September 22, 2020

GT Biopharma Announces GTB-3550 TriKE(TM) Phase I/II Clinical Trial Update

BEVERLY HILLS, CA / ACCESSWIRE / September 22, 2020 /GT Biopharma, Inc. (OTCQB:GTBP)(GTBP.PA) an immuno-oncology company focused on innovative therapies based on the Company's proprietary NK cell engager (TriKE™) technology announced today it completed treatment of the first patient enrolled at Dose Level 3 in its GTB-3550 TriKE™ Phase I/II clinical trial.

The first patient treated with GTB-3550 at a 25mcg/kg/day dose showed a decrease in AML blast levels from 18% to 12% in the bone marrow. Additionally, we observed an increase in the patient's NK cell activity and numbers attributable to the IL-15 component of the TriKE™ molecule with no appreciable increase of a hyper-active T-cell population which could have resulted in cytokine release syndrome (CRS) or other T-cell associated toxicities. The patient experienced no adverse reactions including no constitutional symptoms such as fever, tachycardia, or chills. We also observed improvement in marrow cellularity, a decrease in AML blast levels, and improving platelet and red blood cells numbers. The patient will be retreated with an additional round of GTB-3550 therapy at the 25mcg/kg/day dose.

The open-label, dose-escalation Phase I portion of the trial will evaluate GTB-3550 in patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia (AML) or advanced systemic mastocytosis, and will determine safety and tolerability as well as the pharmacologically active dose and maximum tolerated dose of GTB-3550. The Phase II portion of the trial is planned to further evaluate the efficacy of GTB-3550 in this patient population.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "we are pleased to see a reduction in AML blast levels at a dose of 25mcg/kg/day of GTB-3550." Mr. Cataldo further stated "we hope to see the continued absence of toxicity, and see additional signals of efficacy as we continue to dose escalate GTB-3550."

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 cancer cell and virus infected cell killing using the patient's immune system 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 developed by researchers at the university to target NK cells.

About GTB-3550 TriKE™ FDA Clinical Trial

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment of acute myeloid leukemia (AML). 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 ability to kill. We are presently evaluating GTB-3550 in a Phase I/II clinical trial (ClinicalTrials.gov NCT03214666) for the treatment of CD33 positive leukemias such as AML, myelodysplastic syndrome and other CD33+ hematopoietic malignancies.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the Company's expectations regarding the development of GTB-3550 TriKE™ including its intended therapeutic effect, and plans to conduct future clinical trials in humans. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "outlook", "believes", "target", "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, 2019 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.

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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