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GT Biopharma Announces Update On The Commencement Of The GTB-3550 TriKE™ Monotherapy Phase 2 Clinical Trial And Solid Tumor TriKE™ Product Candidates

BEVERLY HILLS, Calif., May 12, 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, is pleased to provide an update concerning the commencement of the GTB-3550 TriKE™ monotherapy Phase 2 clinical trial, and certain of its solid tumor targeting TriKE™ product candidates.



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

- *Up to 63.7% Reduction in Bone Marrow Blast Levels seen in some patients.*
- *Restoration of Patient's Endogenous NK Cell Function, Proliferation and Immune Surveillance.*
- *No Progenitor-derived or Autologous/Allogenic Cell Therapy Required.*
- *No Cytokine Release Syndrome Observed.*

While the design of the Phase 1 part of the GTB-3550 clinical trial was focused on evaluating safety, indications of anti-tumor activity during Phase 1 have resulted in a refocusing of the Phase 2 design of the clinical trial towards enhancing efficacy, durability of the clinical response, and overall survival with the goal to seek accelerated approval from FDA. We intend to (i) enroll patients with CD33 expression $\geq 50\%$ in two independent cohorts (higher-risk myelodysplastic syndrome and acute myeloid leukemia); (ii) treat patients with two cycles of GTB-3550 therapy with a rest period between cycles as opposed to the single-cycle used during Phase 1; (iii) enroll patients with fewer prior treatment lines; and, (iv) evaluate the potential use of minimal residual disease (MRD) based endpoints that may allow for accelerated approval.

Solid tumor cancers present a significantly larger market opportunity than hematologic cancer indications, and represent the majority of new cancer diagnoses annually. The Company is presently advancing three TriKE™ product candidates in GMP manufacturing and early clinical development. These solid tumor TriKE product candidates will target cancers expressing HER2 (GTB-6550), PD-L1 (GTB-4550) and B7H3 (GTB-5550), and will be evaluated for the treatment of multiple cancers such as breast, lung, gastric, colorectal and ovarian. We believe GTB-3550 established the importance of incorporating IL-15 directly within the TriKE protein biologic, providing NK cells with targeted cytokine stimulation simultaneously with target-directed cancer cell killing. We believe the selective expansion and proliferation of the patient's endogenous NK cells coupled with enhanced target-directed infiltration of activated NK cells into the bone marrow resulting in significantly AML cancer blast killing will translate to the solid tumor microenvironment.

"We believe GTB-3550 TriKE™ sets a new standard for NK cell engager therapies due to the incorporation of interleukin 15 (IL-15) directly in the protein backbone," said Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "The flexibility and versatility of our TriKE™ platform allows us to change the cancer cell targeting mechanism of TriKE™ to attack different cancers while maintaining the core NK cell activation, proliferation and persistence attributes of the molecule," 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](https://clinicaltrials.gov/ct2/show/study/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 on 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, (vi) 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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