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# GT Biopharma Affirms Manufacturing Timeline For Lead Investigational Asset GTB-3650

- GTB-3650's IND application with the FDA expected by end of first quarter of 2023

BRISBANE, Calif., Aug. 30, 2022 (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<sup>®</sup> platform, today announced entering into a Settlement and Investment Agreement (the "Agreement") with its contract manufacturing partner Cytovance Biologics. The signed Agreement, covers all work required to facilitate the registration of an investigational new drug (IND) filing with the U.S. Food and Drug Administration ("FDA") of its lead investigational asset GTB-3650.

GTB-3650 is the Company's lead second-generation Tri-Specific Killer Engager TriKE<sup>®</sup> program currently in preclinical development for the treatment of relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS). The Company previously announced that its second generation TriKE, GTB-3650, will supplant GTB-3550. The MSA with Cytovance covers all changes to scope of work in order to advance GTB-3650 forward. In consideration for this scope of work payments to Cytovance will be in the form of cash and stock but limited to no more than 4.9% of GTB's total shares outstanding.

The Company now expects to file its investigational new drug ("IND") application with the FDA for its GTB-3650 product no later than March 31, 2023, and to file its IND application with the FDA for its GTB-5550 product no later than June 30, 2023.

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

- GTB-3650 is 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
- Proprietary patented molecule, which unlike GTB-3550, is wholly owned by GT Biopharma

## **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<sup>®</sup> NK cell engager platform. Our TriKE<sup>®</sup> 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<sup>®</sup> technology. For more information, please visit [gtbiopharma.com](http://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<sup>®</sup> is a registered trademark owned by GT Biopharma, Inc.

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