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Biopharma, Inc.

GT Biopharma (GTBP) Announces the Elimination of HIV Infected Cells Using its Tri-Specific Killer Engagers (TriKEs) in Preclinical Testing at the University of Minnesota

TAMPA, Florida, April 24, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immunology biotechnology company focused on innovative treatments based on the Company's proprietary NK-engager (TriKE) platform and Multi-Target Bispecific Drug Conjugate (MTBDC) platform, announced today its Tri-Specific Killer Engager can target HIV infected cells in University of Minnesota's preclinical testing.

In preclinical testing led by Drs. Jeffrey Miller, MD, Deputy Director Masonic Cancer Center and Timothy Schacker, MD, Medical School and Director, Program In HIV Medicine, the research team designed a series of Bi- and Tri-Specific killer-engager (BiKE and TriKE) constructs to direct Natural Killer cell antibody dependent cell-mediated cytotoxicity against an HIV infected target.

The data demonstrate that a (BiKE) construct containing the Fab of an HIV bnAb and an anti-CD16 component can eliminate HIV-infected targets that express the HIV envelope on their their surface. Based on the success of the BiKE data, GT Biopharma has now expanded the BiKE's capabilities to be included in the TriKE platform, which the company believes will have further abilities to extend the cytolytic activity currently being demonstrated in its BiKE.

CEO, GT Biopharma, Inc., Anthony Cataldo stated, "According to the World Health Organization, there are over 36 million people currently infected with HIV. The current drugs available to HIV patients only treat the symptoms of HIV at a massive economic cost. They remain infected for the rest of their lives on these drugs and at risk for serious infections and certain cancers, while still being infectious to others. The TriKE/BiKE represents the possibility of a cure."

"Individuals well controlled on anti-retroviral therapy are not cured and dependent on continuous use of their medications. The challenge in the HIV field is to target the reservoir where HIV hides in tissue CD4 T cells and to destroy those sanctuary sites," stated Dr. Schacker.

"We have constructed a TriKE with an IL-15 linker that we believe will target NK cells to HIV infected CD4 T cells with the potential to eliminate the HIV reservoir," stated Dr. Jeffrey Miller.

About HIV - HIV stands for human immunodeficiency virus. It harms your immune system by destroying the white blood cells that fight infection. This puts you 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 for AIDS, but strict adherence to antiretroviral therapy can dramatically slow the disease's progress and prolong life.

About GTB-1550 Multi-Target Directed Bispecific Therapy

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors thereby maximizing cancer cell recognition by binding to CD19+, CD22+ and CD19+/CD22+ cancer cells. When GTB-1550 binds to cancer cells, the cancer cells internalize GTB-1550, and are killed due to the action of drug's cytotoxic diphtheria toxin payload. GTB-1550 has demonstrated success in a Phase 1/2 human clinical trial in patients with relapsed/refractory B-cell lymphoma or leukemia.

At the time of the interim review, 13 patients met the evaluation criteria, including nine NHL and four ALL patients.

More than 50% of patients (seven of 13) exhibited a clinical benefit, defined as stable disease, partial remission or complete remission at Day 29. Of the seven patients, one demonstrated a complete remission (CR), one demonstrated a partial remission (PR) and five demonstrated stable disease (SD). The GTB-1550 Phase 1/2 clinical trial is being led by Dr. Veronika Bachanova, Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota.

About GTB-3550

GTB-3550 (OXS-3550) is the Company's first Tri-specific Killer Engager (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. When the NK stimulating cytokine human IL-15 is used as a crosslinker between the two scFvs, it provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We intend to study this anti-CD16-IL-15-anti-CD33 tri-specific killer engager, or TriKE, in CD33 positive leukemias, a marker expressed on tumor cells in AML, myelodysplastic syndrome, or MDS, and other hematopoietic malignancies. CD33 is primarily a myeloid differentiation antigen with endocytic properties broadly expressed on AML blasts and, possibly, some leukemic stem cells. CD33 or Siglec-3 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC3, gp67, p67) is a transmembrane receptor expressed on cells of myeloid lineage. It is usually considered myeloid-specific, but it can also be found on some lymphoid cells. The anti-CD33 antibody fragment that will be used for these studies was derived from the M195 humanized anti-CD33 scFV and has been used in multiple human clinical studies. It has been exploited as target for therapeutic antibodies for many years. Improved survival seen in many patients when the antibody-drug conjugate gemtuzumab was added to conventional chemotherapy validates this approach. GT Biopharma believes that GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger patient population.

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), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target certain tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics. Our Multi-Target Bispecific Drug Conjugate (MTBDC) platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of antibody directed drug conjugate therapies.

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 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, 2017 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 Phase 1 study of TriKe, GTB-3550 and or our Phase 2 trial of CTB-1550 and 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.

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

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