April 8, 2019

GT Biopharma Receives Institutional Review Board Approval to Proceed With in Human FDA Phase 1 Clinical Trial

TAMPA, Florida, April 8, 2019 /PRNewswire/ --GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immuno-oncology biotechnology company focused on innovative treatments based on the Company's proprietary NK-engager (TriKE) platform and Multi-Target Bispecific Drug Conjugate (MTBDC) platform, announced today it has received authorization from the University of Minnesota's Institutional Review Board (IRB) and Cancer Protocol Review Committee (CPRC) that it can proceed with its planned TriKE Phase 1 clinical trial.

Our Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) was earlier authorized allowing us to initiate a first-in-human Phase 1 study with GTB-3550, its first-in-class (TriKE), for the treatment of acute myelogenous leukemia (AML), myelodysplatic syndrome (MDS) and mastocytosis. The study will be led by Principal Investigator, Erica Warlick, MD, Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at Masonic Cancer Center, University of Minnesota.

"GTB-3550 is a protein immune engager that binds to natural killer (NK) cells and targets them specifically to leukemia cells," said Jeffrey Miller, MD, Deputy Director, Masonic Cancer Center, University of Minnesota. "Our team has been working on the optimal construct for some time, and we are excited to see it is ready for clinical testing. In addition, the same TriKE protein will deliver an interleukin-15 stimulus, a growth factor that makes NK cells proliferate and be more active."

"The clinical trials team at the University of Minnesota are excited to commence the Phase 1 trial testing this novel immunotherapeutic agent, GTB-3550," said Anthony Cataldo (CEO GT Biopyarma). "The pre-clinical data are compelling, and success with GTB-3550 in this Phase 1 study will allow us to further investigate the TriKE in a larger number of cancer patients."

This single center, first-in-human Phase 1 clinical trial of GTB-3550 will enroll up to 60 subjects with CD33-expressing high risk for refractory/relapsed AML, MDS, or advanced systemic mastocytosis. Subjects will receive a single course of GTB-3550 TriKE given as 3 weekly treatment blocks. Each block consists of four consecutive 24-hour continuous infusions of GTB-3550 TriKE followed by a 72-hour break after Block #1 and #2. Disease response will be assessed by bone marrow biopsy performed between Day 21 and Day 42 after the start of the 1st infusion. Follow-up for response and survival continues through 6 months from treatment start. The primary objective from the Phase 1 dose finding portion of the study will be to identify the maximum tolerated dose (MTD) of GTB-3550 TriKE defined as the dose level that most closely corresponds to a dose limiting toxicity rate (DLT) of 20%.

The primary objective from the Phase 2 extended portion of the study will be the potential efficacy of GTB-3550 TriKE, measured using rates of complete and partial remission. Subjects experiencing clinical benefit and no unacceptable side effects may be considered for a 2nd course of GTB-3550 TriKE on a compassionate basis.

About Acute Myelogenous Leukemia (AML)

AML is the most common form of adult leukemia with 21,000 new cases expected in 2018 alone, according to the American Cancer Society. AML patients typically receive frontline therapy, most commonly chemotherapy, which includes cytarabine and an anthracycline, a therapy that has not changed in over 40 years. However, there remains a significant unmet need in these therapies with about half of AML patients experiencing relapses or requiring alternative therapies. The Company is developing GTB-3550 to serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger patient population.

About Myelodysplastic Syndrome (MDS)

Myelodysplastic syndromes (MDS) are conditions that can occur when the blood-forming cells in the bone marrow become abnormal, leading to low numbers of one or more types of blood cells. There are several different types of MDS, based on how many types of blood cells are affected and other factors, although the most common finding in MDS is a shortage of red blood cells (anemia). The number of people with MDS diagnosed in the U.S. each year is estimated to be ~10,000. MDS is uncommon before age 50 and is most commonly diagnosed in people in their 70s. In about 1 in 3 patients, MDS can progress to AML, a rapidly growing cancer of bone marrow cells.

About Mastocytosis

Mastocytosis is a rare disorder characterized by abnormal accumulations of mast cells in the skin, bone marrow, and internal organs (liver, spleen, gastrointestinal tract and lymph nodes). Cases beginning during adulthood tend to be chronic and involve the bone marrow in addition to the skin, whereas, during childhood, the condition is often marked by skin manifestations with no internal organ involvement and can often resolve during puberty. In most adult patients, mastocytosis tends to be persistent, and may progress into a more advanced category in a minority of patients. Mastocytosis affects both males and females and can begin during childhood or adulthood. In children, 80% of cases appear during the first year of life, and the majority is limited to the skin. Adults who develop mastocytosis more often have systemic forms of the disease. Cutaneous forms of the disease account for less than 5% of adult cases. An estimate of prevalence from a recent population-based study is approximately 1 case per 10,000 people.

About GTB-3550

GTB-3550 (OXS-3550) is the Company's first Tri-specific Killer Engager (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. When the NK stimulating cytokine human IL-15 is used as a crosslinker between the two

scFvs, it provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We intend to study this anti-CD16-IL-15-anti-CD33 tri-specific killer engager, or TriKE, in CD33 positive leukemias, a marker expressed on tumor cells in AML, myelodysplastic syndrome, or MDS, and other hematopoietic malignancies. CD33 is primarily a myeloid differentiation antigen with endocytic properties broadly expressed on AML blasts and, possibly, some leukemic stem cells. CD33 or Siglec-3 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC3, gp67, p67) is a transmembrane receptor expressed on cells of myeloid lineage. It is usually considered myeloid-specific, but it can also be found on some lymphoid cells. The anti-CD33 antibody fragment that will be used for these studies was derived from the M195 humanized anti-CD33 scFV and has been used in multiple human clinical studies. It has been exploited as target for therapeutic antibodies for many years. Improved survival seen in many patients when the antibody-drug conjugate gemtuzumab was added to conventional chemotherapy validates this approach. GT Biopharma believes that GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger patient population.

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), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target certain tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics. Our Multi-Target 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 antibody directed drug conjugate therapies.

For more information, please visit www.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 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, 2017 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 Phase 1 study of TriKe, GTB-3550 and or our Phase 2 trial of CTB-1550 and 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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