from the Phase I/II Expansion clinical trial of GTB-3550 TriKE™ for the treatment of high-risk myelodysplastic syndromes (MDS) and refractory/relapsed acute myeloid leukemia (AML) from 9 patients. Results demonstrated up to 63.7% reduction in bone marrow blast levels. All patients treated to date 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).

- **GTB-3550 TriKE™ Interim Results Presented at Innate Killer Summit 2021**: In March 2021, Dr. Jeffrey S. Miller, M.D., GT Biopharma's Consulting Chief Medical Officer and Deputy Director of the Masonic Cancer Center at the University of Minnesota, presented updated interim Phase I/II clinical trial results for GTB-3550 TriKE™, being evaluated for the treatment of MDS and AML at the Innate Killer Summit 2021. Dr. Miller's presentation "NK Cell Therapeutics: Off-the-shelf Strategies to Increase Activity and Specificity" highlighted the clinical power of immune engagement with IL-15 containing TriKEs.

- **Announced Preclinical Results from ROR1 TriKE™ for the Treatment of Prostate Cancer:** In March 2021, GT Biopharma announced preclinical in vitro cell assay results demonstrating the ROR1 TriKE™ was found to be effective at promoting NK cell killing of prostate cells. Significant NK cell activation and interferon gamma

production was also observed as a result of ROR1 TriKE™ engagement.

Fourth Quarter and Year End 2020 Financial Results:

- **Cash Position:** As of December 31, 2020, cash, cash equivalents and investments were $5.3 million, compared to $0.3 million as of December 31, 2019. The increase in cash, cash equivalents and investments was primarily due to proceeds from the issuance of convertible notes payable of $12.5 million, offset by cash used in operating activities of $7.3 million.

- **Research and Development Expenses:** Research and development expenses were $233 thousand for the fourth quarter of 2020, compared to $8 thousand for the same period in 2019. Research and development expenses were $485 thousand for the full year 2020, compared to $1.7 million for the full year 2019. The decrease in research and development expenses for the full year 2020 was primarily due to the reduction of consultant and clinical expenses. The Company anticipates clinical costs to increase significantly in 2021.

- **General Administrative Expenses:** General administrative expenses were $2.0 million for the fourth quarter of 2020, compared to $0.9 million for the same period in 2019. General administrative expenses were $6.3 million for the full year 2020, compared to $9.8 million for the full year 2019. The decrease in general administrative expenses for the full year 2020 was primarily attributable to the reduction of stock compensation costs.

- **Net Income (Loss):** Net loss was $14.9 million for the fourth quarter of 2020, compared to a net loss of $1.5 million for the same period in 2019. Net loss was $28.3 million for the full year 2020, resulting in basic and diluted net loss per share of $(6.45). Net loss was $38.6 million for the full year 2019, resulting in basic and diluted net loss per share of $(11.42) before effect of reverse split. Net loss for the full year 2020 was attributable to a loss from operations of $6.8 million and total other expenses of $21.5 million. Net loss for the full year 2019 was primarily attributable to the loss from operations of $16.0 million and total other expenses of $22.6 million.

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.

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