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GT Biopharma Advances To Dose Level 3 with TriKE(TM) FDA Phase I/II Clinical Trial

BEVERLY HILLS, CA / ACCESSWIRE / August 4, 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 had completed treatment of patients enrolled at Dose Levels 1 and 2, and begun enrolling patients for treatment at Dose Level 3, in its GTB-3550 TriKE™ Phase I/II clinical trial.

Following initial treatment, the first patient treated with GTB-3550 achieved stable disease with respect to the number of acute myeloid leukemia (AML) blasts observed in their bone marrow before and after treatment. Additionally, we observed an increase in the patient's total NK cell population attributable to the IL-15 component of the TriKE™ molecule with no appreciable increase of any hyper-active T-cell population. All patients treated to date with GTB-3550 have experienced no adverse reactions including no constitutional symptoms such as fever, tachycardia, or chills. Patients now being enrolled will be treated at a dose of 25µg/kg/day.

The clinical trial is being conducted at the Masonic Cancer Center, University of Minnesota under the direction of Dr. Erica Warlick. Additional clinical trial sites are being engaged in States that have modified their COVID-19 restrictions to allow for the restarting of clinical trials.

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 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 have advanced treatment to the next higher dose of GTB-3550." Mr. Cataldo further stated "we hope to continue to see additional signals of efficacy at the new higher dose of GTB-3550."

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

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment of AML. 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 AML, myelodysplastic syndrome, and other CD33+ hematopoietic malignancies.

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 Tri-specific Killer Engager (TriKE™) 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 cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer.

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 our ongoing clinical trials and our future clinical focus and proposed clinical trials. 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 GTB-3550, or to meet the FDA's requirements with respect to safety and efficacy (including delays in our clinical trials caused by restrictions on hospital operation implemented in reaction to the COVID-19 pandemic), (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.
Media Contact - 800-304-9888

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