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GT Biopharma Announces Preclinical Results For Its ROR1 TriKE™ As A Treatment For Prostate Cancer

BEVERLY HILLS, Calif., March 8, 2021 /PRNewswire/ -- GT Biopharma, Inc. (NASDAQ: GTBP), a clinical stage biopharmaceutical company focused on disruptive, target-directed Natural Killer (NK) cell engager immunotherapy technologies (TriKE™) for cancer, announces preclinical results for its ROR1 TriKE™ product candidate as a prospective therapy for the treatment of prostate cancer.

Tyrosine kinase transmembrane receptor ROR1 has recently been shown to be overexpressed on certain cancer cells, and appears to play a functional role in promoting migration/invasion and influencing the metastatic potential of various solid tumor cancers. Targeting ROR1 on cancer cells with TriKE™ and redirecting NK cells to attack and kill cancer cells expressing ROR1, could result in a therapeutic treatment that limits the metastatic potential and invasiveness of certain solid tumor cancers.

The ROR1 TriKE™ was evaluated in several preclinical models of prostate cancer, and was found to be effective at promoting NK cell killing of multiple prostate cancer cells including LnCAP, C4-2, PC-3, DU-145, VCaP and 22RV1. Significant NK cell activation and interferon gamma (IFNγ) production was also observed as a result of TriKE™ engagement and activation of the NK cell.

"We are pleased to report our ROR1 TriKE™ has passed this important preclinical milestone, and demonstrated effectiveness in promoting redirected and target-specific killing by NK cells," said Anthony J. Cataldo, GT Biopharma's Chairman and Chief Executive Officer. "We plan to evaluate the ROR1 TriKE™ in additional IND-enabling preclinical studies with the goal of transitioning to a Phase I/II clinical trial."

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 on 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](https://clinicaltrials.gov/ct2/show/study/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.

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