UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report:
(Date of earliest event reported)

January 27, 2025

GT Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction
of Incorporation)

1-40023	**94-1620407**
(Commission File Number)	(IRS Employer Identification No.)

315 Montgomery Street, 10th Floor
San Francisco, CA 94104

(Address of Principal Executive Offices and zip code)

(415) 919 4040
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol(s)	Name of each Exchange on which registered
Common stock, $0.001 par value	GTBP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

First Patient Dosed in Phase 1 Trial of GTB-3650

On January 27, 2025, GT Biopharma, Inc. (the "Company") issued a press release announcing that the first patient was dosed in the Phase 1 Trial of GTB-3650, Second-Generation TriKE for the Treatment of Hematologic Malignancies.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Corporate Presentation

Our updated corporate presentation as of January 27, 2025, which has been posted to our website, is filed as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued January 27, 2025, entitled "GT Biopharma Announces First Patient Dosed in Phase 1 Trial of GTB-3650, Second-Generation TriKE for the Treatment of Hematologic Malignancies".
99.2	GT Biopharma, Inc. Corporate Presentation as of January 27, 2025
104	Cover Page Interactive Data File (embedded as Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GT BIOPHARMA, INC.

Date: January 27, 2025

By: */s/ Alan Urban*
Alan Urban
Chief Financial Officer

Exhibit 99.1

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, January 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 with the identifier: 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.

Investor Relations Contact:

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
212-915-2577

Exhibit 99.2

Tri-Specific NK Cell ENGAGERS (TriKE®)

Targeted NK Cell Therapies to Treat Cancer and Autoimmune Disease

GT Biopharma (Nasdaq: GTBP)

Corporate Presentation – January 2025

Disclaimer

This presentation may not be reproduced, redistributed, published or passed on to any other persons, directly or indirectly, in whole or in part, for any purpose. This presentation is not directed to, intended for distribution to, or to be used by any person or entity that is a citizen or resident of, or located in, any locality, state, country or other jurisdiction where the distribution or use would be contrary to any law or regulation, or which would require any registration or licensing within the jurisdiction.

Forward Looking Statements: This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," "would" or the negative thereof, other variations thereon or other comparable terminology. We operate in a very competitive and rapidly-changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. These risks include, but are not limited to: (i) our financial condition raises substantial doubt to continue as a going concern, (ii) the risk of not developing products to that can be commercialized given the early state of our business, (iii) the expectation of continuing losses in the foreseeable future, (iv) the requirement for additional capital to operate, (v) uncertainty of regulatory approval process, (vi) failure to protect our intellectual property, (vii) over-reliance on non-employee consultants, (viii) uncertainty, cost and delay of obtaining regulatory approvals, (ix) inherent risks of novel technology that our business is based upon not being accepted by the marketplace, (x) our manufacturing, commercialization and marketing capabilities, (xi) degree of acceptance and clinical utility of our product candidates, and other factors mentioned in the "risk factors" sections of our Annual Report on Form 10-K for the year ended December 31, 2023, our subsequent current reports on Form 8-K, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and our other filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance upon such forward looking statements as predictions of future events. Any forward-looking statement included in this presentation speaks only as of the date hereof. Except as required by law, we do not undertake any obligation to update or revise, or to publicly announce any update or revision to, any of the forward-looking statements, whether as a result of new information, future events or any other reason after the date of this presentation. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Additional Information: The Company has filed a registration statement (including a prospectus) on Form S-1 (Registration No. 333-284032) with the U.S. Securities and Exchange Commission (the "SEC"). In the event we conduct an offering, before you invest, you should read the prospectus in the registration statement and other documents we file with the Securities and Exchange Commission for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the Securities and Exchange Commission website at http://www.sec.gov.

Any offering of securities by the Company will only be made by means of a registration statement (including a prospectus) filed with the SEC. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Investment Opportunity – Next Generation of NK Cell ENGAGERS

Proprietary TriKE® Platform – Camelid Nanobodies	• TriKE® are tri-specific NK cell ENGAGERS • Incorporate Camelid "nanobodies"
NK Cell ENGAGERS – Safer than T Cells[1]	• Protein therapeutics to harness the natural killing power of NK cells with – NOT NK cell therapy • Activates NK cells via CD16A and IL-15 while targeting tumor antigens • Potentially safer than T-cell immunotherapy
POC Established and Broad Applicability	• GTB-3550 (targeting CD33) showed POC in Phase 1 in AML patients • GTB-3650 will supplant 3550 as 2nd generation TriKE® with several advantages • TriKE®s target multiple tumor antigens including B7H3, HER2, CD33, PDL1
Multiple Catalysts	• 6+ pipeline assets in preclinical development, both solid tumors and hematological malignancies • IND for GTB-3650 accepted in June 2024, first patient dosed on Jan 21, 2025 • GTB-5550 IND submission expected H1 2025
Broad Indication Potential	• GTB-7550 TriKE® candidate in development for the treatment of lupus, other autoimmune disorders • Exploring manufacturers for GTB-7550
Well-funded Experienced Leadership	• Management team with deep expertise in all stages of oncology drug development • $6.5M in cash + short-term investments as of September 30, 2024 (unaudited), anticipated to be sufficient to fund operations into 2025, debt free balance sheet

1. Demaria, et.al. Eur J. of Immun; (2021)51:8; 1934

TriKE® Pipeline

TriKE® Product Candidates	Approach	Target	Indication	Pre-Clinical	IND-Enabling/ GMP Manufacturing	Phase 1	Phase 2
GTB-3650 2nd Generation Camelid	Monotherapy	CD33	Leukemia – AML, MDS				
	Combination with Chemotherapy	CD33	Leukemia – AML, MDS				
GTB-5550	Monotherapy & Combination	B7H3	Solid Tumors				
GTB-6550	Monotherapy & Combination	HER2	Solid Tumors				
GTB-7550	Monotherapy & Combination	CD19	B-Cell Malignancies				
GTB-1050	Monotherapy & Combination		HIV				
Undisclosed Candidates	Monotherapy & Combination		Solid & Hematological Malignancies				
GTB-3550	*Monotherapy*	*CD33*	*Leukemia – AML, MDS*				

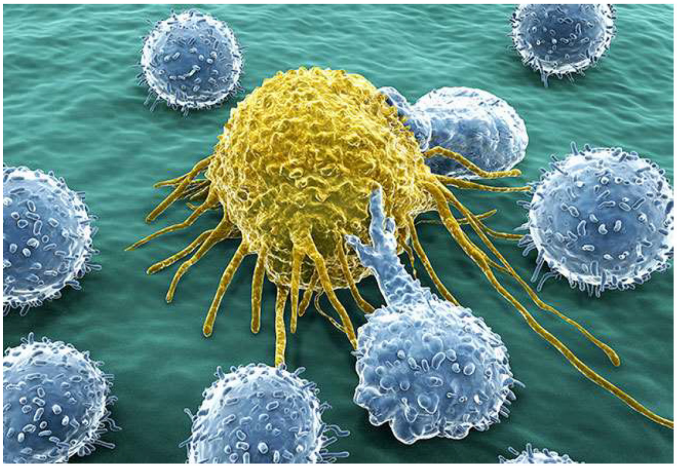
GTB-3650 Phase 1 trial initiated: First patient dosed on 01/21/2025

GTB-5550 IND submission expected H1 2025

GTB-3550 supplanted by second generation GTB-3650

Clinical Product Candidates **Preclinical Product Candidates** **Development abandoned**

Natural Killer Cell ENGAGERS to Fight Cancer



Natural Killer Cells

- Cytotoxic lymphocytes in the innate immune system
- Recognize and kill cancer cells
- Mediate antibody-dependent cellular cytotoxicity (ADCC) via the highly potent CD16 activating receptor

NK Cell ENGAGERS

- TriKE® nanobody platform designed to activate endogenous NK cells to target specific cancer cells
- Potential for less toxicity than other cellular therapies such as CAR-T therapy
  - Less cytokine release syndrome (CRS)
  - Fewer neurological complications

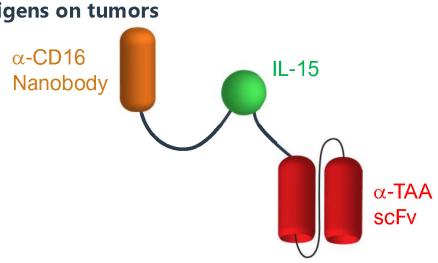
Source: Levy R. Paths of Progress 2019, Natural Killer Cells: How the immune system's first wave of defense may play a newfound role in cancer care; accessed: 6 September 2021 www.dana-farber.org/newsroom/publications/paths-of-progress-2019/natural-killer-cells/

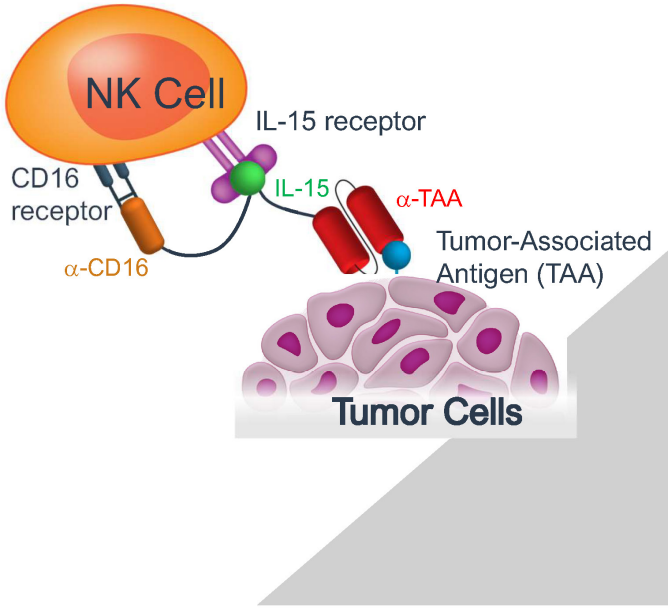
TriKE®: Tri-Specific Natural Killer (NK) Cell ENGAGERS - A Modular Platform

Proprietary platform utilizing camelid nanobody technology designed to bridge NK cells to tumor cells while inducing NK cell activation and expansion at the site of the tumor to enhance killing

Tri-specific Modular Platform with Nanobody Technology

- **Anti-CD16 nanobody*** – binds CD16 receptor on NK cells, triggering antibody directed cell-mediated cytotoxicity (ADCC)[1]
- **IL-15** – crosslinker that binds IL-15/IL-2 receptor on NK cells to induce self-sustaining expansion and extended survival[2,3]
- **Anti-TAA scFv** – scFv domain binds to various tumor-associated antigens on tumors

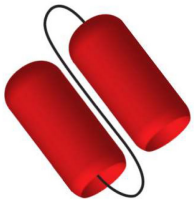




* 1st generation TriKE GTB3550 utilizes scFv for a-CD16

1. Semin Immunol. 2017 Jun; 31: 64–75.
2. J Exp Med. 1994 Oct 1; 180(4): 1395–1403.
3. Vallera et. al. Clin Cancer Res. 22(14) July 15, 2016

TriKE® Modular Platform Allows for Multiple Tumor-Associated Antigen

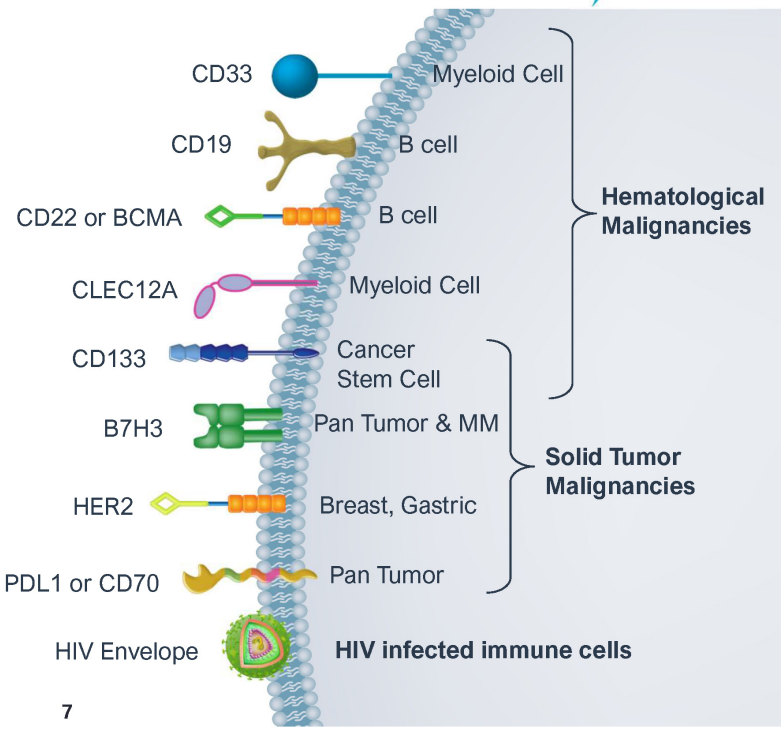


scFv

Nanobody

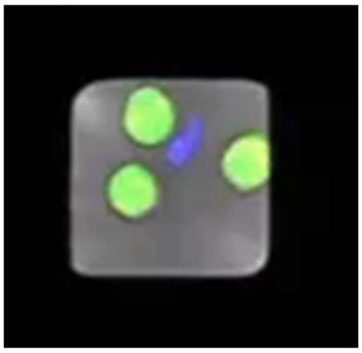
Anti-Tumor Associated Antigen

- Binds to well-known tumor-specific antigens
- Defines the specificity of each TriKE®
- Localizes NK cells at the site of the malignancy
- Utilizes scFv fragments for most TriKE® constructs
- Certain TriKE®s utilize nanobodies for the α-TAA



TriKE® – NK Cell-Driven Serial Killing of AML Tumor Cells

- First-in-class modular immune oncology protein therapeutic platform technology – not a cell therapy
- Target-directed antibody-dependent cellular cytotoxicity (ADCC) killing
- Integrated CD16 and IL-15 driven activation of NK cells:
  - ADCC activation for enhanced serial killing of cancer cells
  - NK cell proliferation
  - NK cell persistence
- Minimizes toxicities such as cytokine release syndrome (CRS) resulting from hyperactivation of T cells
- Can be used to treat BOTH solid tumors and hematological cancers



(Click on Image to Play Video)

Enhanced Serial Killing of Cancer cells (green) by TriKE® directed NK cell (blue)

Source: Sarhan D et al. Blood Adv 2018 Jun 26; 2(12): 1459–1469

GTB-3550 Phase 1 Demonstrates Proof of Concept for CD33 TriKE® in AML/MDS

- GTB-3550 induces reproducible NK cell proliferation, activation and persistence in all patients at all dose levels with minimal clinically significant toxicity
- Minimal CRS resulting from hyperactivation of patient's T-cell population at doses 5–150 µg/kg/day
  - Fever (Grade 1 CRS) observed in Subject #12 (150 µg/kg/day); resolved upon acetominophen treatment
- No loss in CD16 expression on patient's NK cells
- GTB-3550 significantly reduced CD 33+ bone marrow blast levels by 33.3%, 61.7%, 63.6%, 50% in Patient 5 (25 µg/kg/day), Patient 7 (50 µg/kg/day), Patient 9 (100 µg/kg/day), and Patient 11 (150 µg/kg/day), respectively
- After the end of infusion, GTB-3550 & IL-15 concentrations declined rapidly with overall geometric mean terminal phase elimination half-life (T1/2) of 2.2 and 2.52 hours, respectively

GT BIOPHARMA

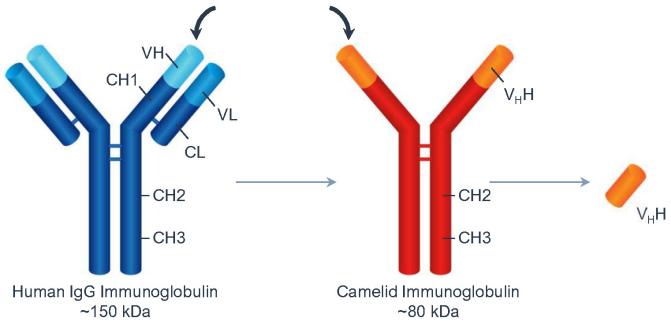
GTB 3650 for AML and MDS
GTB 5550 for Solid Tumors

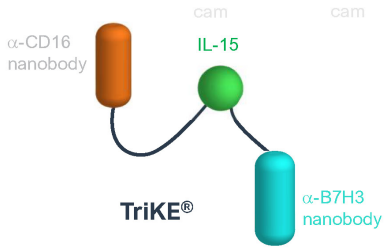
Second generation TriKEs® utilize camelid nanobody technology

Advantages of Camelid Antibodies – Nanobodies in 2nd Generation TriKEs®

- Camelidae family of mammals include llamas, camels, and alpacas
- Camelid antibody is made up of only 2 heavy chains
  - Heavy chain IgG (hcIgG)
  - Do not contain the CH1 region
  - Retain an antigen binding domain – V_HH region
- V_HH are known as single domain antibodies or nanobodies
  - Contain only the V_HH region from the camelid antibody
- 2nd Generation TriKE®s utilize nanobodies
- Advantages over 1st Generation TriKE®s (GTB-3550) include:
  - Improved potency and enhanced binding affinity
  - Commercial manufacturing capabilities through Cytovance
  - Proprietary molecule wholly owned by GT Biopharma
  - Similar preclinical safety profile

Source: www.rndsystems.com/products/llamabody-camelid-antibodies

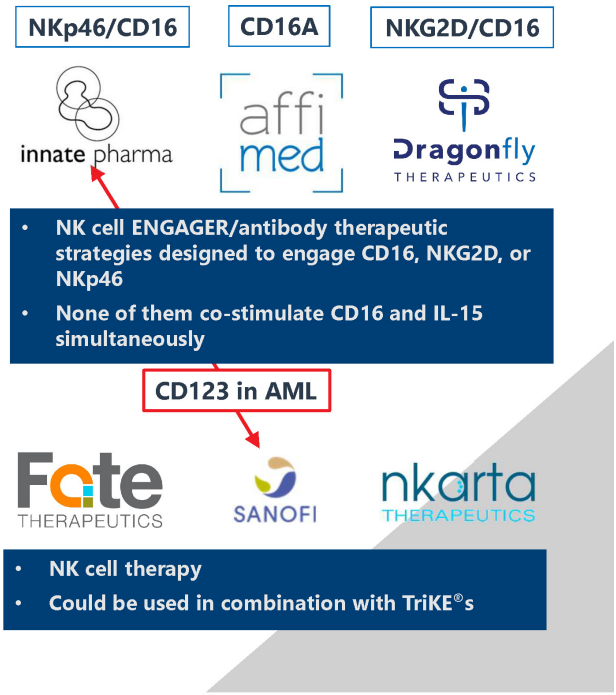




Our Approach – Co-Stimulation of CD16 and IL-15

TriKE® Competitive Differentiation

- The anti-CD16 component of the TriKE® binds FcRγIII with high affinity
- TriKE® does not result in proliferation of T-cells
- IL-15 provides NK cell specific proliferation with less bystander T-cell activity compared to the IL-15 protein itself
- IL-15 in TriKE® is less active surrounded by ENGAGERS than rhIL-15
- TriKE® can be targeted to heme malignancies, solid tumors and infectious diseases



GTB 7550 for Autoimmune Disease

Targeting CD19 for B-Cell Depletion In Vivo

GTB 7550 for Autoimmune Disease

- GTB-7550 TriKE® product candidate is in development for the treatment of lupus and other autoimmune disorders
- GTB-7550 TriKE® is a tri-specific molecule composed of a camelid nanobody that binds the CD16 receptor on NK cells, a scFv ENGAGER against CD19 on malignant and normal B cells, and a human IL-15 sequence between them
- Published data shows that GTB-7550 effectively targets CD19+ malignant cell lines and primary chronic lymphocytic leukemia (CLL)
- Preliminary data shows that GTB-7550 can target and eliminate normal B cells
- NSG mice will be used to test the ability of GTB-7550 to deplete normal B cells in vivo
- Exploring manufacturers for GTB-7550
- Quickest path to clinic may be testing safety in B cell malignancy first

GTB 7550 for Autoimmune Disease

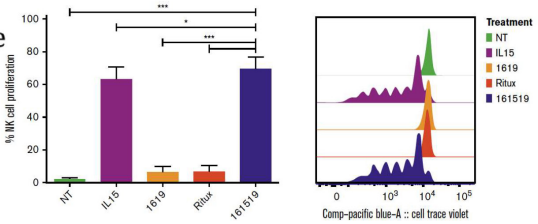
REGULAR ARTICLE

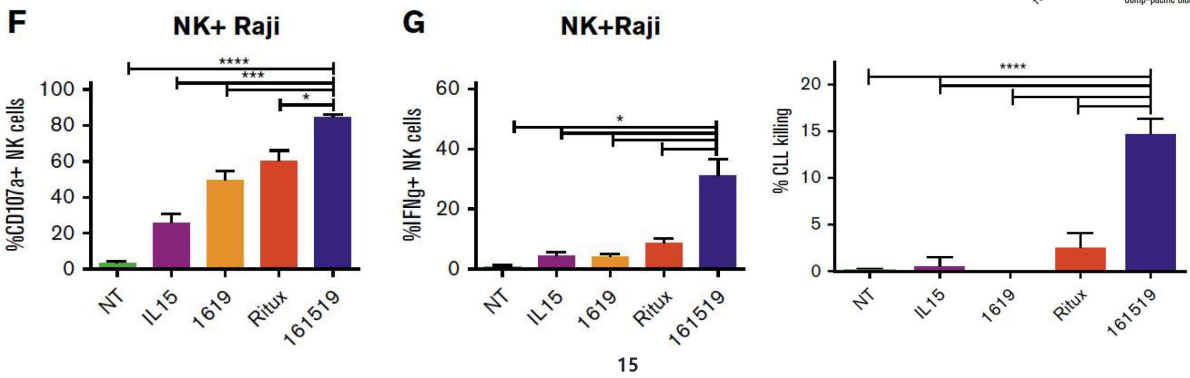
blood advances

Novel CD19-targeted TriKE restores NK cell function and proliferative capacity in CLL

Martin Felices,[1] Behiye Kodal,[1] Peter Hinderlie,[1] Michael F. Kaminski,[1] Sarah Cooley,[1] Daniel J. Weisdorf,[1] Daniel A. Vallera,[2] Jeffrey S. Miller,[1] and Veronika Bachanova[1]

[1]Division of Hematology, Oncology, and Transplantation, Department of Medicine, and [2]Department of Radiation Oncology, University of Minnesota, Minneapolis, MN





Investment Opportunity – Next Generation of NK Cell ENGAGERS

Proprietary TriKE® Platform – Camelid Nanobodies	• TriKE® are tri-specific NK cell ENGAGERS • Incorporate Camelid "nanobodies"
NK Cell ENGAGERS – Safer than T Cells[1]	• Protein therapeutics to harness the natural killing power of NK cells with – NOT NK cell therapy • Activates NK cells via CD16A and IL-15 while targeting tumor antigens • Potentially safer than T-cell immunotherapy
POC Established and Broad Applicability	• GTB-3550 (targeting CD33) showed POC in Phase 1 in AML patients • GTB-3650 will supplant 3550 as 2nd generation TriKE® with several advantages • TriKE®s target multiple tumor antigens including B7H3, HER2, CD33, PDL1
Multiple Catalysts	• 6+ pipeline assets in preclinical development, both solid tumors and hematological malignancies • IND for GTB-3650 accepted in June 2024, first patient dosed on Jan 21, 2025 • GTB-5550 IND submission expected H1 2025
Broad Indication Potential	• GTB-7550 TriKE® candidate in development for the treatment of lupus, other autoimmune disorders • Exploring manufacturers for GTB-7550
Well-funded Experienced Leadership	• Management team with deep expertise in all stages of oncology drug development • $6.5M in cash + short-term investments as of September 30, 2024 (unaudited), anticipated to be sufficient to fund operations into 2025, debt free balance sheet

1. Demaria, et.al. Eur J. of Immun; (2021)51:8; 1934

Contact Us

Michael Breen, Exec. Chairman & Interim CEO
Alan Urban, CFO
GT Biopharma, Inc.
315 Montgomery Street, 10th Floor
San Francisco, CA 94104
ir@gtbiopharma.com
415-919-4040

Investor Relations Contact:
Corey Davis, Ph.D.
LifeSci Advisors
cdavis@lifesciadvisors.com
212-915-2577

For more information, please visit: www.gtbiopharma.com

GT BIOPHARMA

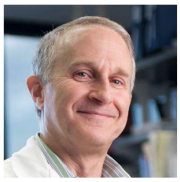
APPENDIX

Experienced Team With Deep Immuno-Oncology Experience

Proven Record in Biotech, Pharma, Product Development, Financing

Michael Breen, LL.B
Executive Chairman and Interim Chief Executive Officer

Alan Urban
Chief Financial Officer
CPA (Inactive)



Jeffrey Miller, MD
Consulting Senior Medical Director [1]

Martin Felices, PhD
Consulting Scientist

Chris Hendry
Consultant, CMC and Pharmaceutical Science

Bruce Wendel
Board of Directors
Compensation Committee Chair

Rajesh Shrotriya, MD
Board of Directors
Nominating and Corp. Gov. Committee Chair

Charles J Casamento
Board of Directors
Audit Committee Chair

BNP PARIBAS
INSINGER de BEAUFORT
CLYDE&CO
Research Solutions
infotrieve
REACHLOCAL
UNIVERSITY OF MINNESOTA
UNIVERSITY OF MINNESOTA
STC Biologics
Allena PHARMACEUTICALS
seragen
Hepalink
Bristol Myers Squibb
Abraxis BioScience
SPECTRUM PHARMACEUTICALS
SuperGen
MGi PHARMA
Bristol Myers Squibb
Indevus Pharmaceuticals, Inc.
SANOFI GENZYME

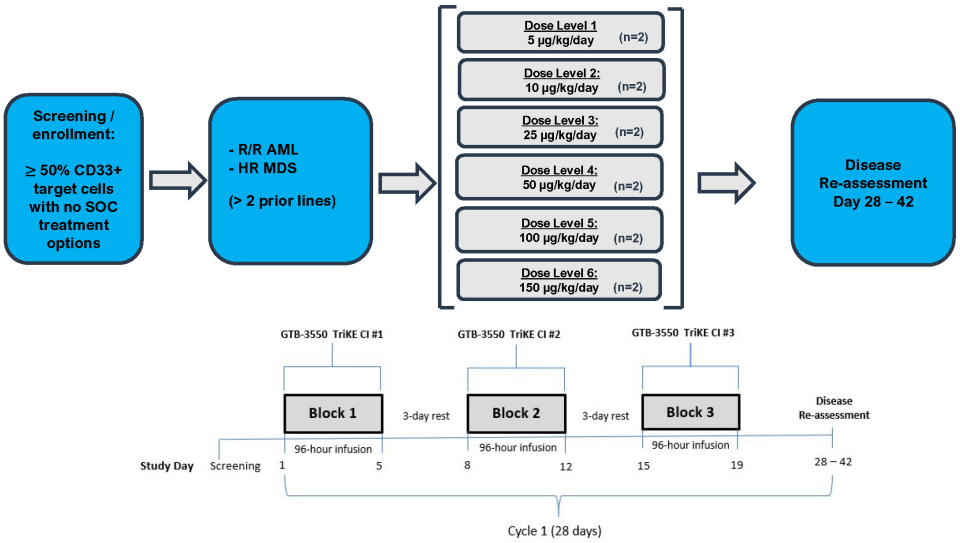
The University of Minnesota, pursuant to its license agreement with GT Biopharma, is entitled to receive royalties should commercial sales of GTB-3650 be realized. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

1. Dr. Miller is the Consulting Senior Medical Director at GT Biopharma and holds stock and options in GTBP.

Recent M&A and BD Deals Highlight Value of NK Cell ENGARERS and Immuno-Oncology

Innovator	AFFIMED	AFFIMED	AMUNIX	Dragonfly	innate pharma
Acquirer	SANOFI	ROIVANT SCIENCES	SANOFI	GILEAD	SANOFI
Date	8/27/2018	11/9/2020	12/21/2021	5/2/2022	12/19/22
Deal Type	License Deal	Single Molecule Preclinical License Deal	Company Acquisition	Single Molecule Preclinical License Deal	Collaboration Expansion License Deal
Key Deal Terms	• $96M upfront • $5B in additional milestones	• $60M upfront • $2B in milestones	• $1 billion upfront • $225M in milestones	• $300M cash upfront • Undisclosed milestones • 20% royalties	• €25M upfront • €1.3B in milestones • Royalties
Technology / Mechanism	Redirected Optimized Cell Killing (ROCK®) platform to generate both NK cell and T cell-engaging antibodies	ROCK® platform generates tetravalent, bispecific antibodies as innate cell ENGAGERS (ICE®) customized to target specific domains on hematologic and solid tumor cells	• Portfolio of T cell ENGAGERS using XTEN technology • Lead asset AMX-818 in pre-clinicals	• NK-cell ENGAGER • DF7001 is a TriNKET designed to activate and direct NK and cytotoxic T cell killing of cancer cells	• NK cell ENGAGER • Targeting B7H3 • ANKET™ platform • Option to add 2 additional targets
Rationale	Allowed Roche access to Affimed platform to explore range of ENGAGER constructs for multiple oncology applications	Grants Roivant a license to the preclinical molecule AFM32	Combine Amunix's complementary molecules with Sanofi's immuno-oncology portfolio	Enhance Gilead's portfolio with complementary MOAs and scientific rationale for combination opportunities	Allogeneic NK cell immunotherapy is pillar of Sanofi's overall oncology strategy and using engineered lymphokines to stimulate NK cells is a key component

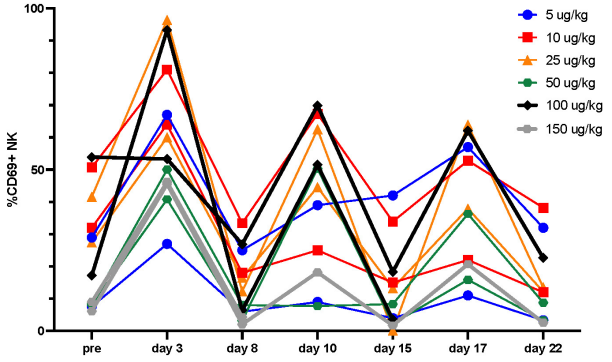
GTB-3550 AML/MDS Phase 1 Study Design



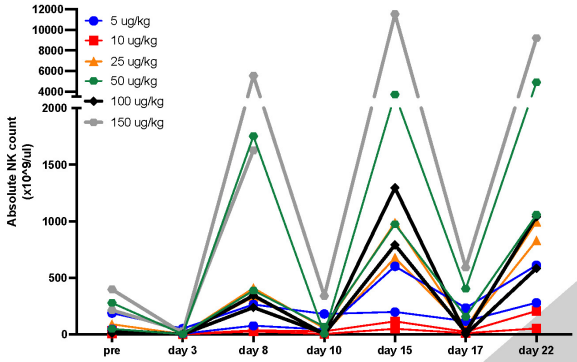
Phase 1 (safety and dose finding)
- **Six dose levels**
- **Escalation based on continual reassessment method; Cohorts of 2 subjects**
- **Day 28 (end of DLT assessment period)**

GTB-3550 Activation of Endogenous NK Cells

Panel A: Increase in NK cell activation upon administration of GTB-3550 (n= 2 patients per dose)



Panel B: Increase in absolute number of NK cells during treatment (n= 2 patients per dose)



Source: Data on File, GT Biopharma, Inc.

GTB-3550 First in Human Phase 1 Clinical Trial – Individual Results

Subject	Dose level (µg/kg/d)	Disease and Prior Treatment History	Disease Characteristics Before GTB-3550 Therapy	Disease Characteristics After GTB-3550 Therapy	Response Post Cycle 1
1	5	r/r AML. Triple Hit Lymphoma - 6 therapies: 1. R-EPOCHx6, 2. RICE x3, 3. XRT to abdominal lymphadenopathy, 4. NAM-NK Clinical Trial, 5. CAR-T, 6. andi-CD20 and Anti-CD3 monoclonal antibody clinical trial	Cellularity: 10% Blast: 5 – 10%	Cellularity: 10 – 30% Blast: 10%	Stable AML with improved platelet transfusion needs
2	5	r/r AML. AML- 3 therapies before TriKE: 1. Vyxeos + Midostaurin 2. FLAG-IDA + midostaurin 3. Decitabine + Gilteritinib	Cellularity: 70 – 80% Blast: 7%	Cellularity: 90 – 95% Blast: 94%	Progression
3	10	r/r AML. AML- 3 therapies before TriKE: 1. Azacitidine, 2. Enasidenib, 3. Hydrea	Cellularity: 100% Blast: 85%	Cellularity: 100% Blast: 92%	Stable AML
4	10	t-MDS. Multiple Myeloma - 5 therapies: 1. CyBorD, 2. Bortezomib, 3. Dexamethasone + lenalidomide + idazomib, 4. Daratumumab + Pomalidomide + Dexamethasone, 5. Dara maintenance	Cellularity: 5% Blast: 5.5%	Cellularity: 5% Blast: 20%	Stable MDS
5	25 33% reduction in blast count	Secondary AML, progressed from MDS.	Cellularity: 10 – 15% Blast: 18%	Cellularity: 20% Blast: 12%	Blast count reduction, improved platelet needs
6	25	r/r AML. 2 therapies before TriKE: 1. 7+3 with CR1 then relapse, 2. Azacitidine + Venetoclax	Cellularity: 10 – 20% Blast: 29%	Cellularity: 10 – 20% Blast: 35%	Mild blast increase
7	50 61.7% reduction in blast count	HR MDS. MDS - 3 therapies: 1. Decitabine, 2. Luspatercept, 3. Decitabine 10 day	Cellularity: 70 – 80% Blast: 12%	Cellularity: 60% Blast: 4.6%	Partial remission
8	50	HR MDS. MDS - 3 therapies before TriKE1. Azacitidine, 2. NMA DUCBT, CR1 for 7 years before relapse 3. Azacitidine - CR2 then relapse	Cellularity: 20% Blast: 12%	Cellularity: 30% Blast: 19%	Mild blast increase
9	100 63.6% reduction in blast count	High Grade MDS- 1. Azacitidine. 2. Decitabine, 3. 7+3, 4. Allo transplant with CR then relapse and progression to AML then no response to Decitabine + Venetoclax	Cellularity: 20% Blast: 22%	Cellularity: 10 – 20% Blast: 8%	Partial remission
10	100	r/r AML. Breast Cancer: 4 therapies: 1. Masectomy/LN dissection, 2. XRT, 3. Adriamycin/Cyclophosphamide, 4. Taxol.	Cellularity: 10% Blast: 17%	Cellularity: 40% Blast: 31%	Stable AML
11	150 50% reduction in CD33+ blast count	DLBCL - 3 therapies 1. R-DA-EPOCH, 2. Auto Transplant, 3. ADAM-17+Rituximab, Therapy-related MDS: 2 therapies: 1. Azacitidine, 2. Allo transplant -- CR, Relapse/transformed to AML (bi-phenotypic) - 1 therapy before TriKE: 1. Venetoclax + Decitabine x 2 cycles	Cellularity: 25% Blast: 80%	Cellularity: 80% Blast: 73%	Blast reduction by FLOW
12	150	r/r AML - 2 therapies: 1. FLAG-IDA + venetoclax, 2. Decitabine	Cellularity: 30 – 40% Blast: 36%	Cellularity: 60 % Blast: 64%	Disease Progression

Selected Financial Information

ASSETS	UNAUDITED AS OF SEPT 30, 2024	AUDITED AS OF DEC 31, 2023
Cash + Short Term Investments	$ 6,511,000	$ 13,972,000
Other Assets	248,000	137,000
Total Assets	6,759,000	14,109,000
LIABILITIES		
Accounts Payable + Accrued Expenses	$ 4,480,000	$ 5,523,000
Other Liabilities	-	58,000
Warrant Liability	182,000	1,052,000
Total Liabilities	4,662,000	6,633,000
STOCKHOLDERS' EQUITY		
Total Stockholders' Equity	$ 2,097,000	$ 7,476,000

Capitalization Table

SECURITY	AS OF DEC 31, 2024	WEIGHTED AVERAGE EXERCISE PRICE	PERCENTAGE FULLY DILUTED
Common Stock Outstanding	2,234,328	N/A	64%
Legacy Warrants	291,629	$59.72	8%
2024 Warrants	828,800	$4.47	24%
Stock Options	124,600	$32.69	4%
Fully Diluted Shares	3,479,375		100%

MAJOR SHAREHOLDERS	AS OF DEC 31, 2024	SECURITY	PERCENTAGE OF COMMON STOCK OUTSTANDING
Cytovance Biologics, Inc.	219,457	Common Stock	9.8%
Robert A. Marzilli	200,000	Common Stock	8.9%