November 10, 2021

GT BioPharma Reports Third Quarter 2021 Financial Results and Provides Corporate Update

-- Previously updated positive safety data for the GTB-3550 Phase 1 trial in relapsed/refractory AML and MDS with first-in-human trials, providing proof-of-concept support

-- GTB-3650, second-generation Tri-Specific Killer Engager (TriKE®) utilizing nanobody technology advanced into IND-enabling studies

-- Two new patents were issued securing IP related to the TriKE® platform technology underpinning novel portfolio of molecules through 2036

-- $35.8 million in cash and cash equivalents as of September 30 provides ample runway into 2023

BEVERLY HILLS, Calif., Nov. 10, 2021 /PRNewswire/ -- GT Biopharma, Inc. (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 platform, today announced third quarter 2021 results for the period ended September 30, 2021.

"We have made significant progress in the advancement of the Company's proprietary portfolio of novel cancer killing TriKEs, and our recent strategic executive team transition has us well positioned for the future," noted Gregory Berk, MD, Interim CEO. "The marked progress in the quarter included securing newly issued IP, which serves to further protect the commercial development of the TriKE platform through 2036. In September, we announced further proof of concept safety data in our first in human Phase 1 clinical trial and announced the start of IND-enabling studies with GTB-3650, which is the Company's second-generation TriKE based on camelid nanobody technology that has several advantages over traditional IgG monoclonal antibodies. We are focused on rapidly advancing our extensive TriKE platform of molecules targeting a variety of tumor types."

As the Company works toward the launch of initial IND-enabling studies for GTB-3650, our data published to date, highlights the therapeutic and commercial advantages of GTB-3650 compared to GTB-3550 including improved potency, enhanced binding affinity, a similar well-tolerated preclinical safety profile, and commercial manufacturing capabilities through our arrangement with Cytovance. The Company aims to accelerate the GTB-3650 IND enabling studies and subsequent Phase 1/2 study, for patients with relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS).

Key Operational Highlights

- Dr. Jeffrey Miller, the Company's Consulting Chief Scientific Officer presented a mini-oral presentation at the European Society for Medical Oncology (ESMO) Congress, September 2021.
    - The presentation highlighted the activity of camelid TriKEs in preclinical B7H3 positive and HER2+ solid tumor cancer models.
- On September 20, the Company provided a clinical update on the Phase 1 trial with GTB-3550. The three most recent patients (numbers 10-12) have all tolerated the treatment well. One patient at the 150 mcg/kg/day dose experienced a mild Grade 1 cytokine release syndrome (CRS) event (fever), which was not dose limiting. Immune monitoring on these three most recent patients was consistent with the data previously reported on the first nine patients, and demonstrated activation, proliferation, and persistence of CD16 positive NK cells. Patient 11 had a bi-phenotypic leukemia which co-expressed both CD19 (a lymphoid marker) and CD33 (the myeloid marker which is targeted by GTB-3550); this patient showed a 50% reduction in CD33-positive leukemic cells (blasts), evidence of anti-leukemic activity of GTB-3550. Patients 10 and 12 did not experience blast cell reduction. The Company has previously reported that three of the first nine patients experienced a reduction in blast cells.
- On September 13, the Company announced that GTB-3650, a second-generation Tri-Specific Killer Engager TriKE® had advanced into IND-enabling studies.
    - Company plans to supplant the GTB-3550 clinical program with GTB-3650
    - Therapeutic and commercial advantages of GTB-3650 compared to GTB-3550 include:
        - Based on second generation camelid single-domain antibody technology that holds several advantages over traditional IgG monoclonal antibodies
        - Improved potency and enhanced binding affinity
        - Similar preclinical safety profile
        - Commercial manufacturing capabilities through arrangement with Cytovance

    - Proprietary patented molecule, which unlike GTB-3550, is wholly owned by GT Biopharma
- On November 8, the Board appointed Dr. Berk as Interim CEO, and Dr. Gavin Choy as Acting CFO. Michael Breen has assumed the role of Executive Chairman of the Board, remains Chair of the Audit Committee and will oversee the transition. The Board has initiated a search process to identify individuals for permanent positions for both the CEO and CFO roles.

Third Quarter 2021 Financial Summary

Cash position: As of September 30, 2021, the Company had total cash and cash equivalents of $35.8 million, compared to $7 million as of December 31, 2020.

Research and Development (R&D) expenses: R&D expenses for the third quarter of 2021 were $1 million compared to $84,000 in the same period in 2020. Research and development costs increased due primarily to the admittance of additional patients into the Phase 1/2 GTB-3550 clinical trial and the continued development of our most advanced TriKE® product candidate, GTB-3650.

Selling, General and Administrative (SG&A) expenses: SG&A expenses for the third quarter of 2021 were $4.9 million compared to $2.0 million in the same period in 2020. The increase of $2.9 million in selling, general and administrative expenses is primarily attributable the increase in stock-based compensation.

Net loss: For the third quarter of 2021, the Company reported a net loss of $5.5 million, compared to a net loss of $2.9 million in the same period in 2020 or $0.17 per share compared to $0.64 per share for the prior year.

About Camelid Antibodies

Camelid antibodies are single domain antibodies (sdAbs) from the Camelidae family of mammals that include llamas, camels, and alpacas. These animals produce 2 main types of antibodies. One type of antibody camelids produce is the conventional antibody that is made up of 2 heavy chains and 2 light chains. They also produce another type of antibody that is made up of only 2 heavy chains and no light chain. This is known as heavy chain IgG (hcIgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the VHH region. VHH antibodies, also known as single domain antibodies, contain only the VHH region from the camelid antibody. Camelid antibodies have key characteristics, which include high affinity and specificity (equivalent to conventional antibodies), high thermostability, good solubility and strictly monomeric behavior, small size, relatively low production cost, ease of genetic engineering, format flexibility or modularity, low immunogenicity, and a higher penetration rate into tissues.

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

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 Annual Report on Form 10-K for the year ended December 31, 2020, our subsequent current reports on Form 8-K, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and our other 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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