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GT Biopharma Announces Publication of GTB-3550 TriKE Interim Results at the Prestigious 62nd American Society of Hematology (ASH) Annual Meeting

TAMPA, FL / ACCESSWIRE / November 12, 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 is pleased to announce its abstract *"GTB-3550 TriKE™ for the Treatment of High-Risk Myelodysplastic Syndromes (MDS) and Refractory/Relapsed Acute Myeloid Leukemia (AML) Safely Drives Natural Killer (NK) Cell Proliferation At Initial Dose Cohorts"* has been selected by the Program Committee for presentation in an Oral Session at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition as detailed below:

Session Name: 704. *Immunotherapies: Beyond T to NK*
Session Date: Saturday, December 5, 2020
Session Time: 7:30 AM - 9:00 AM Eastern Time
Presentation Time: 8:00 AM Eastern Time

In addition to the presentation, the abstract will also be published online in November supplemental issue of the journal *Blood*. First publication will be in the online ASH meeting program on November 5, 2020 (https://ash.confex.com/ash/2020/webprogram/Paper136398.html).

Relapsed/refractory AML and MDS present a clinical challenge. Despite FDA approval of multiple new targeted agents, many patients lack actionable mutations and have exhausted conventional chemotherapeutic options.

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.

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. Six patients (5-25 mcg/kg/day) have completed therapy to date, with one patient (50mcg/kg/day) entering their third week of therapy. The first patient at 5 mcg/kg/day had stable disease after course 1 of GTB-3550 therapy, and the first patient at 25 mcg/kg/day saw AML blast levels decrease from 18% to 12% by morphological analysis after course 1 of GTB-3550 therapy.

Of particular note, the previous reported MTD of continuous infusion rhIL-15 was 2 mcg/kg/day (Waldmann, TA et al, Clin Cancer Res. (2019) 25:4945-54) was associated with fevers, tachycardia and constitutional symptoms. Validating our pre-clinical data, patients treated with GTB-3550 TriKE displayed no signs of clinical immune activation or serious adverse events (SAEs) at the 5, 10 or 25 mcg/kg/day dose cohorts.

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.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "we are pleased to have the opportunity to present our interim results for GTB-3550 TriKE™ for the treatment of High-Risk Myelodysplastic Syndromes (MDS) and Refractory/Relapsed Acute Myeloid Leukemia (AML) patients." Mr. Cataldo further stated, "This early data suggest proof-of-principle that GTB-3550 has immune activity in humans. We believe as we continue to dose escalate, subsequent patients given higher dose levels of GTB-3550 will translate into meaningful clinical efficacy."

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 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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https://www.accesswire.com/616161/GT-Biopharma-Announces-Publication-of-GTB-3550-TriKE-Interim-Results-at-the-Prestigious-62nd-American-Society-of-Hematology-ASH-Annual-Meeting