March 19, 2020

UPDATE: GT Biopharma Announces Preliminary Results for GTB-3550 TriKE(TM) Phase I/II Clinical Trial for Treatment of Acute Myeloid Leukemia

Patient Achieves Stable Disease

BEVERLY HILLS, CA / ACCESSWIRE / March 19, 2020 /GT Biopharma, Inc. (OTCQB:GTBP) (GTBP.PA) a biotherapeutics company focused on developing innovative therapeutic treatments in oncology and infectious diseases based on its proprietary NK cell engager TriKE™ platform announced today that it had successfully completed dosing of the first patient in a Phase I/II clinical trial of GTB-3550 for the treatment of relapsed/refractory acute myeloid leukemia (AML).

All patients enrolled in the open label clinical trial receive a single course of GTB-3550 given as four, 24-hour consecutive continuous infusions, for three consecutive weeks. The first patient with advanced relapsed/refractory AML who enrolled in the clinical trial was treated at a dose of 5µg/kg/day with GTB-3550. There were no observed adverse or serious adverse events recorded during the course of therapy, and the patient achieved stable disease as measured by AML blast count. We observed an increase in the patient's total NK cell population that we believe is attributable to the IL-15 component of the TriKE™ molecule. and with no appreciable increase of any hyper-active T-cell populations, which otherwise results in cytokine storm or other T-cell associated toxicities.

GTB-3550 is a tri-specific 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 NK cell stimulating cytokine human IL-15 portion of the molecule provides a self-sustaining signal that activates NK cells and enhances their cytotoxic activity.

Acute myeloid leukemia is a heterogeneous hematologic stem cell malignancy in adults with incidence rate of 3% to 5% per 100,000 people. The median age at the time of diagnosis is 65 to 69 years. AML is an aggressive cancer that is fatal on the absence of treatment. The five-year expected overall survival rate for AML is 27.4 percent, according to the National Cancer Institute (NCI).

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented, "we are pleased to see these results in our first patient who is being administered GTB-3550." Mr. Cataldo further commented, "we remain optimistic that GTB-3550 will demonstrate therapeutic benefit in patients who have relapsed/refractory AML and other hematologic malignancies that are at an advanced stage." Mr. Cataldo added, "we believe the robustness of the TriKE™ platform will enable the development of therapeutics for the treatment of other cancers and certain infectious diseases, such as HIV and coronavirus infections."

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology and infectious disease therapeutic products based our proprietary Tri-specific Killer Engager (TriKE™) platform. Our TriKE platform is designed to harness and enhance the patient's immune system by stimulating and causing to persist 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 proprietary 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, 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 any of our drug product candidates, 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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