October 3, 2019

GT Biopharma Announces HIV TriKE™ Data Demonstrating NK Cell Killing of Patient HIV Infected Cells

TAMPA, Florida, Oct. 3, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA), an immuno-oncology company focused on innovative treatments based on the Company's patent pending TriKE™ technology, announced today that Tim Schacker, M.D., Jeffrey S. Miller, M.D., and their colleagues at the University of Minnesota presented data during a poster session held at the 18th meeting of the Society for Natural Immunity in Luxembourg discussing their design of an HIV-TriKE™ containing an antigen binding fragment (Fab) from a broadly-neutralizing antibody targeting the HIV-Env protein. The HIV-TriKE™ is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells.

While the use of anti-retroviral drugs have substantially 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.

Research findings from Dr. Schacker's and Dr. Miller's laboratories show enhanced NK cell cytokine production and killing of infected targets expressing HIV-Env when incubated with the HIV-TriKE™. Peripheral blood mononuclear cells (T-cells, B-cells, NK cells and monocytes) from healthy donors incubated with the HIV-TriKE™ showed marked increases in immune cell activation in NK cell, CD4 T-cell and CD8 T-cell population subsets. The HIV-TriKE™ also induced NK cell proliferation, and demonstrated the ability *in vitro* to reactivate and kill HIV-infected 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 the antibody-directed cellular cytotoxicity (ADCC).

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma, commented, "We are pleased to see how the TriKE™ technology is able to be extended to the treatment of infectious disease, and is able to kill HIV in the reservoir." Mr. Cataldo further stated, "We believe the HIV-TriKE™ will become part of a scalable and curative therapeutic strategy."

About HIV

HIV (human immunodeficiency virus) harms the immune system by destroying white blood cells which fight infection. Infected individual are at risk for serious infections and certain cancers. The virus can be transmitted through contact with infected blood, semen, or vaginal fluids. The disease is usually asymptomatic until it progresses to AIDS (acquired immunodeficiency syndrome). No cure exists, but strict adherence to expensive antiretroviral therapy can dramatically slow the disease's progress and prolong life. 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.

About GTB-3550 TriKE™ and GTB-3550 TriKE™ Phase I/II Clinical Trial

GTB-3550 is the Company's first TriKE™ product candidate which is a single-chain, tri-specific recombinant fusion protein construct 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 GTB-3550 Phase I/II clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis opened for patient enrollment September 2019. 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.

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™) and Multi-Target Directed Bispecific Drug Conjugate technology platforms. 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. Our Multi-Target Directed Bispecific Drug Conjugate platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of targeted therapy.

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, 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.

Disclosures

TriKE™ is a trademark of GT Biopharma, Inc.

Dr. Miller also serves as Consulting Chief Medical Officer of GT Biopharma, Inc.

For more information, please visit www.gtbiopharma.com
800-304-9888

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