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)
September 13, 2021

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.)

9350 Wilshire Blvd., Suite 203
Beverly Hills, CA 90212
(Address of Principal Executive Offices and zip code)

(800) 304-9888(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 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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.

On September 13, 2021, the Registrant's will present information regarding the Registrant's business via teleconference. The Registrant's presentation for such teleconference as of September 13, 2021 is filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	GT Biopharma, Inc. Presentation as of September 10, 2021.

SIGNATURE

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: September 13, 2021

By: /s/ Michael Handelman
Michael Handelman
Chief Financial Officer

EXHIBIT 99.1

Target Directed NK Cell Immunotherapy

NASDAQ: GTBP

10 September 2021

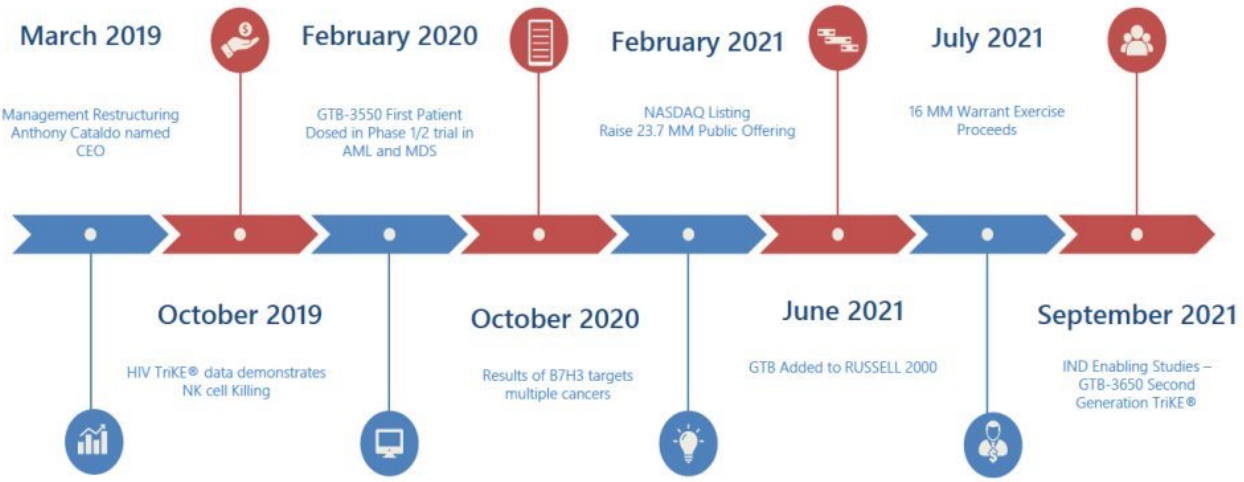
Non-Confidential

FORWARD LOOKING STATEMENT

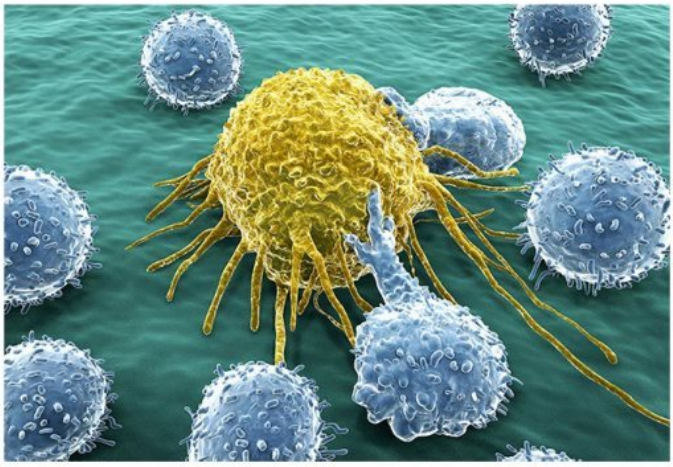
This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "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. You are cautioned not to place undue reliance upon such forward looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We direct you to our Annual Report on Form 10-K for the year ended December 31, 2020, our subsequent current reports on Form 8-K, our Quarterly Report on Form 10-Q for the quarter ended, and our other filings with the Securities and Exchange Commission. 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.

This presentation is made pursuant to Rule 163B under the Securities Act of 1933, as amended, and is intended solely for investors that are either qualified institutional buyers or institutions that are accredited investors (as such terms are defined under Securities and Exchange Commission rules) solely for the purpose of determining whether such investors might have an interest in a securities offering contemplated by us. Any such offering of securities will only be made by means of a registration statement (including a prospectus) filed with the Securities and Exchange Commission, after such registration statement becomes effective. No such registration statement has become effective as of the date of this presentation. 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. 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.

GT BioPharma Recent Major Milestones



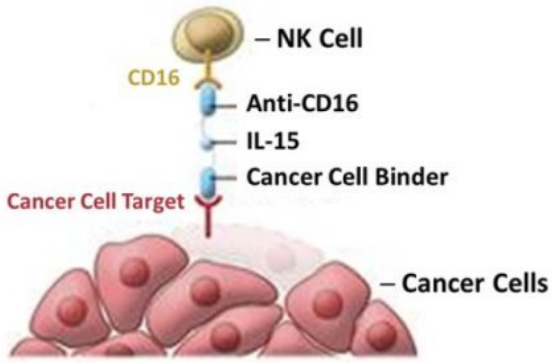
COMPANY FOCUS – HARNESSING NATURAL KILLER CELLS TO FIGHT CANCER



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
https://www.dana-farber.org/newsroom/publications/paths-of-progress-2019/natural-killer-cells/

- Restore patient's exhausted/inhibited endogenous NK cell population to again recognize and kill cancer cells.
- Natural Killer (NK) cells are cytotoxic lymphocytes of the innate immune system.
- NK cells are analogous to cytotoxic T-cells of the adaptive immune system.
- NK cells are early responders that recognizes and kills stressed cells in the absence of antibodies.
- Minimize toxicities such as cytokine release syndrome (CRS) resulting from hyperactivation of T-cells.
- TriKE® is an immune oncology protein therapeutic which activates NK cells, and directs them to specific cancer cell targets. TriKE® is not a cell therapy.

WHAT IS A TRIKE® THERAPEUTIC?



Key Therapeutic Features:

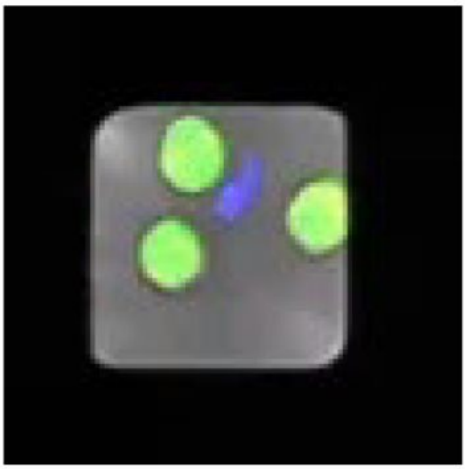
- Target-directed ADCC killing.
- Integrated cytokine support within the tumor micro-environment (TME).
- Simultaneous NK cell ADCC activation, proliferation and persistence.
- First-in-Class modular immune oncology protein therapeutic platform technology.

* Persistence means the ability of an NK cell population to exist at activated levels in the body for periods of several weeks, with each activated NK cell able to mediate the serial killing of multiple cancer cells.

TriKE® Product Candidate Pipeline

TriKE® Product Candidates	Approach	Indication	Stage					Status
			Pre-Clinical	GMP Manufacturing	Phase 1	Phase 2	Phase 3	
GTB-3550	Monotherapy	Leukemia – AML, MDS						Phase 1
GTB-3650 2nd Generation Camelid	Monotherapy	Leukemia – AML, MDS, MRD						Pre-IND
	Combination with Chemotherapy	Leukemia – AML, MDS, MRD						Pre-IND
GTB-4550 Camelid	Monotherapy & Combination	PD-L1 / Solid Tumor Cancers						Pre-IND
GTB-5550 Camelid	Monotherapy & Combination	B7H3 / Solid Tumor Cancers						Pre-IND
GTB-6550 Camelid	Monotherapy & Combination	HER2 / Breast & Gastric Cancers						Pre-IND
Other Undisclosed Candidates	Monotherapy & Combination	Solid tumors & Infectious Disease						Pre-IND

TriKE® Directed NK Cell Serial Killing of AML Cancer Cells

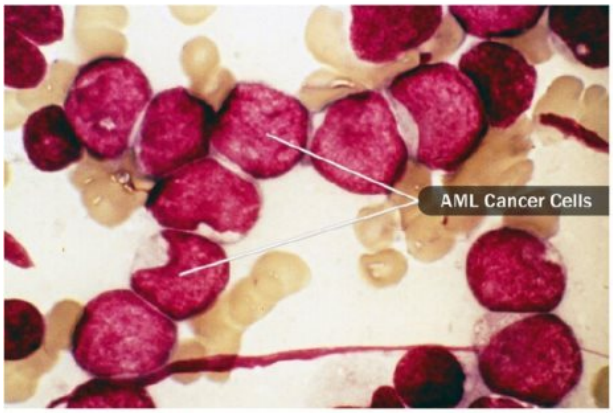


Enhanced Serial Killing of Cancer cells (green) by TriKE directed NK cell (blue).

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

- Integrated CD16 and IL-15 in TriKE drives:
  - NK cell ADCC activation for enhanced serial killing of cancer cells
  - NK cell proliferation
  - NK cell persistence
- TriKE minimizes toxicities such as cytokine release syndrome (CRS) resulting from hyperactivation of T-cells.
- TriKE therapeutics can be used to treat solid tumors and hematological cancers.
- TriKE is an immune oncology protein therapeutic – not a cell therapy.

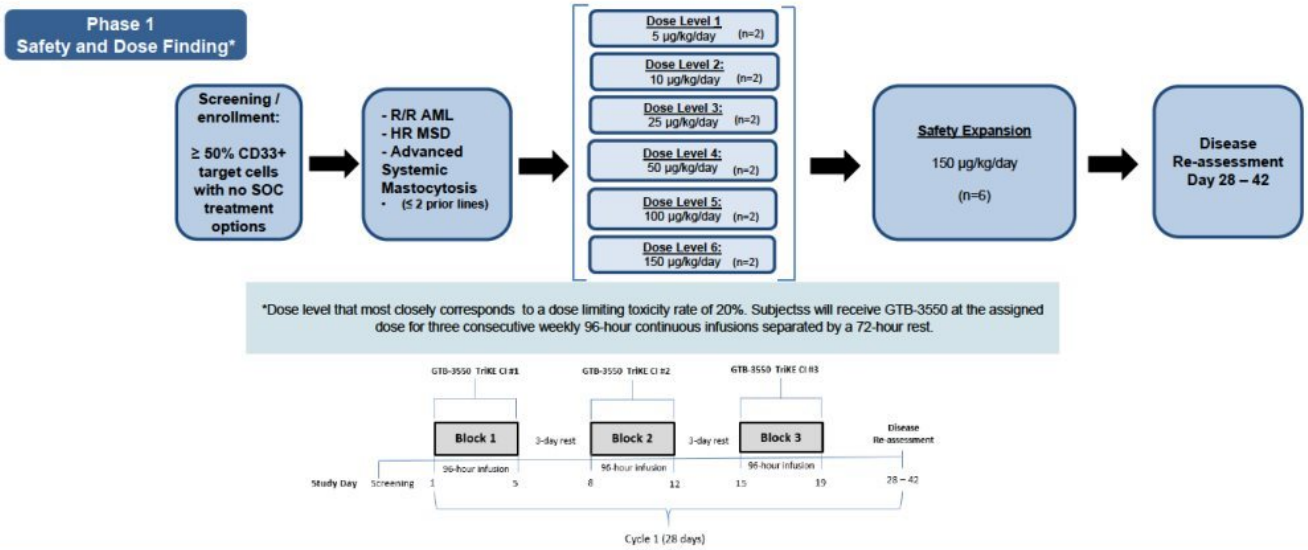
GTB-3550 TriKE® Product Candidate



Source: Pr. J Bernard/CNRI/Science Source

- First-in-Class immune oncology therapy.
- Target-directed NK cell ADCC killing of CD33+ hematological cancers.
- Incorporates IL-15 within therapeutic for enhanced NK cell proliferation and persistence.
- Currently being evaluated in a First-in-Human Phase 1 clinical trial.

TRIKE® GTB-3550 PHASE 1 STUDY DESIGN



*Dose level that most closely corresponds to a dose limiting toxicity rate of 20%. Subjectss will receive GTB-3550 at the assigned dose for three consecutive weekly 96-hour continuous infusions separated by a 72-hour rest.

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)

Phase 1 Safety Expansion
- **Primary Endpoints**: Determine safety and maximum tolerated dose, RP2D and schedule
- **Secondary Endpoints**: Estimate OS at 6 months
- **Exploratory Endpoints**: Number, activation status, and function of NK cells, T-cells, T-regs, and MDSC pre and post therapy (CD16 and CD62L)

GTB-3550 TriKE® First-in-Human Clinical Trial Interim Results

Patient	Dose Level	Disease and Prior Treatment History	Disease Characteristics Before GTB-3550 Therapy	Disease Characteristics After GTB-3550 Therapy
1	5 mcg/kg/day	Therapy-related AML. Failed 3 lines of induction therapy.	Cellularity: 10% Blasts: 5-10%	Cellularity: 10-20% Blasts: 10%
2	5 mcg/kg/day	AML w/ FLT-3 ITD mutation. Induction therapy x2, with CRi. Relapse, then 2x therapy with refractory disease.	Cellularity: 70-80% Blasts: 5-7%	Cellularity: 90-95% Blasts: 94%
3	10 mcg/kg/day	AML. Azacitidine x1 year with disease control before progression. Brief remission with Venetoclax + cytarabine. No response to IDH2 inhibitor.	Cellularity: 100% Blasts: 85%	Cellularity: 100% Blasts: 92%
4	10 mcg/kg/day	Therapy-related MDS. Residual disease after HMA and HMA+ Venetoclax.	Cellularity: < 5% Blasts: 10-20%	Cellularity: < 5% Blasts: 10-20%
5	25 mcg/kg/day	Secondary AML. 18 month CR with Venetoclax + Azacitidine prior to relapse. Unique FLT-3 mutation not responsive to Gilterinib.	Cellularity: 10-15% ***Blasts: 18%***	Cellularity: 20% ***Blasts: 12%***
6	25 mcg/kg/day	AML. Failed reinduction with Ventoclax and HMA	Cellularity: 10-25% Blasts: 29%	Cellularity: 10-20% Blasts: 35%
7	50 mcg/kg/day	MDS/MPN with Red Cell transfusion dependence post HMA and Luspatercept	Cellularity: 70-80% ***Blasts: 12%***	Cellularity: 60% ***Blasts: 4.6%***
8	50 mcg/kg/day	High Grade MDS. 7 year remission post UCB HCT.	Cellularity: 20%	Cellularity: 30%
		Post-HCT relapse treated with Azacitidine Remission duration: 1 year prior to disease progression	Blasts: 12%	Blasts: 19%
		Concurrent asymptomatic smoldering myeloma	Concurrent smoldering myeloma 20% plasma cells	Concurrent smoldering myeloma with 20-25% plasma cells
9	100 mcg/kg/day	High Grade MDS: Azacitidine, Decitabine, 7+3, MUD RIC HCT Relapse Day +100, Progression to AML, Lack of Response to Decitabine + Venetoclax	Cellularity: 10% ***Blasts: 22%***	Cellularity: 10-20% ***Blasts: 8%***

Clinical Efficacy Demonstrated:

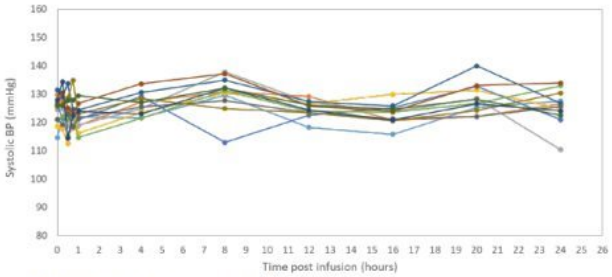
- **Subject 5: 33.3% Reduction in Blast Levels**
- **Subject 7: 61.7% Reduction in Blast Levels**
- **Subject 9: 63.6% Reduction in Blast Levels**

GTB-3550 TriKE® Is Well Tolerated By Subjects Enrolled

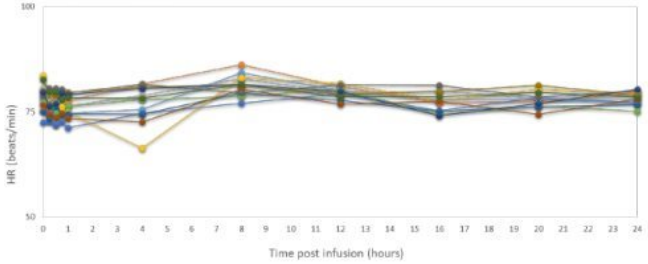
Panel A: **Dose Equivalent of GTB-3550 and Systemic Maximum Therapeutic Dose of IL-15**

PER MOLE BASIS	
Dose of GTB-3550 (µg/kg)	**Fold Higher than MTD rhIL-15**
5	0.54
10	1.08
25	2.69
50	5.38
100	10.75
150	16.13

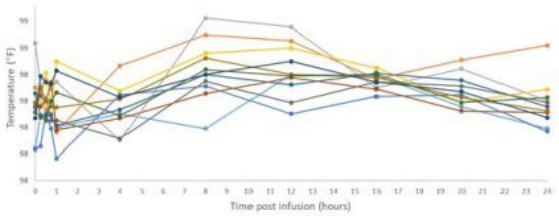
Panel B: **Systolic Blood Pressure**



Panel C: **Heart Rate**



Panel D: **Body Temperature**

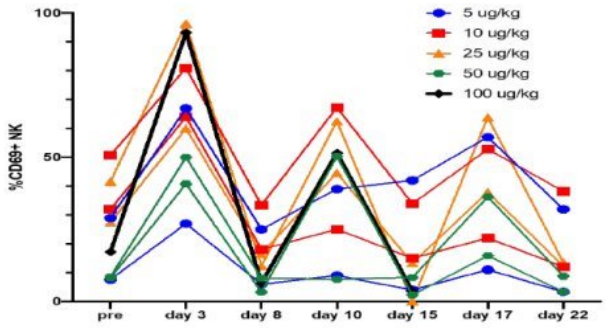


Data cut: OnCore DB 26 July 21

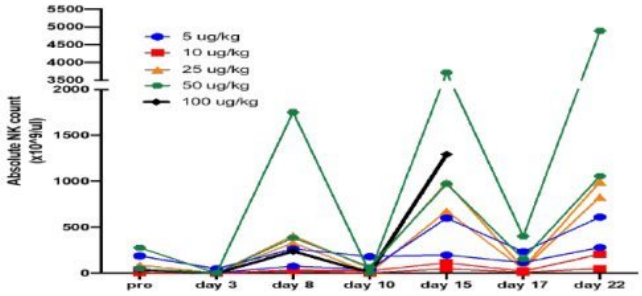
GTB-3550 TriKE® First-in-Human Clinical Trial Interim Results

TriKE® activates endogenous NK cells in the periphery and they egress into tissues

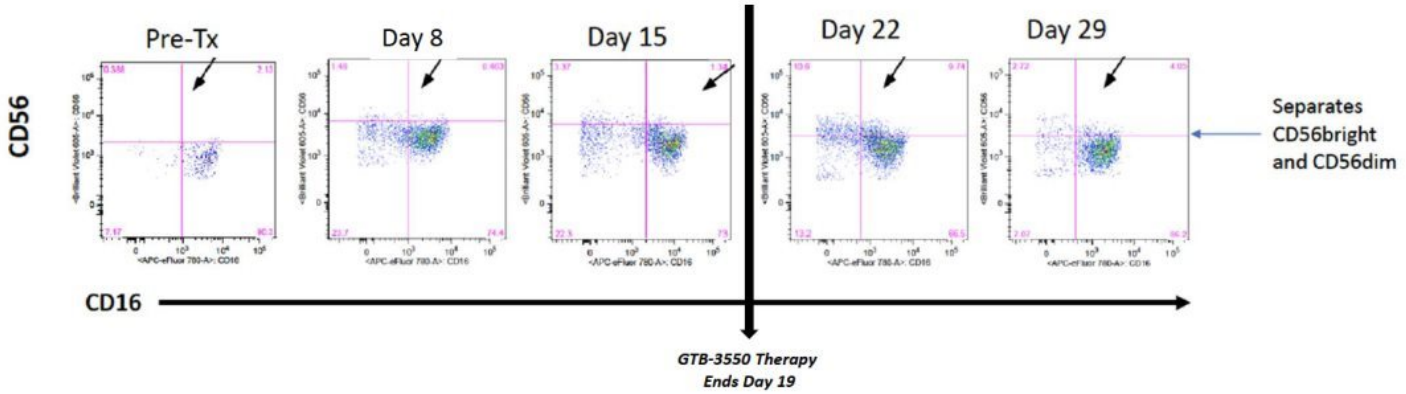
Panel A: Increase in NK cell activation upon administration of GTB-3550.



Panel B: Increase in absolute number of NK cells during treatment.



No Loss of CD16 During GTB-3550 Therapy



Data from Subject #7 treated with 50 µg/kg/day

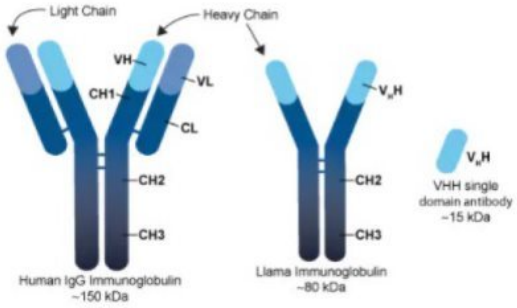
GTB-3550 TriKE® First-in-Human Clinical Trial Interim Results

- GTB-3550 TriKE induces reproducible NK cell proliferation in all subjects at all dose levels evaluated with no clinically significant toxicity. No CRS resulting from hyperactivation of subject's T-cell population at doses 5 – 100 µg/kg/day.
- Clinical responses to date demonstrate strong NK cell activation, persistence, proliferation and targeted cancer cell killing.
- GTB-3550 significantly reduced bone marrow blast levels 33.3%, 61.7% and 63.6%, in Subject 5 (25 µg/kg/day), Subject 7 (50 µg/kg/day), and Subject 9 (100 µg/kg/day), respectively.
- No loss in CD16 expression on subject's NK cells. No need for supplemental NK cell therapy.

CAMELID ANTIBODIES – SECOND GENERATION TRIKE®

- Camelid antibodies are antibodies from the Camelidae family of mammals that include llamas, camels, and alpacas.
- Camelid antibody is made up of only 2 heavy chains. This is known as heavy chain IgG (hcIgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the V_HH region.
- V_HH antibodies, also known as single domain antibodies or Nanobodies®, contain only the V_HH region from the camelid antibody.

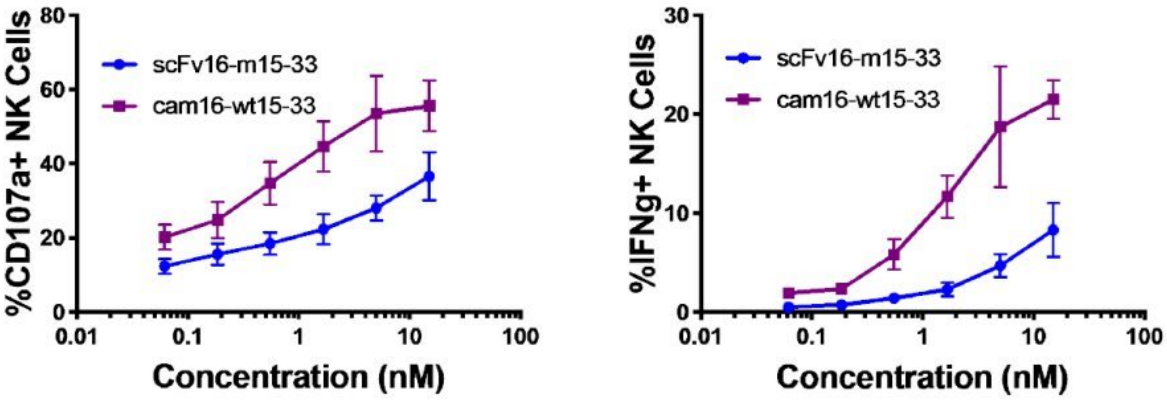
- Therapeutic and Commercial Advantages of GTB-3650 as compared to first generation GTB-3550
  - Improved potency and enhanced binding affinity
  - Commercial manufacturing capabilities through Cytovance
  - Proprietary molecule wholly owned by GT Biopharma
  - Similar preclinical safety profile



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

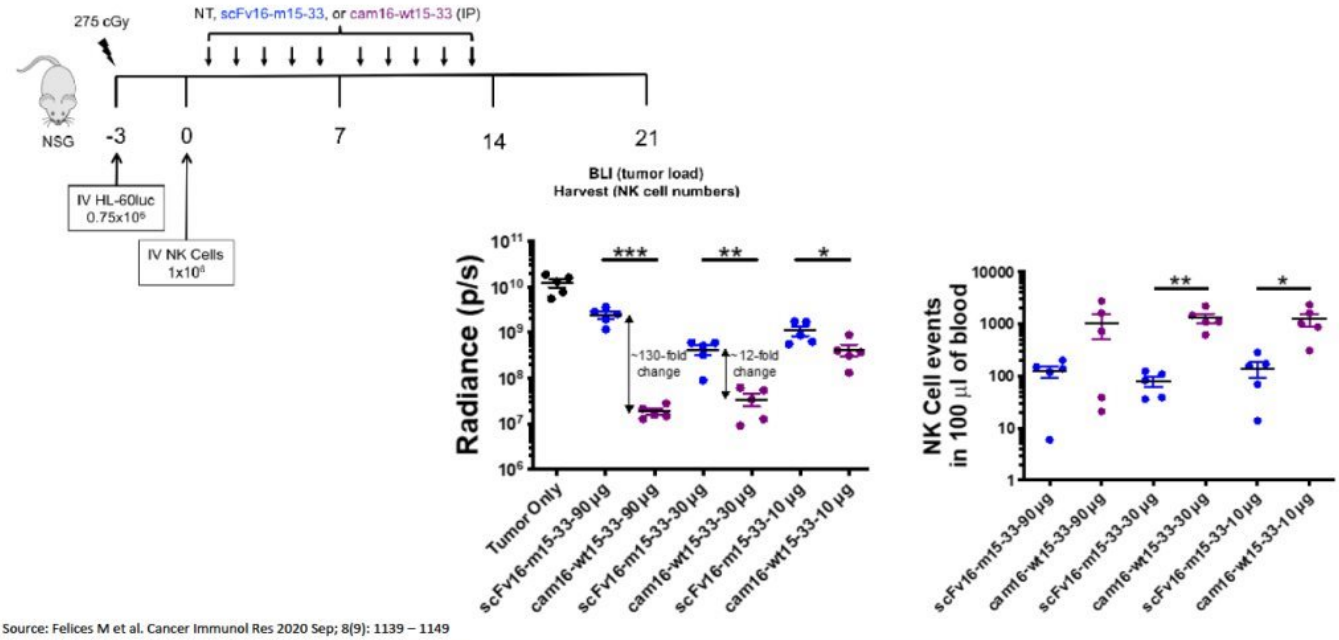
SECOND GENERATION TRIKE® (CAMELID) IMPROVES NK FUNCTION

CD 33+ HL60 Targets



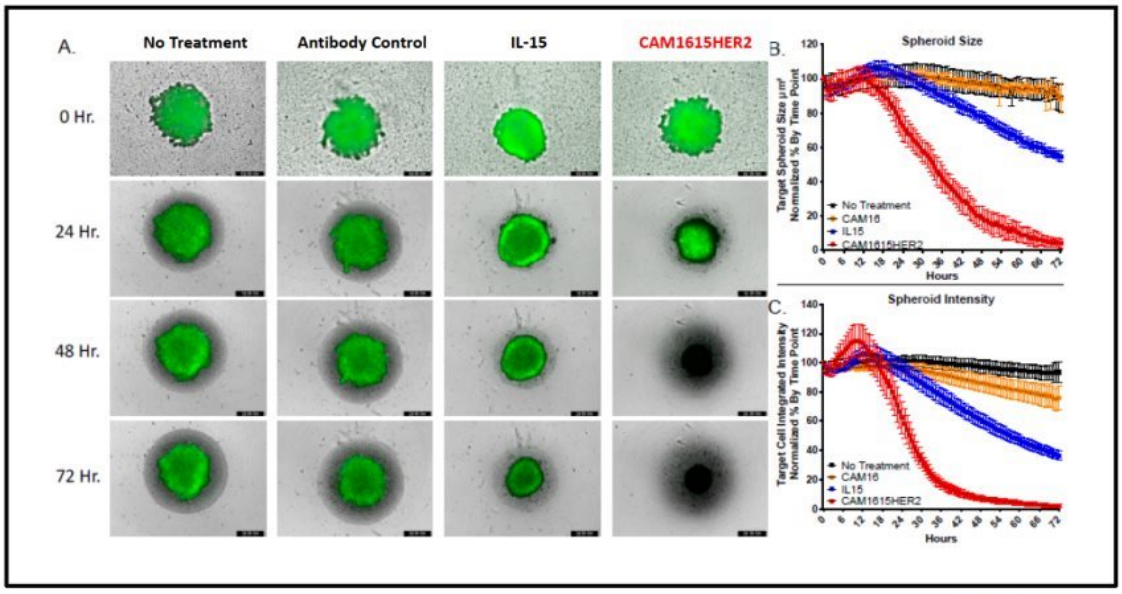
Source: Felices M et al. Cancer Immunol Res 2020 Sep; 8(9): 1139 – 1149

SECOND GENERATION TRIKE® (CAMELID) SUPERIOR IN-VIVO



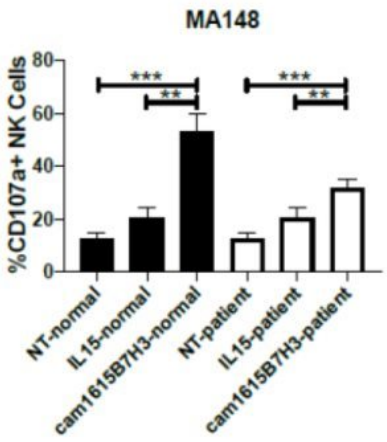
Source: Felices M et al. Cancer Immunol Res 2020 Sep; 8(9): 1139 – 1149

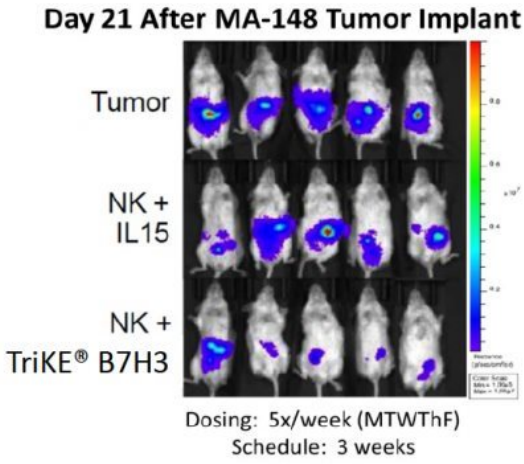
SECOND GENERATION TRIKE® (CAMELID) HIGHLY EFFECTIVE AGAINST HER2+ TUMORS



Source: Vallera DA et al. Cancer 2021 Aug 8; 13(16):3994

PIPELINE TRIKE® B7H3: MULTI-CANCER STRATEGY



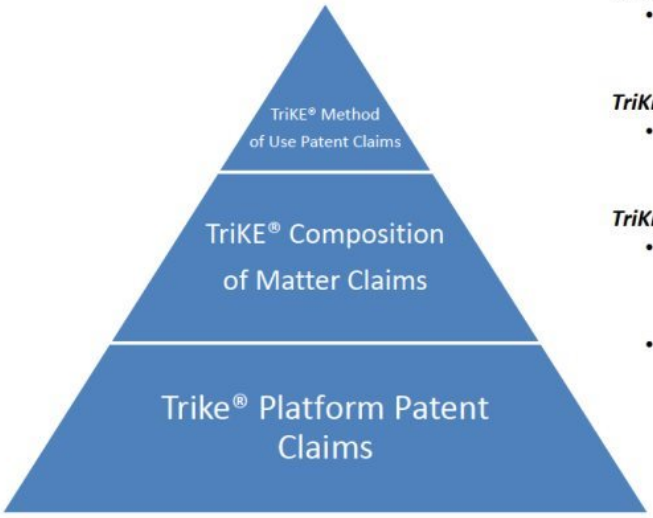


Dosing: 5x/week (MTWThF)
Schedule: 3 weeks

Significant killing of MA148 Ovarian Cancer by TriKE® B7H3

Source: Vallera DA et al. Cancer 2020 Sep 18;12(9):2659

MULTI-LAYERED PATENT STRATEGY



TriKE® Method of Use Patent Claims

- Methods of use claims highlighting coverage for oncology and infectious disease therapeutic applications.

TriKE® Composition of Matter Patent Claims

- Composition of matter claims covering DNA and amino acid sequences for all TriKE™ therapeutic product opportunities.

TriKE® Platform Patent Claims

- Claims focused on simultaneously engaging and activating NK cells using a single therapeutic construct incorporating IL-15 to minimize toxicity and the need for co-administration of IL-15.
- Claims focused on target-directed NK cell killing and IL-15 trafficking to TME.

Two New Patents Issued (24 August 2021) Covering TriKE® Platform

1. Patent No. 11,098,100 – broad coverage for CD16, IL-15, and any targeting domain
2. Patent No. 11,098,101 – broad coverage for any HIV target antigen

COMPETITION

TriKE® Competitive Advantages

- The anti-CD16 component of the TriKE binds FcRγIII at high affinity compared to ADCC mediated strategies that bind at low affinity.
- CD16 +/- other receptor engagement does not result in proliferation of T-cells contributing to CRS.
- IL-15 provides NK cell specific proliferation with less bystander activity and has a greater safety profile than cytokine therapy.
- TriKE can be targeted to heme malignancies, solid tumors and infectious diseases.
- Overall therapeutic regimen costs the same as today's antibody therapies.

innate pharma affimed Dragonfly THERAPEUTICS

NK cell engager/antibody therapeutic strategies designed to engage CD16, NKG2D, or NKp30, but none of them co-stimulate CD16 and IL-15 simultaneously.

Fate THERAPEUTICS nkarta THERAPEUTICS

NK cell therapy. Significantly more expensive.

EXPERIENCED MANAGEMENT TEAM

PROVEN RECORD IN BIOTECH, PHARMA, PRODUCT DEVELOPMENT, FINANCING

Anthony Cataldo
Chairman and Chief Executive Officer

IOVANCE CALYPTE

Gregory Berk, MD
President R&D and Chief Medical Officer

celularity Verastem intellikine SIDERIS Abraxis BioScience

Michael Handelman, CPA
Chief Financial Officer

IOVANCE OXIS

Jeffrey Miller, MD
Chief Scientific Officer, Consultant

UNIVERSITY OF MINNESOTA
Driven to Discover℠

Gavin Choy, PharmD, MBA
Chief, Clinical Development Officer

CrystalGenomics apollomics astex pharmaceuticals GILEAD

Stacy Herb, MPH, MBA
SVP, Portfolio Management

celularity Celgene

Target Directed NK Cell Immunotherapy

NASDAQ: GTBP

10 September 2021

Non-Confidential