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GT Biopharma Announces Dosing First Patient In GTB-3550 TriKE(TM) Phase I/II Clinical Trial

TAMPA, FL / ACCESSWIRE / February 26, 2020 /GT Biopharma, Inc. (OTCQB:GTBP) (GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE™) platform announced today that the first patient has been dosed in a Phase I/II clinical trial of its anti-CD16/IL-15/anti-CD33 TriKE™, GTB-3550. The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick.

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 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 recommended dose of GTB-3550 in this patient population.

Multiple strategies to redirect immunity have been developed in the past two decades, but they have technical hurdles, cause undesirable side-effects, or are very expensive as exemplified by the T cell therapy-based chimeric antigen receptor (CAR-T) therapies from Bristol-Myers Squibb [NYSE: BMY] and Gilead Sciences [Nasdaq: GILD]). Because TriKE is a targeted immuno-oncology protein-based therapeutic, the cost and patient delivery/administration of TriKE therapy are far superior compared to CAR-T cell therapies.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "we are pleased to have dosed the first patient in our GTB-3550 clinical trial, and thank our investors for helping us achieve this important milestone." Mr. Cataldo further stated "what makes the multi-targeting TriKE ™ unique from all the other single targeting NK cell therapies (Affimed NV [Nasdaq: AFMD], Innate Pharma SA [Nasdaq: IPHA] and Dragonfly Therapeutics [www.dragonflytx.com]) is the proprietary incorporation of IL-15 (an NK cell stimulating cytokine) directly into the core TriKE construct thereby enhancing activation, proliferation and persistence of NK cells while minimizing the toxicities associated with the systemic administration of cytokine therapy to stimulate the patient's immune system."

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

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment 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 acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), 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 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 guarantees 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 GTB-3550 or GTB-1550, 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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