

June 10, 2019



## GT Biopharma Company Update

TAMPA, Florida, June 10, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (OTCQB: GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE) platform and Multi-Target Directed Bispecific Drug Conjugate (MTBDC) platform, today provided an update of the company's drug development programs.

GT Biopharma continues to move forward with its development of the HIV TriKE. On April 24<sup>th</sup> GT Biopharma announced the elimination of HIV infected cells using its Tri:Specific Killer Engagers (TriKEs) in Preclinical Testing at the University of Minnesota. Which could represent a possible cure to HIV which now has over 35 million infected people worldwide.

### About the HIV TriKE

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 Natural Killer Cell Engagers (BiKE and TriKE) constructs to direct Natural Killer cell mediated cytotoxicity against an HIV infected target. The data demonstrate that a BiKE construct can eliminate HIV infected targets expressing the HIV envelope on their surface. Based on the success of the BiKE data, GT Biopharma is planning to develop a TriKE version by incorporating IL-15 into the BiKE scFv construct to increase the level of NK cell killing of targeted HIV infected cells.

Additional TriKEs (Trispecific NK cell engagers) which target hematological malignancies (liquid tumors), and solid tumor cancers, are also progressing under the TriKE platform. The TriKE platform's ability to expand into solid tumors (80% of the cancer market) allows for a much more economical and wider approach than CAR-T. Most recently KITE Pharma was bought by Gilead Sciences, Inc. for \$12 Billion (NASDAQ: GILD) and Juno Therapeutics was acquired (\$9 Billion) by Celgene Corporation (NASDAQ: CELG). These highly expensive cell therapies are limited to only liquid tumors (20% of the cancer market). The TriKE off the shelf technology is a protein (drug) version of CAR-T using the TriKE's ability to employ NK (Natural Killer) cells from the immune system as the catalyst to target, attack and kill specific cancers.

GTB-3550 (OXS-3550) is the Company's first Tri-specific NK cell Engager (TriKE) product candidate being initially developed for the treatment AML. GTB-3550 (OXS-3550) is being readied to begin enrolling patients with advanced Acute Myeloid Leukemia (AML) in a Phase I/II expansion clinical trial starting mid- July 2019.

### About GTB-3550 Trispecific NK cell Engager (TriKE)

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. 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.

GTB-1550 (DT2219) top-line Phase I/II expansion clinical trial results have been promising; two patients exhibited a complete remission (CR) with one patient currently disease-free at 50 months post completion of the study. A Phase 2 study is being planned.

### **About GTB-1550 Multi-Target Directed Bispecific Drug Conjugate**

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.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma, commented, "We are pleased with the progress of our clinical development programs." The HIV TriKE's possibility to kill the HIV virus would solve a massive economic burden as well as stop infected patients from spreading the disease. Mr. Cataldo also noted that the Company has two key platform technologies to attack cancer: the TriKE platform, and the Multi-Targeted Directed Bispecific Cytotoxic Payload platform. Mr. Cataldo stated, "We believe that these Platform technologies present first-in-class therapeutic opportunities for the Company, and will be the main focus going forward."

### **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 (MTBDC) 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 (MTBDC) 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.

For more information, please visit [www.gtbiopharma.com](http://www.gtbiopharma.com).

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