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GT Biopharma Announces GTB-3550 TriKE(TM) Reduces Bone Marrow Blast Levels, Improves NK Cell Function and Proliferation, and No Toxicities Observed in AML and MDS Patients

GTB-3550 Interim Results Presented at 62nd American Society of Hematology Annual Meeting and Exposition

BEVERLY HILLS, CA / ACCESSWIRE / December 8, 2020/ GT Biopharma, Inc. (OTCQB:GTBP)(GTBP.PA) an immuno-oncology company focused on innovative therapies based on the Company's proprietary NK cell engager (TriKE™) technology platform is pleased to announce the presentation of interim results for the Company's lead therapeutic candidate, GTB-3550 for the treatment of high-risk myelodysplastic syndromes (MDS) and refractory/relapsed acute myeloid leukemia (AML). Erica Warlick, M.D, the Principal Investigator for the GTB-3550 clinical trial, presented the interim results during an Oral Session at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition on December 5, 2020. Dr. Warlick's presentation can be viewed on the GT Biopharma web site at https://ir.gtbiopharma.com/presentations.

Reduction in Bone Marrow Blast Levels Achieved

To date, 7 patients have been enrolled, two at 5 mcg/kg/day, two at 10 mcg/kg/day, two at 25 mcg/kg/day, and one at 50 mcg/kg/day. All seven patients (5-50 mcg/kg/day) have completed therapy. The first patient treated at 5 mcg/kg/day had stable disease after GTB-3550 therapy, and the first patient treated at 25 mcg/kg/day saw AML blast levels decrease from 18% to 12% after GTB-3550 therapy.

Patient #7, a high-risk MDS patient who had failed hypomethylating agent (HMA) and Luspatercept therapies, treated with GTB-3550 at 50mcg/kg/day (three consecutive 96-hour continuous infusions) achieved a bone marrow blast level reduction from 12% to 4.6% and stable hematologic parameters including normal platelet counts throughout therapy. Following this single course of GTB-3550 therapy, Patient #7 now meets criteria for a bone marrow transplant that is planned for next week.

No Toxicities Observed
Patients treated with GTB-3550 TriKE displayed no signs of clinical immune activation such as cytokine release syndrome (CRS) or serious adverse events (SAEs) or fevers, tachycardia or constitutional symptoms at any dose (5-50mcg/kg/day) evaluated to date. Of particular note, GTB-3550 is currently being administered to patients at 25x the previous reported MTD for continuous infusion of recombinant human IL-15 (Waldmann, TA et al, Clin Cancer Res. (2019) 25:4945-54). 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.

Improved NK Cell Function, Proliferation & Persistence
Correlative studies have shown reproducible NK cell activity in all patients. NK cell activation increases early during treatment. The greatest NK cell proliferation starts at day 3, is maximal at Day 8, and maintained above baseline at Day 15 and Day 22. This finding correlated with an increase proportion and absolute number of NK cells during treatment. Targeted delivery of IL-15 to NK cells via GTB-3550 TriKE showed preferential proliferation of NK cells and significantly less effect on CD8+ T cells. Additionally, the frequency of NK cells and absolute lymphocyte count decreased early during the continuous infusion of the GTB-3550 TriKE, which rebounded after the 72-hour rest period to higher levels than the pre-treatment baseline. We also observed no CD16 shedding by patients' NK cells, and saw enhanced HL-60 AML target cell killing.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "unlike expensive iPSC NK cell therapy or other such costly autologous/allogenic NK cell therapies, we believe our clinical data demonstrates that CD16 and IL-15 incorporated in TriKE safely activates and harnesses the patient's native NK cell cancer killing ability in a target-directed fashion." Mr. Cataldo further stated "our off-the-shelf GTB-3550 TriKE product clinical data demonstrates immune activity in humans, and reduces blast levels in AML and MDS cancer patients. We believe as we continue to dose escalate, subsequent patients given higher dose levels of GTB-3550 will experience greater clinical efficacy."

About High-Risk Myelodysplastic Syndromes (MDS)
MDS is a rare form of bone marrow-related cancer caused by irregular blood cell production within the bone marrow. As a result of this irregular production, MDS patients do not have sufficient normal red blood cells, white blood cells and/or platelets in circulation. High-risk MDS is associated with poor prognosis, diminished quality of life, and a higher chance of transformation to acute myeloid leukemia. Approximately 40% of patients with High-Risk MDS transform to AML, another aggressive cancer with poor outcomes.

About Acute Myeloid Leukemia (AML)
Acute myeloid leukemia (AML) is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets. According to the National Cancer Institute (NCI), the five-year survival rate is about 35% in people under 60 years old, and 10% in people over 60 years old. Older people whose health is too poor for intensive chemotherapy have a typical survival of five to ten months. AML accounts for roughly 1.8% of cancer deaths in the United States.

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 GTB-3550 TriKE™ Clinical Trial
Patients with CD33+ malignancies (primary induction failure or relapsed AML with failure of one reinduction attempt or high-risk MDS progressed on two lines of therapy) age 18 and older are eligible (NCT03214666). The primary endpoint is to identify the maximum tolerated dose (MTD) of GTB-3550 TriKE. Correlative objectives include the number, phenotype, activation status and function of NK cells and T cells.

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 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 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.

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, 2019 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent Form 10Q Quarterly 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.

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

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