August 3, 2021

GT Biopharma Announces Positive Preclinical Results For GTB-5550 B7H3 TriKE™

POTENTIAL TREATMENT OF SEVERAL SOLID TUMOR CANCERS INCLUDING: NON-SMALL CELL LUNG CANCER, SQUAMOUS CELL CARNINOMA, BREAST CANCER, RENAL CANCER, PANCREATIC CANCER, OVARIAN CANCER, LIVER CANCER, COLORECTAL CANCER

BEVERLY HILLS, Calif., Aug. 3, 2021 /PRNewswire/ -- GT Biopharma, Inc. (NASDAQ: GTBP), a clinical stage biopharmaceutical company focused on developing target-directed, tri-specific Natural Killer (NK) cell engager therapies (TriKE™) incorporating interleukin 15 (IL-15) for the treatment of cancer, announced preclinical results for GTB-5550, its B7H3 TriKE™ product candidate as a prospective therapy for the treatment of several different types of cancers.

GTB-5550 TriKE™ was evaluated in several preclinical models overexpressing B7H3, and was found to be effective at promoting NK cell killing of multiple cancer cell types. B7H3 is over-expressed on several cancer types including non-small cell lung cancer, squamous cell carcinoma, and breast, renal, pancreatic, ovarian, liver and colorectal cancers. GTB-5550 TriKE™ is presently undergoing GMP manufacturing scale-up in preparation for filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for evaluation in humans.

B7H3 is a member of the B7 family of immune checkpoint inhibitors which includes PD-1/PD-L1 and CTLA-4/CD80. Merck's Keytruda® (pembrolizumab) and Bristol-Myer Squibb's

YERVOY® (ipilimumab) targeting the PD-1/PD-L1 and CTLA-4/CD-80 checkpoints, respectively, have demonstrated significant survival benefit and are blockbuster immune-oncology therapeutics.

B7H3 expression on cancer cells is highly associated with undesirable treatment outcomes and survival time. Targeting B7H3 on cancer cells with TriKE™ and redirecting NK cells to attack and kill cancer cells expressing B7H3, could result in a therapeutic treatment that limits the metastatic potential and invasiveness of certain solid tumor cancers.

Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer, commented: "We are pleased to report our GTB-5550 TriKE™ has passed this important development milestone, and demonstrated effectiveness in promoting redirected and target-specific killing by NK cells."

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. The TriKE™ platform is designed to activate and redirect the target cell killing abilities of the patient's natural killer cells (NK cells) without the need for supplemental *ex vivo* engineered donor or autologous NK cells, or induced pluripotent stem cells (iPSC). The Company has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE™ technology. GT Biopharma's lead TriKE™ product candidate, GTB-3550 TriKE™, is being evaluated in a multicenter Phase I/II trial (ClinicalTrials.gov NCT03214666) for the treatment of acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and other CD33+ hematopoietic malignancies.

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, 2020 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.

Contact:

Investor & Media Relations:
David Castaneda
David@gtbiopharma.com
414-351-9758

View original content to download multimedia:https://www.prnewswire.com/news-releases/gt-biopharma-announces-positive-preclinical-results-for-gtb-5550-b7h3-trike-301346754.html

SOURCE GT Biopharma, Inc.