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GT Biopharma Announces Interim GTB-3550 Trike™ Monotherapy Clinical Trial Results At 2021 Raymond James Human Health Innovation Conference

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BEVERLY HILLS, Calif., June 23, 2021 /PRNewswire/ -- GT Biopharma, Inc. (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary NK cell engager (TriKE™) protein biologic technology platform, announced Jeffrey S. Miller, M.D., Deputy Director of the Masonic Cancer Center and Consulting Chief Scientific Officer, provided an update concerning GTB-3550 TriKE™ monotherapy clinical trial interim results at the 2021 Raymond James Health Innovation Conference. The presentation will be available on the "News & Media" page of the GT Biopharma website at www.gtbiopharma.com/news-media/presentation.

Highlights to date from patients treated with GTB-3550 TriKE™ monotherapy in the dose escalation Phase 1 clinical trial for the treatment of high-risk MDS and refractory/relapsed AML:

- *57% of patients experienced significant reduction in AML/MDS cancer cell burden*

when treated with doses of GTB-3550 ranging from 25mcg/kg/day to 150mcg/kg/day.
- *Up to 63.7% reduction in bone marrow blast levels observed in some patients.*
- *GTB-3550 was well tolerated by all patients with no cytokine release syndrome observed.*
- *Restoration of patient's endogenous NK cell function, proliferation and immune surveillance observed in all patients – No progenitor-derived or autologous/allogenic cell therapy required.*

The on-going Phase 1 clinical trial of GTB-3550 TriKE™ monotherapy is focused on evaluating safety, and the determination of the recommended Phase 2 dose (RP2D), dose schedule and the maximum tolerated dose (MTD). Additional information is being collected concerning anti-tumor activity against CD33+ acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) cancer cells, and restoration of the patient's exhausted/inhibited endogenous NK cell population. To date, 11 patients have completed treatment in the GTB-3550 Phase 1 clinical trial. Patient 5, Patient 7, Patient 9, Patient 11 experienced 33%, 61%, 63% and 50% reduction in CD33+ AML/MDS bone marrow blast levels, respectively. The Phase 1 safety part of the study is expected to conclude in late August 2021 with data publication currently scheduled for end of September 2021.

"We continue to be pleased with the safety profile of GTB-3550, and its ability to restore function of the patient's NK cells without the need for the administration of *ex vivo* engineered NK cells", said Anthony Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "We have now completed treatment of eleven patients. In addition to strong safety results, we have seen significant reductions in CD33+ cancer cells in four of the last seven patients (57%) treated with doses of GTB-3550 ranging from 25mcg/kg/day to 150mcg/kg/day. This early sign of CD33+ target-specific cancer cell killing is very encouraging as we begin to focus on transitioning to the expanded efficacy part of the current GTB-3550 clinical trial", Mr. Cataldo further stated.

About High-Risk Myelodysplastic Syndromes
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
Acute myeloid leukemia 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 of AML and MDS, and other CD33+ hematologic cancers. 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 Interleukin 15 (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. For more information, please visit 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 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, 2020 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.

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