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GT Biopharma Advances GTB-3650, a Second-Generation Tri-Specific Killer Engager -TriKE®, Into IND-Enabling Studies

- GTB-3650 is a novel molecule based on camelid single-domain antibody technology with advantages that build upon the strong proof-of-concept data from the Company's first-generation TriKE® program, GTB-3550**
- GTB-3650 has shown significantly higher potency than GTB-3550 in preclinical models, as detailed in a recent peer reviewed publication¹**
- Company now plans to accelerate its transition from the ongoing GTB-3550 Phase 1 program into its next generation TriKE®, GTB-3650, for patients with relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS)**

BEVERLY HILLS, Calif., Sept. 13, 2021 /PRNewswire/ -- GT Biopharma, Inc. (the "Company") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager, TriKE® protein biologic technology platform, today, announces the advancement of GTB-3650 into IND-enabling studies, with which it plans to supplant the ongoing Phase 1 program with GTB-3550.



Therapeutic and commercial advantages of GTB-3650 compared to GTB-3550 include:

- Based on second generation camelid single-domain antibody technology that holds several advantages over traditional IgG monoclonal antibodies
- Improved potency and enhanced binding affinity
- Similar preclinical safety profile
- Commercial manufacturing capabilities through arrangement with Cytovance
- Proprietary patented molecule, which unlike GTB-3550, is wholly owned by GT Biopharma

"We look forward to advancing GTB-3650 toward the clinic" noted Greg Berk, M.D., GT Biopharma's President of R&D and Chief Medical Officer. "This transition marks the next logical evolution of our TriKE® platform. As the company focuses its resources on the most promising pipeline candidates, GTB-3650 will now be able to take advantage of the strong evidence gathered from our first-generation pilot TriKE® program. Complementing this development advance, has been the transition of all manufacturing processes to Cytovance Biologics, a leading specialty cGMP contract manufacturing organization. We have now achieved another strategic milestone consistent with our mission to advance novel immunology drugs to patients with advanced cancers", commented Dr. Berk.

About Camelid Antibodies

[Camelid antibodies](#) are single domain antibodies (sdAbs) from the Camelidae family of mammals that include llamas, camels, and alpacas. These animals produce 2 main types of antibodies. One type of antibody camelids produce is the conventional antibody that is made up of 2 heavy chains and 2 light chains. They also produce another type of antibody that is made up of only 2 heavy chains and no light chain. This is known as heavy chain IgG (hcIgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the VHH region. VHH antibodies, also known as single domain antibodies, contain only the VHH region from the camelid antibody. Camelid antibodies have key characteristics, which include high affinity and specificity (equivalent to conventional antibodies), high thermostability, good solubility and strictly monomeric behavior, small size, relatively low production cost, ease of genetic engineering, format flexibility or modularity, low immunogenicity, and a higher penetration rate into tissues.

About GTB-3650

GTB-3650 is the Company's lead second-generation Tri-Specific Killer Engager TriKE® program currently in preclinical development for the treatment of relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS).

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. Our TriKE® platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit gtbiopharma.com.

[1. "Potent Cytolytic Activity and Specific IL15 Delivery in a Second-Generation Trispecific Killer Engager", by Felices, R. Lenvik, Kodal et al., July 13, 2020, Cancer Immunology Research.](#)

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 Annual Report on Form 10-K for the year ended December 31, 2020, our subsequent current reports on Form 8-K, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, and our other 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, (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.

TriKE® is a registered trademark owned by GT Biopharma, Inc.

Contacts:

Investor Relations:

David Castaneda

David@gtbiopharma.com

414-351-9758

LifeSci Advisors

Corey Davis, Ph.D.

cdavis@lifesciadvisors.com

212-915-2577

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