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GT Biopharma Announces IND Submission for GTB-3650 for Treatment of CD33+ Leukemia

BRISBANE, CALIFORNIA, Dec. 04, 2023 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (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 the submission of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for the development of GTB-3650, a 2nd generation nanobody TriKE[®] for the treatment of patients with CD33+ leukemia, including relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS).

"Today's announcement is an important milestone for GT Biopharma, and we look forward to advancing GTB-3650 for treatment of CD33+ leukemia. We are excited to expeditiously move this molecule into the clinic as we execute on our clinical objectives in 2024," stated Michael Breen, GT Biopharma's Executive Chairman, Board of Directors 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.

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