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GT Biopharma GTB-1550

Multi-Targeted Bispecific Drug Conjugate

Strategically positioned in new class of ADC Drugs

TAMPA, Florida, June 13, 2019 /PRNewswire/ -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immuno-oncology company developing GTB-1550, a novel multi-target bispecific drug conjugate therapy for the treatment of chemotherapy-refractory B-cell malignancies.

Today, [Bloomberg](#) discussed antibody-drug conjugates (ADC) as effective cancer therapies having the potential to replace traditional chemotherapy. ADCs are essentially a "trojan horse" therapeutics which have several advantages over traditional chemotherapy including less toxicity and higher efficacy due to a more precise targeting of cancer cells compared to non-cancer cells.

An ADC is composed of an antibody which specifically identifies cancer cells and a cytotoxic agent (the payload) which has been grafted onto the antibody. When injected into patients, the ADC traffics through the patient's body to find the targeted cancer cells. Upon binding to the cancer cell, the ADC is internalized by the cancer cell, and the cytotoxic payload kills the cancer cell.

Anthony Cataldo (CEO GT Biopharma, Inc.) said, "The Bloomberg article points out the excitement that big pharma is now realizing as the potential for ADC's as a realistic alternative to Chemo Therapies. What differentiates our ADC Bispecific GTB-1550, is the ability for our drug to hit multiple target sites of B-cell malignancies as opposed to the one target ADC's represented in the Bloomberg article. We are happy to see the attention of the large pharmaceuticals moving in this direction."

GTB-1550 is a novel, multi-target bispecific cytotoxic therapeutic agent consisting of diphtheria toxin and bispecific single-chain variable fragments (scFV) of antibodies targeting human CD19 and CD22. By simultaneously targeting cancer cells that express either CD19 or CD22 or both, GTB-1550 is capable of killing a broader variety of hematological malignancies than either a traditional a CD19 antibody drug conjugate or a CD19 CAR-T immunotherapy which are only able to target and attack CD19 expressing hematological malignancies. Simultaneously targeting multiple cancer targets such as CD19 and CD22 using a single therapeutic agent potentially makes GT Biopharma's multi-target bispecific drug conjugate therapy the next generation of advanced cancer therapies.

To date, GTB-1550 has completed one dose escalation Phase I-II expansion clinical trial, and one fixed dose Phase I-II expansion clinical trial which collectively enrolled a combined

43 patients.

Top-line Consolidated Results:

- Two patients exhibited a Complete Remission (CR) with one patient currently disease-free at 50 months post treatment.
- Five patients exhibited Stable Disease (SD) with the longest response lasting 12 months post treatment.
- Two patients with transformed lymphoma showed transient tumor shrinkage, however, therapy was discontinued due to dose-limiting toxicities after the 1st cycle.
- Greater than 50% of evaluable patients receiving 60 mg/kg dose had positive clinical response defined as stable disease, partial remission, or complete remission.

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 Bispecific Drug Conjugate (MTBDC) 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 Bispecific Drug Conjugate (MTBDC) platform can generate product candidates that are bispecific, 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 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, 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.

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