

October 22, 2019



## **GT Biopharma Announces Solid Tumor Targeting TriKE™ Kills Non-small Cell Lung Cancer (NSCLC) Tumor Cells**

TAMPA, Florida, Oct. 22, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE™) platform, announced today that Drs. Jeffrey Miller, Martin Felices and Pippa Kennedy from the University of Minnesota presented research results at the recently concluded 18<sup>th</sup> meeting of the Society for Natural Immunity concerning a solid tumor targeting TriKE™ which demonstrates killing of non-small cell lung cancer tumor cells.

According to the American Cancer Society, non-small cell lung cancer (NSCLC) is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses. In 2019, it is estimated there will be 228,150 cases of newly diagnosed lung cancer. Lung cancer is the second most common cancer, and this year it is estimated that 142,670 people will die from lung cancer. The 5-year survival rate for all people with all types of lung cancer is 19%.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented "we are excited about the progress Dr. Miller and his colleagues are making developing a TriKE™ which targets solid tumors." Mr. Cataldo further stated "we believe the NSCLC TriKE™ has the potential to offer lung cancer patients with a treatment option that achieves targeted killing of metastatic lung cancer cells in all locations within the body, and hopefully will become part of a scalable and curative therapeutic strategy for lung cancer patients."

### **About GTB-3550 TriKE™ and GTB-3550 TriKE™ Phase I/II Clinical Trial**

GTB-3550 is the Company's first TriKE™ product candidate which is a single-chain, tri-specific recombinant fusion protein construct 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 GTB-3550 Phase I/II clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis opened for patient enrollment September 2019. The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick.

### **About GT Biopharma, Inc.**

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the

development and commercialization of immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE™) and Multi-Target Directed Bispecific Drug Conjugate technology platforms. 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 cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer. Our Multi-Target Directed Bispecific Drug Conjugate platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of targeted therapy.

## **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 guarantees 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 GTB-3550 or GTB-1550, 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.

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](http://www.gtbiopharma.com).

**Disclosures**

TriKE™ is a trademark of GT Biopharma, Inc.

Dr. Miller also serves as Consulting Chief Medical Officer of GT Biopharma, Inc.

For more information, please visit [www.gtbiopharma.com](http://www.gtbiopharma.com)  
(800) 304-9888

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