May 29, 2019

GT Biopharma GTB-1550 PHASE I-II Results to be Published in Conjunction With 2019 ASCO Meeting May 31 - June 4 in Chicago

TAMPA, Florida, May 29, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (OTC: GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE) platform and Multi-Target Directed Bispecific Drug Conjugate (MTBDC) platform, announced today that the results of its second Phase I-II trial (NCT02370160) for GTB-1550 (DT2219), an MTBDC targeting CD22 and CD19 for treatment of refractory B-cell malignancies, will be published (J Clin Oncology 37, 2019 suppl; abstract e19066) on-line in conjunction with the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago from May 31 – June 4.

Top Line Results Summary:

- Treatment was well tolerated at 60 mcg/kg x 8 doses and the most common adverse events included capillary leak syndrome, elevated AST/ALT, low albumin, weight gain and leukopenia. All were Grade 1-2 and resolved after 3-5 days allowing day 15 GTB-1550 administration.
- There were no neutropenic fever or immune mediated adverse events. Four patients experienced dose limiting toxicity (DLT) at dose 80 µg/kg/day: Grade 4 capillary leak syndrome (n=1), Grade 3 liver function test (LFT) abnormalities (n=2) and Grade 4 thrombocytopenia >7 days duration (n=1).
- Thirteen patients were evaluable for response, and 3 experienced objective clinical benefit. One patient with primary refractory pre-B acute lymphoblastic leukemia achieved complete remission after 1st cycle. Two patients with transformed lymphoma demonstrated transient tumor shrinkage, however, GTB-1550 therapy was discontinued due to DLT and increased neutralizing antibody titer after 1st cycle (pre C1 28%, pre C2 108%).
- Correlative studies showed a low incidence of neutralizing antibody in Non-Hodgkin Lymphoma (NHL) patients recently exposed to Rituximab.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented, "We are pleased with the results GTB-1550 has shown in the current Phase I-II

clinical trial and in our earlier Phase I-II clinical trial. This now positions us to move forward with the FDA phase II clinical trial."

Dr. Veronika Bachanova, Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota and the Principal Investigator for both clinical trials commented, "We are excited about the progress GTB-1550 is making in the clinic, and look forward to the possibility of exploring additional monotherapy and synergistic combination studies against various B-cell malignancies." Both clinical studies were conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis.

About GTB-1550 Multi-Target Directed Bispecific Therapy

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors thereby maximizing cancer cell recognition by binding to CD19+, CD22+ and CD19+/CD22+ cancer cells. When GTB-1550 binds to cancer cells, the cancer cells internalize GTB-1550, and are killed due to the action of drug's cytotoxic diphtheria toxin payload. GTB-1550 has previously demonstrated success in a Phase I-II human clinical trial in patients with relapsed/refractory B-cell lymphoma or leukemia. At the time of the interim review, 13 patients met the evaluation criteria, including nine NHL and four ALL patients. More than 50% of patients (seven of 13) exhibited a clinical benefit, defined as stable disease, partial remission or complete remission at Day 29. Of the seven patients, one demonstrated a complete remission (CR), one demonstrated a partial remission (PR) and five demonstrated stable disease (SD).

About the TriKE Platform

The Company's TriKE product candidates are single-chain, tri-specific scFv recombinant fusion proteins composed of the variable regions of the heavy and light chains (or heavy chain only) of anti-CD16 antibodies, wild-type or a modified form of IL-15 and the variable regions of the heavy and light chains of an antibody designed to precisely target a specific tumor antigen. GT Biopharma utilizes the NK stimulating cytokine human IL-15 as a cross linker between the two scFvs which is designed to provide a self-sustaining signal leading to the proliferation and activation of NK cells thus enhancing their ability to kill cancer cells mediated by antibody-dependent cell-mediated cytotoxicity (ADCC). GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE) and Multi-Target Directed Bispecific Drug Conjugate (MTBDC) technology platforms. Our TriKE platform is designed to harness and enhance the cancer killing abilities of a patient's immune system natural killer cells (NK cells). Our Multi-Target Directed Bispecific Drug Conjugate (MTBDC) platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of targeted therapy.

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 guarantees 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, 2018 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent 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 for GTB-3550 or GTB-1550, 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.

For more information, please visit www.gtbiopharma.com.

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