

October 6, 2020



# GT Biopharma Announces Expanded TriKE(TM) Partnership With Cytovance Biologics

## ***Sign \$6,000,000.00 Agreement***

**BEVERLY HILLS, CA / ACCESSWIRE / October 6, 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 partnership 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").

Under the terms of the partnership agreement, Cytovance will be the exclusive GMP manufacture for three of the Company's TriKE™ therapeutic product candidates. Cytovance will manufacture TriKE™ in accordance with GMP using Cytovance's proprietary Keystone® bacterial or mammalian expression systems. Subject to the completion of certain milestones by Cytovance, GT Biopharma has the option to pay Cytovance up to \$6 million for its manufacturing services in either cash or in shares of the Company's common stock valued at the time Cytovance achieves each of several milestones over the next 12 months.

Matt Delaney, MBA, M.I.B., Vice President Business Development & Marketing of Cytovance said "we are pleased to have been selected as GT Biopharma's exclusive GMP manufacturer for its first three TriKE™ product candidates." Mr. Delaney also stated "we believe our proprietary Keystone® bacterial or mammalian expression systems will deliver high production yields of TriKE™ further enhancing economies of scale."

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "We are pleased to have the opportunity to expand our partnership with Cytovance," 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."

## **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.

### **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" 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, (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](http://www.gtbiopharma.com).

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