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GT Biopharma Announces First Patient Dosed in Phase 1 Trial of GTB-3650, Second-Generation TriKE for the Treatment of Hematologic Malignancies

- *Initial data from the Phase 1 trial expected in 2025*

SAN FRANCISCO, CALIFORNIA, Jan. 27, 2025 (GLOBE NEWSWIRE) -- 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 that the first patient was dosed in a Phase 1 trial evaluating GTB-3650, its second-generation TriKE, for the treatment of relapsed or refractory (r/r) CD33 expressing hematologic malignancies.

"We are thrilled to initiate patient dosing with GTB-3650 in the Phase 1 trial to evaluate the potential in patients with hematological malignancies, which represents a significant milestone for the company. As we continue to progress through clinical development, we eagerly anticipate sharing initial data from the study in 2025", said Michael Breen, Executive Chairman and interim Chief Executive Officer of GT Biopharma.

GTB-3650 is GT Biopharma's wholly owned second-generation TriKE. It utilizes camelid nanobody technology, with the potential to improve potency and enhance binding affinity. The Phase 1 dose escalation study will evaluate GTB-3650 in up to approximately 14 patients (seven cohorts) with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). GTB-3650 will be dosed in two-week blocks, two weeks on and two weeks off, for up to four months based on clinical benefit. The trial will assess safety, pharmacokinetics, pharmacodynamics, in vivo expansion of endogenous patient NK cells and clinical activity. More details can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT06594445) with the identifier: [NCT06594445](https://clinicaltrials.gov/ct2/show/study/NCT06594445).

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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