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GT Biopharma Provides Update Concerning Trike(TM) Drug Development Programs and Other Strategic Initiatives

BEVERLY HILLS, CA / ACCESSWIRE / January 21, 2020 /GT Biopharma, Inc. (OTCQB:GTBP) (GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary TriKE™ NK cell engager platform provided the following update concerning its drug development programs and certain other initiatives:

- The Company recently commenced enrollment in its first-in-human GTB-3550 TriKE™ Phase I/II clinical trial for the treatment of certain types of leukemia. The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick. The open-label, dose-escalation Phase I portion of the trial will evaluate GTB-3550 TriKE™ in patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis, and will determine safety and tolerability as well as the pharmacologically active dose and maximum tolerated dose of GTB-3550 TriKE™. The Phase II portion of the trial is planned to further evaluate the recommended dose of GTB-3550 TriKE™ in this patient population.
- Dr. Jeffrey Miller and colleagues from the University of Minnesota presented research results concerning the development of an HIV TriKE™ which directs NK cell killing of HIV-infected CD4 T-cells. Dr. Miller and colleagues presented their HIV TriKE™ research at the 18th meeting of the Society for Natural Immunity held in Luxembourg September 30th to October 3rd, 2019. The data demonstrated that natural killer (NK) cells are stimulated by the human IL-15 cytokine portion of the TriKE™ molecule which provided a self-sustaining signal, activating NK cells and enhancing their ability to kill. The data also demonstrated that the HIV TriKE™ was able to reactive HIV replication in latent HIV-infected CD4+ T-cells. These findings indicate a potential role for the HIV-TriKE™ in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell's ability to mediate antibody-directed cellular cytotoxicity (ADCC).
- Drs. Jeffrey Miller, Martin Felices and Pippa Kennedy from the University of Minnesota presented TriKE™ research results at the recently concluded 18th meeting of the Society for Natural Immunity concerning the development of a solid tumor targeting TriKE™ which demonstrates killing of non-small cell lung cancer (NSCLC) cells. NSCLC represents approximately 85% of all lung cancers. The NSCLC TriKE™ was shown to enhance functional responses of NK cells directed towards NSCLC cell killing, and induce proliferation of NK cells from both lung cancer patients and healthy donors.

- Dr. Jeffrey Miller from the University of Minnesota presented TriKE™ research results at the 34th annual meeting of the Society for Immunotherapy of Cancer (SITC) which was held November 6-10, 2019 at the Gaylord National Hotel & Convention Center in National Harbor, MD. Dr. Miller discussed TriKE™ therapy in the context of multi-targeted therapeutic platforms for the treatment of cancer.
- The Company sold its myasthenia gravis generic drug asset to DAS Therapeutics in September 2019. The decision to sell its development-stage generic drug portfolio is the result of a strategic review conducted by management and the board of directors announced in April 2019. The Company expects to sell its remaining development-stage generic drug assets in 2020.
- The Company appointed Dr. Jeffrey Miller as Consulting Chief Medical Officer and Mr. Martin Schroeder as Consulting Chief Technology Officer.

Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented, "we are pleased with the progress of our TriKE™ development programs, and appreciate the support of Dr. Miller, his colleagues, and the University of Minnesota". Mr. Cataldo also stated, "we expect to make further progress during 2020 as we continue expanding our TriKE™ platform to address other therapeutic indications".

About GTB-3550 TriKE™

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment of certain leukemias. GTB-3550 TriKE™ is a single-chain, tri-specific 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 the HIV TriKE™

According to the World Health Organization, there are over 36 million people currently infected with HIV. Current drugs only treat the symptoms of HIV at a significant economic cost. HIV infected individuals remain infected for the rest of their lives. The challenge in the HIV field is to kill virus infecting a patient's T-cells, and destroy virus hiding in sanctuary reservoir sites within the body. The use of anti-retroviral drugs has improved the health and increased the longevity of individuals infected with the human immunodeficiency virus (HIV). These drugs are designed to suppress virus replication to help modulate progression to AIDS and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and re-establish an active HIV infection. For a curative therapy, destruction of these latent HIV infected cells must take place. In preclinical testing led by Dr. Jeffrey Miller, M.D., Deputy Director Masonic Cancer Center and Dr. Timothy Schacker, M.D., Medical School and Director, Program in HIV Medicine, the research team designed a series of bispecific and trispecific constructs to direct natural killer (NK) cell mediated cytotoxicity against an HIV infected target. GT Biopharma is developing an HIV TriKE™ version to increase the level of NK cell killing of targeted HIV infected cells.

About NSCLC TriKE™

The Company's first solid tumor TriKE™ product candidate is a single-chain, tri-specific recombinant fusion protein construct which targets non-small cell lung cancer. According to the American Cancer Society, non-small cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses. In 2019, it is estimated there will be 228,150 cases of newly diagnosed lung cancer. Lung cancer is the second most common cancer, and this year it is estimated that 142,670 people will die from lung cancer. The 5-year survival rate for all people with all types of lung cancer is 19%.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE) 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 cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer.

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 guarantees 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, 2018 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent 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 for GTB-3550 or GTB-1550, 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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