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Biopharma, Inc.

GT BioPharma's Next Generation Camelid TriKE® Nanobody Platform Highlighted at ESMO Congress 2021

- Preclinical data presented at ESMO demonstrates activity of the camelid TriKE in B7H3 positive and HER2+ solid tumor cancer models**
- In addition, the company also provides update on the ongoing GTB-3550 Phase 1 trial in relapsed/refractory AML and MDS**

BEVERLY HILLS, Calif., Sept. 20, 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 platform, today announced Dr. Jeffrey Miller's mini-oral presentation at the European Society for Medical Oncology (ESMO) Congress 2021. Jeffrey Miller, MD is a Professor of Medicine, University of Minnesota Medical School, Division of Hematology, Oncology and Transplantation and GT Biopharma's consulting Chief Scientific Officer.



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The presentation at ESMO highlighted the activity of camelid TriKEs in preclinical B7H3 positive and HER2+ solid tumor cancer models. GT Biopharma plans to advance these TriKEs into the clinic in 2022. The abstract is currently available on the ESMO website at

www.esmo.org.

In addition to the ESMO presentation, GT Biopharma provided an update on its ongoing Phase 1 safety and feasibility clinical trial with GTB-3550. A total of 12 relapsed/refractory acute myelogenous leukemia (AML) and high grade myelodysplastic syndromes (MDS) patients have now been administered one cycle of GTB-3550, the company's first-generation TriKE which targets CD33 on the surface of the leukemic cells in patients with AML and MDS.

The three most recent patients (numbers 10-12) have all tolerated the treatment well. One patient at the 150 mcg/kg/day dose experienced a mild Grade 1 cytokine release syndrome (CRS) event (fever), which was not dose limiting. Immune monitoring on these three most recent patients was consistent with the data previously reported on the first nine patients, and demonstrated activation, proliferation, and persistence of CD16 positive NK cells. Patient 11 had a bi-phenotypic leukemia which co-expressed both CD19 (a lymphoid marker) and CD33 (the myeloid marker which is targeted by GTB-3550); this patient showed a 50% reduction in CD33-positive leukemic cells (blasts), evidence of anti-leukemic activity of GTB-3550. Patients 10 and 12 did not experience blast cell reduction. The Company has previously reported that three of the first nine patients experienced a reduction in blast cells.

Gregory Berk, MD, President of R&D and Chief Medical Officer of GT Biopharma commented "We are very pleased with what we have learned from the Phase 1 GTB-3550 clinical trial. The TriKE is safe and well tolerated. The TriKE results in NK cell activation, proliferation, and persistence. There are also early signs of anti-leukemic activity. We are excited to advance GT Biopharma's next generation camelid program for this difficult-to-treat patient population."

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 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.

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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