December 17, 2020

GT Biopharma And Cytovance Biologics Announce Milestone Achievement

BEVERLY HILLS, Calif., Dec. 17, 2020 /PRNewswire/ -- 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 Cytovance, a USA-based contract development and manufacturing organization (CDMO) and a subsidiary of the Shenzhen Hepalink Pharmaceutical Group Co., Ltd. ("Hepalink"), have reached an agreement for license rights to use certain bacterial and mammalian cell lines and for GMP manufacturing services performed to date regarding the Company's TriKE™ product candidates.

Under the terms of the partnership agreement entered into between the companies, Cytovance is 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 licenses to use certain of Cytovance's bacterial and mammalian cell lines and for manufacturing services performed 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.

GT Biopharma issued $1 million of GT Biopharma restricted common stock (GTBP) to Cytovance. The number of shares of GT Biopharma restricted common stock was based on the closing price ($0.31) of the Company's common stock on December 15, 2020.

Anthony Cataldo, Chairman and Chief Executive Officer of GT Biopharma commented "We are pleased to have the opportunity to work with Cytovance and their experienced team for the GMP manufacture of our TriKE product candidates. Achievement of the subject Milestone was achieved on-time and on-budget by Cytovance and we believe our partnership and their acceptance of our company stock illustrates their commitment to us and this partnership for the long term."

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 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 GTB-3550 TriKE™ Clinical Trial

Patients with CD33+ malignancies (primary induction failure or relapsed AML with failure of one reinduction attempt or high-risk MDS progressed on two lines of therapy) age 18 and older are eligible (NCT03214666). The primary endpoint is to identify the maximum tolerated dose (MTD) of GTB-3550 TriKE. Correlative objectives include the number, phenotype, activation status and function of NK cells and T cells. Interim results presented at the American Society of Hematology meeting December 5, 2020 demonstrates GTB-3550 TriKE™ reduces bone marrow blast levels in AML and MDS patients with reported no toxicities, and improves NK cell function and proliferation.

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 TriKE™ NK cell engager 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 therapies using TriKE™ technology.

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, 2019 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent Form 10Q Quarterly 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, 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.

View original content:http://www.prnewswire.com/news-releases/gt-biopharma-and-cytovance-biologics-announce-milestone-achievement-301195206.html

SOURCE GT Biopharma, Inc.