May 18, 2021

GT Biopharma to Host Interim GTB-3550 TriKE™ Data Review Call with Dr. Jeffrey S. Miller on May 19, 2021 at 4:00 PM ET

BEVERLY Hills, Calif., May 18, 2021 /PRNewswire/ -- GT Biopharma, Inc. (NASDAQ: GTBP) a clinical stage biopharmaceutical company focused on the development and commercialization of disruptive, target-directed Natural Killer (NK) cell engager immunotherapy protein biologic platform technology, TriKE™, for the treatment of cancer and infectious diseases, today announced that it will be hosting a call with Dr. Jeffrey S. Miller and GT Biopharma on **Wednesday, May 19th at 4:00 PM Eastern Time**.

Interim GTB-3550 TriKE™ Data

Clinical Highlights

- **Updated Interim Results from First-in-Human GTB-3550 TriKE™ Phase I/II Clinical Trial for the Treatment of High-Risk Myelodysplastic Syndromes (MDS) and Refractory/Relapsed Acute Myeloid Leukemia (AML):** Results demonstrated up to 63.7% reduction in bone marrow blast levels, and restoration of endogenous NK cell function, proliferation and immune surveillance without combination *ex vivo* supplemental NK cell therapy. All patients treated displayed no signs of any grade of cytokine release syndrome (CRS) across all dose cohorts. GTB-3550 TriKE™ is

currently being administered to patients at doses significantly higher than the reported maximum tolerated dose (MTD) for continuous infusion of recombinant human interleukin-15 (IL-15).

- **Enrollment in Phase I Portion of GTB-3550 TriKE™ Phase I/II Clinical Trial in MDS and AML Continues:** GTB-3550 TriKE™ Phase I/II Clinical Trial in high-risk MDS and AML patients continues to enroll patients. Patient 11 began treatment dosed at 150mcg/kg/day.
- **New Findings Supporting GTB-3550 TriKE™ Monotherapy:** GTB-3550 TriKE™ monotherapy is able to rescue the patient's otherwise exhausted/inhibited/non-functional endogenous NK cell population, and target direct killing of the patient's AML and MDS cancer cells without the need for the co-administration addition of supplemental progenitor-derived or autologous/allogenic engineered NK cells.
- **Preliminary Phase II Clinical Trial Design:** The Phase II expansion part of the current GTB-3550 clinical trial intends to enroll patients with CD33 expression ≥50% in independent cohorts (higher-risk MDS and AML); treat patients with two cycles of GTB-3550 therapy with a rest period between cycles as opposed to the single-cycle used during Phase 1; enroll patients with fewer prior treatment lines; and, evaluate the potential use of minimal residual disease (MRD) based endpoints that may allow for accelerated approval.

A live webcast of the presentation may be accessed by visiting https://www.webcaster4.com/Webcast/Page/4/41418 as well as from the Investors section of the GT Biopharma website at https://ir.gtbiopharma.com/.

Those who wish to dial in for the audio portion only of the event an audio only may do so at:

PARTICIPANT DIAL-IN (TOLL FREE): -**1-877-870-4263**
PARTICIPANT INTERNATIONAL DIAL IN: **1-412-317-0790**
Canada Toll Free: **1-855-669-9657**
Please ask to be joined into the **GT Biopharma call.**

An archived replay of the webcast will be available on the Company's website by visiting:

https://services.choruscall.com/ccforms/replay.html
Replay Access Code: 10156826

About GTB-3550 TriKE™

GTB-3550 TriKE™ is a first-in-class immuno-oncology therapeutic being evaluated in patients age 18 and older in a Phase I/II clinical trial (NCT03214666) having CD33+ malignancies (primary induction failure or relapsed AML with failure of one reinduction attempt or high-risk MDS progressed on two lines of therapy). Interim results demonstrated GTB-3550 TriKE™ reduces bone marrow blast levels in AML and MDS patients, and improved NK cell function and proliferation.

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 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 natural killer cells (NK cells). GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE™ technology.

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 a guarantee 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, 2020 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent Form 10Q Quarterly 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.

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

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SOURCE GT Biopharma, Inc.