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GT Biopharma Announces Eighth Patient Begins Treatment Of GTB-3550

BEVERLY HILLS, Calif., Jan. 12, 2021 /PRNewswire/ -- 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 continuation of enrollment with patient 8 in its GTB-3550 clinical trial following the conclusion of a 30-day Covid-19 related pause in enrolling patients in all clinical trials currently being conducted at the University of Minnesota's Masonic Cancer Center.

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 to participate in the GTB-3550 TriKE™ clinical trial (NCT03214666). The primary endpoint of the Study 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.

GTB-3550 TriKE™ Demonstrates Clinical Benefit in Patients and 61.7% Reduction in Cancer Burden in patient 7

The GTB-3550 TriKE™ clinical trial commenced patient enrollment in February 2020 for the treatment of relapsed/refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (HR-MDS). To date, seven patients have been enrolled in the clinical trial; two patients treated at 5 mcg/kg/day, two patients treated at 10 mcg/kg/day, two patients at 25 mcg/kg/day, and one patient treated at 50 mcg/kg/day. All seven patients have completed therapy. **The results to date have been positive and the company continues to expand the enrollment.**

Clinical Benefit Achieved and Reduction in Cancer Burden in HR-MDS Patient

A high-risk myelodysplastic syndromes (HR-MDS) patient had failed hypomethylating agent and Luspatercept therapies prior to being treated with GTB-3550 at 50mcg/kg/day (three consecutive 96-hour continuous infusions). The patient achieved bone marrow blast level reduction from 12% before GTB-3550 therapy to 4.6% post GTB-3550 therapy determined by morphological assessment (61.7% reduction in cancer cells), and had stable hematologic parameters including normal platelet counts throughout therapy. Following this single course of GTB-3550 therapy and the significant reduction in bone marrow blast levels, the patient demonstrated clinical benefit from GTB-3550 therapy, and qualified for and has received a hematopoietic stem cell transplant (HSCT). The only treatment with curative intent for a majority of elderly HR-MDS or relapsed/refractory AML patients is allogeneic hematopoietic stem cell transplant (HSCT). GTB-3550 TriKE™ therapy represents a novel, low intensity therapeutic option which has the potential to increase HSCT eligibility for

elderly HR-MDS and relapsed/refractory AML patients.

Achievement of Stable Disease and Reduction in Cancer Burden in AML Patients

Two patients with relapsed/refractory acute myeloid leukemia who has previously failed prior therapies prior to being treated with GTB-3550; one patient treated at 5mcg/kg/day achieved stable disease and another patient treated at 25mcg/kg/day experienced a 33% reduction in bone marrow blast levels.

No Toxicities / Potent Native NK Cell Activation and Proliferation without Supplemental NK Cell Therapy

No signs of clinical immune activation, and no dose limiting toxicity such as cytokine release syndrome (CRS) or serious adverse events (SAEs) or fevers, tachycardia or constitutional symptoms have been observed in any patient treated to date with GTB-3550 TriKE™. Correlative studies also showed no shedding of CD16 from patient's NK cells, and potent NK cell activation, proliferation and target cell killing without the need for supplemental autologous NK cell therapy.

Targeted delivery of IL-15 to NK cells via GTB-3550 TriKE™ therapy showed preferential proliferation of NK cells, significantly less effect on CD8+ T-cells, and no observed toxicity at 25x the previous reported MTD for continuous infusion of recombinant human IL-15. GTB-3550 TriKE™ 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,

Mr. Anthony Cataldo, Chairman and Chief Executive Officer of GT Biopharma commented "We are pleased to once again be allowed to proceed with patient enrollment now that the Covid-19 enrollment pause has been removed at the University of Minnesota's Masonic Cancer Center."

About GTB-3550 TriKE™

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment or relapsed/refractory acute myeloid leukemia (AML), high-risk myelodysplastic syndrome (HR-MDS). 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 cancer 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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