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GT Biopharma Issues Open Letter to Shareholders Detailing Recent Activities

BRISBANE, CALIFORNIA, Feb. 02, 2023 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the "Company" or "GTB") (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, issued an open letter from the CEO to shareholders, detailing the Company's recent activities. The full letter is published below:

Dear GT Biopharma Shareholders,

I am proud to say that we have made significant progress towards fulfilling our corporate mission. It remains our goal to bring to market, a novel camelid nanobody technology platform, with target-directed immunotherapy in the fight against cancers. At the moment, we have more than 6 promising pipeline assets in active preclinical development, targeting both solid tumors and hematological malignancies. On the corporate development side our board and executives continue to manage the task of taking GT Biopharma's promising assets into the clinic. Earlier in the year, Manu Ohri, joined the executive leadership team as our chief financial officer to lead the Company's finance team and I was appointed interim CEO in addition to my existing role as Executive Chairman.

Operationally, we reached an exciting milestone in our development lifecycle and signed an agreement with Cytovance Biologics Inc. in the third quarter of fiscal 2022. The agreement covers all work required to facilitate the registration of an investigational new drug (IND) filing with the U.S. Food and Drug Administration for our lead investigational asset GTB-3650. GTB-3650, a second generation TriKE[®] will move forward in its development and we expect to file an IND submission in the first half of 2023. An IND submission for GTB-5550 in solid tumors is expected to follow thereafter. We are proud of the work that the team has performed in order to reach this juncture.

As previously noted, GTB-3650 is in place of GTB-3550, the Company's first generation, first-in-human TriKE[®]. The pivoting to GTB-3650 continues to be underpinned by the safety data that was carried forward from GTB-3550's Phase 1 safety study. The therapeutic and commercial advantages of GTB-3650 as compared to GTB-3550 however are many and include:

- Traditional IgG monoclonal antibodies based on second generation camelid single-domain antibody technology;
- Improved potency and enhanced binding affinity;
- Similar preclinical safety profile; and
- Commercial manufacturing capabilities through arrangement with Cytovance.

While the biotech capital markets continue to remain volatile, we remain well capitalized and expect our current cash runway to fund operations into 2023. Additionally, we remain actively engaged with the capital markets at large and have presented at numerous investment conferences throughout the year. On the scientific front, we continue to be an active participant in order to bring awareness of our technology and have presented at many of the important annual oncology medical meetings that have taken place thus far. Most recently, Dr. Jeff Miller presented a study at the American Society of Hematology's 64th Annual Meeting. The presentation highlighted the potential of a novel dual antigen targeting approach for the treatment of acute myeloid leukemia (AML), combining GT Biopharma's Tri-specific Killer Engager (TriKE) with the induced pluripotent stem cell (iPSC) product platform of Fate Therapeutics, Inc. (NASDAQ:FATE).

In addition, I am delighted to report that in mid-December of this year, Dr. Jeff Miller, renowned NK Cell Cancer Specialist, was appointed Consulting Chief Medical Officer to the Company.

In conclusion, we have placed great emphasis in this past year to bring about the next stages of value creation on behalf of GT Biopharma's shareholders. We have also taken capital allocation into consideration relative to the current market. While GTB-3650 and GTB-5550 both share the advantages of being a second generation TriKE, it is important to note that the significance of the commercial size for GTB-5550 for solid tumors is appreciably larger than the size of the hematologic cancer market at present.

We are thankful that you have entrusted the senior executive leadership team with this charge, a matter that we do not take lightly. Furthermore, we believe that will be able to carry this momentum with us and look forward to sharing the next steps of our strategic operating plan with investors in the forthcoming year. We also want to thank our employees for whom GT Biopharma's innovations would not be possible without their hard-won efforts.

Wishing you and your family a wonderful New Year.

Best regards,

Michael Breen
Executive Chairman and Interim Chief Executive Officer

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

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections

about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

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

Investor Relations Contacts:

LifeSci Advisors

Corey Davis, Ph.D.

cdavis@lifesciadvisors.com

212-915-2577



Source: GT Biopharma, Inc.