May 30, 2019

GT Biopharma GTB-1550 Clinical Development Update

Durable Complete Remission in Patient Currently Disease-free at 50 Months Post Treatment

Greater than 50% of Evaluable Patients Receiving 60 mg/kg Dose had Positive Clinical Response

TAMPA, Florida, May 30, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (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, today provided an update with respect to the further clinical development of GTB-1550.

GTB-1550 (DT2219) is a novel multi-target directed therapy for the treatment of chemotherapy-refractory B-cell malignancies, including Non Hodgkins Lymphoma and Leukemia. To date, GT Biopharma has completed one dose escalation Phase I-II expansion clinical trial, and one fixed dose Phase I-II expansion clinical trial which collectively enrolled a combined 43 patients.

Top-line Consolidated Results:

- Two patients exhibited a Complete Remission (CR) with one patient currently disease-free at 50 months post treatment.
- Five patients exhibited Stable Disease (SD), cancers that are neither increasing or decreasing in severity, with the longest response lasting 12 months post treatment.
- Two patients with transformed lymphoma showed transient tumor shrinkage, however, therapy was discontinued due to dose-limiting toxicities after the 1st cycle.
- Greater than 50% of evaluable patients, (patients where response to treatment can be measured because enough data has been collected), receiving 60 mg/kg dose had positive clinical response defined as stable disease, partial remission, or complete remission.

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 pleased the patient who experienced a complete remission following treatment with GTB-1550 is doing well, and we are excited about moving forward with a GTB-1550 Phase II clinical trial for the treatment of chemotherapy-refractive B-cell malignancies."

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented: "GTB-1550 has shown positive results in its two Phase I-II clinical trials in advanced cancer patients who have failed all other therapies, and we are now planning to proceed with a Phase II clinical trial."

The initial Phase I-II expansion clinical trial (clinicaltrials.gov NCT00889408; *Clin Cancer Res 21(6) pgs 1267–72*) demonstrated decreased tumor mass in one patient, and a complete response in a second patient that remains on-going at 50 months post treatment. After a single course of GTB-1550 (DT2219) at dose level 40 mg/kg/day x 4, a 77-year-old patient with chemotherapy-refractory $CD19^{+}/CD22^{-}$ chronic lymphocytic leukemia (CLL) experienced a 40% reduction in cervical and axillary adenopathy with decrease of an abdominal tumor mass at day 28 after treatment, which was sustained for 2 months. The second clinical response occurred in a 53-year-old patient with relapsed $CD19^{+}/CD22^{+}$ diffuse large B cell lymphoma (dose level 60 mg/kg) who experienced a 75% reduction in size of lymphoma lesion after a single course complicated by a grade 3 capillary leak syndrome. Eight weeks later after FDA approval, this patient received a second DT2219 course at a reduced dose of 40 mg/kg/dose for 4 days, which resulted in a complete resolution of a subcutaneous mass and pelvic lymphadenopathy. The patient is alive and in complete remission with no neutralizing antibodies, currently at 50 months after therapy.

The results of the second GTB-1550 Phase I-II expansion trial (clinicaltrials.gov NCT02370160; *J Clin Oncology 37, 2019 suppl; abstract* e19066) targeting CD22 and CD19 for treatment of refractory B-cell malignancies showed treatment was well tolerated at 60 mg/kg x 8 doses. 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.

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). 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. 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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