

September 26, 2019



GT

Biopharma, Inc.

GT Biopharma Announces HIV TriKE™ Data to be Published

At The 18Th Meeting Of The Society For Natural Immunity

LOS ANGELES, Sept. 26, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE™) platform, announced today that Dr. Jeffrey Miller and colleagues from the University of Minnesota will present research results concerning an HIV TriKE™ which directs NK cell killing at HIV-infected CD4 T-cells. Dr. Miller and colleagues will present their HIV TriKE™ research at the 18th meeting of the Society for Natural Immunity in Luxembourg, September 30 to October 3, 2019.

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.

"Natural killer (NK) cells are stimulated by the cytokine human IL-15 portion of the TriKE™ molecule which provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We have constructed an HIV TriKE™ that directs NK cells to HIV infected CD4 T-cells, and have demonstrated the ability of the HIV TriKE™ to kill HIV infected targets in preclinical models suggesting that further testing to eliminate the HIV reservoir is warranted," stated Dr. Miller.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented, "we are excited about the progress Dr. Miller and his colleagues are making developing the HIV TriKE™." Mr. Cataldo further stated, "we believe the HIV TriKE™ has the potential to offer many people living with HIV a treatment option that achieves sustained viral remission by eradicating the virus in all locations within the body, and hopefully will become part of a scalable and curative therapeutic strategy for HIV patients."

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 antiretroviral therapy can dramatically slow the disease's progress and prolong life.

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 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, (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.

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

View original content: <http://www.prnewswire.com/news-releases/gt-biopharma-announces-hiv-trike-data-to-be-published-300925787.html>

SOURCE GT Biopharma, Inc.