March 17, 2021

GT Biopharma Announces Updated Interim GTB-3550 Trike™ Clinical Trial Results

Up to 63.7% Reduction in Bone Marrow Blast Levels

Restores Patient's Endogenous NK Cell Function, Proliferation and Immune Surveillance

No Progenitor-derived or Autologous/Allogenic Cell Therapy Required

No Cytokine Release Syndrome Observed

3 out of the Last 5 Patients Treated (25mcg/kg/day to 100mcg/kg/day) Respond

BEVERLY HILLS, Calif., March 17, 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 announce updated interim Phase I/II clinical trial results for the Company's lead therapeutic candidate, GTB-3550, being evaluated for the treatment of high-risk myelodysplastic syndromes (MDS) and refractory/relapsed acute myeloid leukemia (AML).

Reduction in Bone Marrow Blast Levels Achieved

To date, 9 patients have been enrolled in the Phase I/II Expansion clinical trial. Patients enrolled early in the Study (patients 1-4) were treated with doses of GTB-3550 below the anticipated therapeutic dose (RP2D) and maximum tolerated dose (MTD) to address possible safety concerns. All patients treated at the lower doses exhibited no signs of toxicity, and did not experience any Grade of Cytokine Release Syndrome (CRS).

Patients 5-9 were treated with increasing doses of GTB-3550 (25mcg/kg/day, 50mcg/kg/day and 100mcg/kg/day, respectively). Three of the five patients (60%) experienced reduction in bone marrow blasts with two patients (one patient treated at the 50mcg/kg/day dose level and one patient treated at the 100mcg/kg/day dose level) experiencing significant reductions in bone marrow blast levels. As previously reported, Patient 7 treated at the 50mcg/kg/day dose level achieved a 61.7% reduction in bone marrow blast levels from 12% before therapy to 4.6% after GTB-3550 therapy. Patient 9 treated at the 100mcg/kg/day dose level achieved a 63.7% reduction in bone marrow blast levels from 22% before therapy to 8% after therapy. All patients treated at these higher doses of GTB-3550 did not experience any

Grade of Cytokine Release Syndrome (CRS).

No Cytokine Release Syndrome (CRS) Observed

All patients treated to date with GTB-3550 TriKE displayed no signs of any Grade of cytokine release syndrome (CRS). Of particular note, GTB-3550 is currently being administered to patients at doses significantly higher than the reported MTD (Maximum Tolerated Dose) for continuous infusion of recombinant human IL-15 (Interleukin-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 endogenous ("native") NK cell activity in all patients. NK cell activation increases early during treatment. 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+ and CD4+ T-cells. We also observed no CD16 shedding by patients' NK cells, and saw enhanced HL-60 AML target cell killing. This data indicates GTB-3550 TriKE™ rescues the patient's exhausted/inhibited endogenous NK cells resulting in their activation, proliferation and persistence.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented: "We are pleased with the continued clinical performance of our lead GTB-3550 TriKE™ product candidate as we continue dose escalation." Mr. Cataldo further stated "this early data indicates GTB-3550 therapy demonstrates significant bone marrow blast level reductions in AML and MDS patients without the need for expensive progenitor-derived or autologous/allogenic cell therapies. We believe as we continue to dose escalate GTB-3550 TriKE™, more patients will experience greater clinical efficacy. TriKE's ability to work in the patient without outside supplemental engineered NK cells or the need for any combination drugs, sets TriKE apart from other cancer therapies. This is also the reason why TriKE™ therapy will be significantly less expensive than other treatments, opening the door to an off-the-shelf therapeutic."

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. For more information. Please visit www.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.

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

Contact:

Institutional Investors:
Julie Seidel
Stern Investor Relations, Inc.
Julie.seidel@sternir.com
212-362-1200

Investor Relations:
David Castaneda
David@gtbiopharma.com
414-351-9758

Media Relations
Susan Roush
Susan@gtbiopharma.com
805-624-7624

View original content:http://www.prnewswire.com/news-releases/gt-biopharma-announces-updated-interim-gtb-3550-trike-clinical-trial-results-301248091.html

SOURCE GT Biopharma, Inc.