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GT

Biopharma, Inc.

GT Biopharma Provides Update on Development of TriKE(TM) Therapeutic for Treatment of COVID-19 Infection

LOS ANGELES, CA / ACCESSWIRE / August 20, 2020 /GT Biopharma, Inc.

(OTCQB:GTBP) (GTBP.PA) (the "Company" or "GT Biopharma") a company focused on developing innovative therapeutic treatments based on its proprietary NK cell engager (TriKE™) platform announced today an update concerning the development of its TriKE™ therapeutic for the treatment of COVID-19 infection. The TriKE™ COVID-19 therapeutic is designed to seek out and kill Novel Coronavirus 2019 (2019-nCoV) virus infected cells before the release of additional virus particles from such infected cells. The ability of the TriKE™ therapeutic to direct the immune system's Natural Killer (NK) cells to target and eliminate distressed cells is a key part of the therapeutic strategy.

GT Biopharma and [Cytovance® Biologics](#), a USA-based contract development and manufacturing company and a member of the Shenzhen Hepalink Pharmaceutical Group of companies, have entered into a collaboration agreement whereby Cytovance is providing drug development services to assist the GT Biopharma with its TriKE™ therapeutic for the treatment of COVID-19 infection.

Severe acute respiratory syndrome-associated coronavirus infection produces devastating viral pneumonia. Pathologic changes are most prominent in the lungs, with disruptions of the pulmonary epithelial cells in gas exchange areas and conducting airways. It has been reported that the angiotensin converting enzyme 2 (ACE2) receptor is the main host cell receptor targeted by the 2019-nCoV virus, and plays a crucial role in the entry of virus into the cell.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "development is continuing according to plan, and we are working to prepare TriKE™ COVID-19 for further preclinical testing and GMP manufacturing." Mr. Cataldo also stated "we are pleased with the progress Cytovance is making, and are looking forward to being able to evaluate the TriKE™ COVID-19 therapeutic in humans."

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 on 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](https://clinicaltrials.gov/ct2/show/study/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 TriKE™ COVID-19, 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, (vi) 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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