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GT Biopharma and Cytovance Biologics Announce Collaboration Agreement TriKE(TM) Therapeutic for Treatment of Coronavirus Infection

BEVERLY HILLS, CA / ACCESSWIRE / March 10, 2020 /GT Biopharma, Inc. (OTCQB:GTBP)(GTBP.PA) a company focused on developing innovative therapeutic treatments based on its proprietary NK cell engager (TriKE™) platform announced today that it had entered into a collaboration agreement with Cytovance® Biologics, a USA-based contract development and manufacturing organization (CDMO) and a subsidiary of the Shenzhen Hepalink Pharmaceutical Group Co., Ltd. ("Hepalink") (002399:SZ) a publicly traded company with a market capitalization of CNY 31.5 billion, to provide development services for a TriKE™ therapeutic for the treatment of coronavirus infection.

Severe acute respiratory syndrome-associated coronavirus (SARS-CoV) 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 Novel Coronavirus 2019 (2019-nCoV), and plays a crucial role in the entry of virus into the cell to cause the final infection.

Under the terms of the collaboration agreement, the companies will focus on preparing sufficient quantities of GT Biopharma's coronavirus TriKE drug product for preclinical evaluation using Cytovance's *E. coli*-based *Keystone Expression System*™ and subsequently, will scale-up production using Cytovance's GMP microbial manufacturing platform for evaluation of TriKE in humans to treat coronavirus infection. Jesse McCool, Ph.D., Chief Technology Officer of Cytovance said "we are pleased to have the opportunity to work with GT Biopharma on this timely endeavor and help move their TriKE product into clinical testing for the treatment of coronavirus infection."

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "we are pleased to have the opportunity to collaborate with Cytovance in furthering our TriKE infectious disease research program to investigate the therapeutic utility of TriKE to attack coronavirus infection." Mr. Cataldo further stated "the flexibility and breadth of our TriKE therapeutic platform allows us to quickly adapt to new disease targets, and rapidly advance TriKE product opportunities into the clinic." Mr. Cataldo additionally said "our experience developing the HIV TriKE which demonstrated virus infected cell killing has led us to employ a similar design strategy for our new coronavirus TriKE."

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 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 developed by researchers at the university to target NK cells.

About GTB-3550 TriKE™

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment 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 intend to study GTB-3550 in CD33 positive leukemias such as acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and other CD33+ hematopoietic malignancies.

About HIV TriKE™

Natural killer (NK) cells are stimulated by the cytokine human IL-15 portion of the TriKE™ molecule which provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We have constructed an HIV TriKE™ that directs NK cells to HIV infected CD4+ T-cells, and have demonstrated the ability of the HIV TriKE™ to kill HIV infected targets in preclinical models suggesting that further testing to eliminate the HIV reservoir is warranted. We believe the HIV TriKE™ has the potential to offer many people living with HIV a treatment option that achieves sustained viral remission by eradicating the virus in all locations within the body, and hopefully will become part of a scalable and curative therapeutic strategy for HIV patients.

About Cytovance® Biologics

Cytovance® Biologics is a leading biopharmaceutical Contract Development and Manufacturing Organization (CDMO) that excels in the rapid and cost-effective development and manufacture of large molecule active pharmaceutical ingredients (APIs) from both mammalian cell culture and microbial fermentation such as monoclonal antibodies, fragment antibodies, bispecific antibodies, enzymes, fusion proteins, vaccines, and other biological products including plasmid DNA and cell-based therapeutics. In addition to our clinical and commercial CGMP API manufacturing services, Cytovance offers well-integrated development services supporting the entire product lifecycle including cell line development, cell banking, microbial strain development, process and analytical development, and process characterization. A centralized, responsive program management team coordinates all critical chemistry, manufacturing and controls (CMC) activities for each client program including technology transfer, development, production, raw materials management, QC testing, ICH stability studies, and regulatory support. Our 140,000 sq. ft. state-of-the-art facilities in Oklahoma City are designed to meet the U.S., EU, and other global regulatory

standards.

About Cytovance® Biologics Keystone Expression System™

The *Keystone Expression System*™ is an *E. coli*-based protein production platform that combines industry leading DNA synthesis technologies for gene and vector design (ATUM, Newark, CA) with Cytovance's standard microbial platforms for cell substrate development, fermentation, pilot, and CGMP manufacture with standard analytics and a phase-appropriate CMC approach.

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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SOURCE: GT Biopharma, Inc.

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https://www.accesswire.com/579888/GT-Biopharma-and-Cytovance-Biologics-Announce-Collaboration-Agreement-TriKETM-Therapeutic-for-Treatment-of-Coronavirus-Infection