

June 10, 2022



GT Biopharma Presents Preclinical Data Demonstrating Second-Generation CD19 Targeting Tri-Specific Killer Engager (TriKE®) Driving Robust NK Cell Function Against B Cell Malignancies at EHA 2022 Congress

- *Ongoing experiments will evaluate the functionality and efficacy of GTB-7550 in vivo*
- *Future studies will also involve assessments of GTB-7550 TriKE efficacy in other hematologic cancers*

BRISBANE, Calif., June 10, 2022 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. ("the Company") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary tri-specific natural killer (NK) cell engager, TriKE® protein biologic technology platform, announced today, preclinical data in chronic lymphocytic leukemia ("CLL") to be presented at the European Hematology Association (EHA) 2022 Congress. The poster presentation titled, "Second-Generation CD19 Targeting Tri-Specific Killer Engager Drives Robust NK Cell Function Against B Cell Malignancies," presented by Dr. Jeff Miller's laboratory, University of Minnesota.

GTB-7550 ("CAM-161519") is the Company's CD19-targeted tri-specific killer engager (TriKE) targeted against B-cell lymphomas and is part of GT Biopharma's portfolio of TriKE product candidates being investigated in several preclinical models against a broad class of solid tumors and hematological cancers.

Dr. Gregory Berk, President of R&D and Chief Medical Officer noted, "We are excited to broaden preclinical development of GT Biopharma's proprietary platform of NK cell immunotherapies to include B cell malignancies. These exciting new data suggests GTB-7550 can be a viable potential CLL treatment option in light of current challenges and shortfalls of current standard of care. We look forward to investigating GTB-7750 as a novel approach with other hematological cancers as well."

Poster Title – "Second-Generation CD19 Targeting Tri-Specific Killer Engager Drives Robust NK Cell Function Against B Cell Malignancies"

Background – According to the American Cancer Society, CLL accounts for about one-quarter of the new cases of leukemia. In 2022, an estimated 20,160 people will develop CLL,

and about 4,410 will die from CLL. Existing targeted therapies for B cell malignancies work well in a subsegment of the (CLL) patient population, but face limitations such as development of drug resistance and lower treatment efficacy ratio in high-risk patients. Other therapeutic options such as CAR-T cell immunotherapy have failed to produce effective treatment outcomes against CLL, mostly due to the defects in the effector T cells leading to product failures, as well as being associated with high levels of off-target cytotoxicity. Therefore, there is a critical need for novel and targeted therapeutic interventions for the treatment of CLL patients.

Study Design and Analysis – CLL involves uncontrollable clonal expression of CD5+/CD19+ B lymphocytes. While patients can sometimes coexist with CLL for years, eventually there is progression to bulky adenopathy and pancytopenia from bone marrow suppression requiring therapy. We developed and tested the ability of GTB-7550, a second-generation tri-specific killer engager (TriKE) to enhance NK killing specific to CD19+ cancer targets. This TriKE molecule includes a humanized camelid anti-CD16 VHH single domain antibody CAM16, a wild-type IL-15 component, and anti-CD19 tumor antigen scFv all linked via short peptide linkers. We assessed GTB-7550 killing of Raji tumor targets by C9-derived expanded NKs in IncuCyte real time imaging assay.

Results – GTB-7750 TriKE enhances NK cell proliferation as compared to IL-15 moiety and no treatment at the end of a seven-day long assay. GTB-7550 TriKE enhanced CLL patient NK activation and Raji target killing, and it amplified feeder-expanded NK cell function against B-ALL targets.

Conclusions – There is a critical need for a novel approach to CLL treatment that can effectively address the limitations in existing approaches that induce development of drug resistance and have lower treatment efficacy in high-risk patients. Other novel approaches such as CAR-T cell immunotherapy have failed to produce effective treatment outcomes against CLL, mostly due to defects in the effector T cells leading to product failures, as well as high levels of off-target cytotoxicity. Treatment with GTB-7750 TriKE enhances proliferation of NK cells and improves normal NK cell function against multiple B cell malignancies. Ongoing experiments will evaluate the functionality and efficacy of GTB-7750 in vivo. Future studies will involve assessments of the GTB-7750 TriKE in other hematological malignancies.

EHA 2022 Congress Poster Details:

Title: Second-Generation CD19 Targeting Tri-Specific Killer Engager Drives Robust NK Cell Function Against B Cell Malignancies (submission ID: EHA:3732)

Abstract Number: P618

Presentation Type: Poster presentation

Session Date and Time: Friday, June 10, 2022 - 4:30 PM - 5:45 PM CEST

About Chronic Lymphocytic Leukemia

[Chronic lymphocytic leukemia \(CLL\)](#) is the most common leukemia in adults. It is a type of cancer that starts in cells that become certain white blood cells (called lymphocytes) in the bone marrow. The cancer (leukemia) cells start in the bone marrow but then go into the blood. In CLL, the leukemia cells often build up slowly. Many people do not have any symptoms for at least a few years. But over time, the cells grow and spread to other parts of

the body, including the lymph nodes, liver, and spleen.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE[®] NK cell engager platform. Our TriKE[®] platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE[®] technology. For more information, please visit gtbiopharma.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects," "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

TriKE[®] is a registered trademark owned by GT Biopharma, Inc.

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