July 7, 2021

GT Biopharma Announces Sponsored Research Agreement With Dr. Jeffrey S. Miller Of The University Of Minnesota

Deepening relationship between GT Biopharma and Dr. Jeffrey Miller

TriKE™ improves FT538 iPSC NK cells from Fate Therapeutics in prostate cancer model

GTB-3550 continues to demonstrate clinical success without significant toxicities

BEVERLY HILLS, Calif., July 7, 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 it has entered into a sponsored research agreement (SRA) with Jeffrey S. Miller, M.D., Deputy Director of the University of Minnesota's Masonic Cancer Center and Consulting Chief Scientific Officer of GT Biopharma.

The SRA is focused on supporting GT Biopharma's continued clinical develop of TriKE™ therapeutic product candidates, and to gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE™ therapy. The SRA is a fixed sum contract worth Two Million Seventy-Four Thousand Six Hundred Eighty-Six dollars ($2,074,686) payable over the next two years in equal quarterly payments. GT Biopharma has early termination rights without financial penalty, and will receive an exclusive worldwide license to any patentable inventions which arise under the SRA.

TriKE™ is a robust and versatile protein biologic therapeutic platform which facilitates NK

recognition and killing of cancer cells. TriKE™ is a tri-specific recombinant protein biologic composed of an NK cell engaging domain targeting CD16 on the NK cell, an NK cell activating domain consisting Interleukin IL-15, and a cancer cell targeting domain. The natural killer (NK) cell-stimulating cytokine human IL-15 portion of the molecule provides a self-sustaining signal that activates the patient's endogenous, exhausted/inhibited NK cells enhancing their ability to kill and proliferate without the need for the supplemental addition of *ex vivo* engineered NK cells. TriKE™ does not require costly or specialized manufacturing facilities nor is pretreatment of the patient required prior to its administration. TriKE™ is also significantly less expensive than iPSC NK cell therapies and autologous/allogenic NK cell therapies.

Recently published data at the November 2020 meeting of the Society for Immunotherapy of Cancer (SITC) by researchers at Fate Therapeutics and the University of Minnesota (see https://jitc.bmj.com/content/8/Suppl_3/A287) demonstrates TriKE™ is able to activate and target direct Fate Therapeutics' *ex vivo* engineered iPSC NK cells (FT538), and turn those cells into more effective killers resulting in the complete eradication of the prostate cancer cells. Without the assistance of TriKE™, the FT538 iPSC NK cells were unable to eradicate the prostate cancer cells.

TriKE™ monotherapy has demonstrated in its first-in-class clinical trial the ability to revive the patient's exhausted/inhibited NK cells, significantly reduce cancer cell numbers, and to do so without any toxicities including no cytokine release syndrome (CRS). 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.*

"We have now completed treatment of eleven patients. In addition to strong safety results, we have seen significant reductions in CD33+ cancer cells," stated Anthony Cataldo, Chairman and Chief Executive Officer of GT Biopharma. "We are pleased to sponsor additional TriKE™ research in Dr. Miller's laboratory in support of our TriKE™ clinical development programs," Mr. Cataldo further stated.

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.

TriKE™ is a trademark of GT Biopharma, Inc.

Contacts:

Institutional Investors:	*Investor Relations:*
Brendan Payne	David Castaneda
Stern Investor Relations, Inc.	David@gtbiopharma.com
brendan.payne@sternir.com	(414) 351-9758
(212) 362-1200	

View original content to download multimedia:https://www.prnewswire.com/news-releases/gt-biopharma-announces-sponsored-research-agreement-with-dr-jeffrey-s-miller-of-the-university-of-minnesota-301326645.html

SOURCE GT Biopharma, Inc.