GT BIOPHARMA

Clinical Stage Company

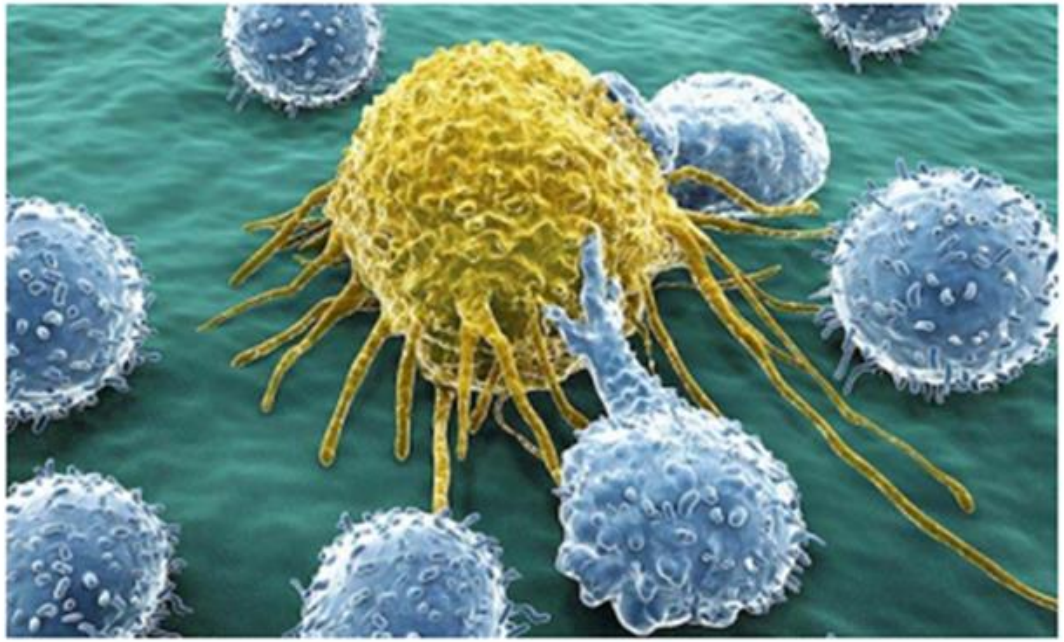
OTCQB: GTBP and Euronext/OTCMKTS: GTBP.PA

August 2020

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 or 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, 2019, our subsequent current reports on Form 8-K 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.

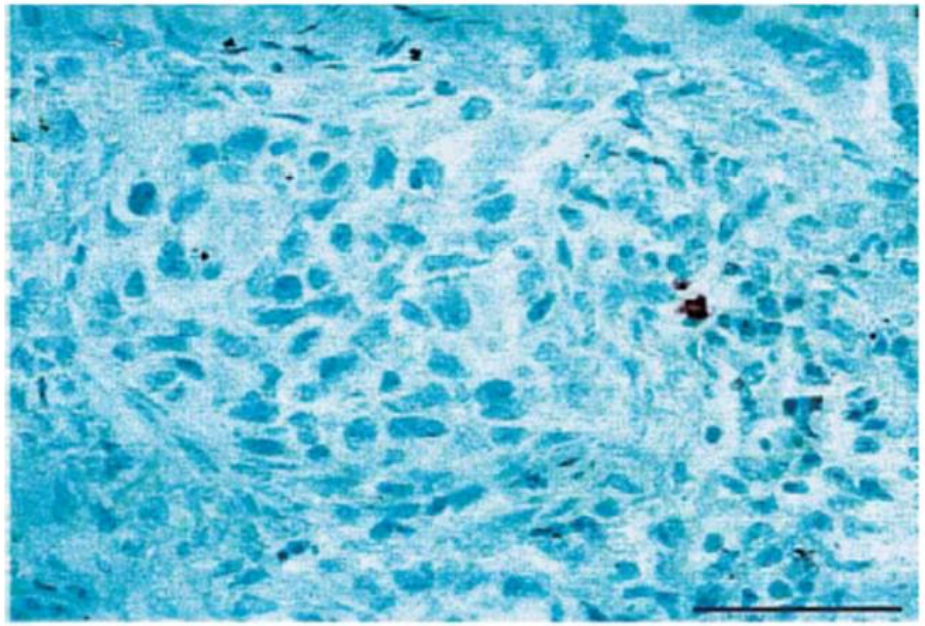
COMPANY FOCUS – HARNESSING NATURAL KILLER CELLS TO FIGHT CANCER



- Natural Killer (NK) cells are cytotoxic lymphocytes of the innate immune system.
- Analogous to cytotoxic T-cells of the adaptive immune system.
- Early responder that recognizes and kills stressed cells in the absence of antibodies and MHC antigen presentation, allowing for a much faster immune response.
- Cancer cells missing MHC markers cannot be detected and destroyed by other immune cells, such as T-cells.

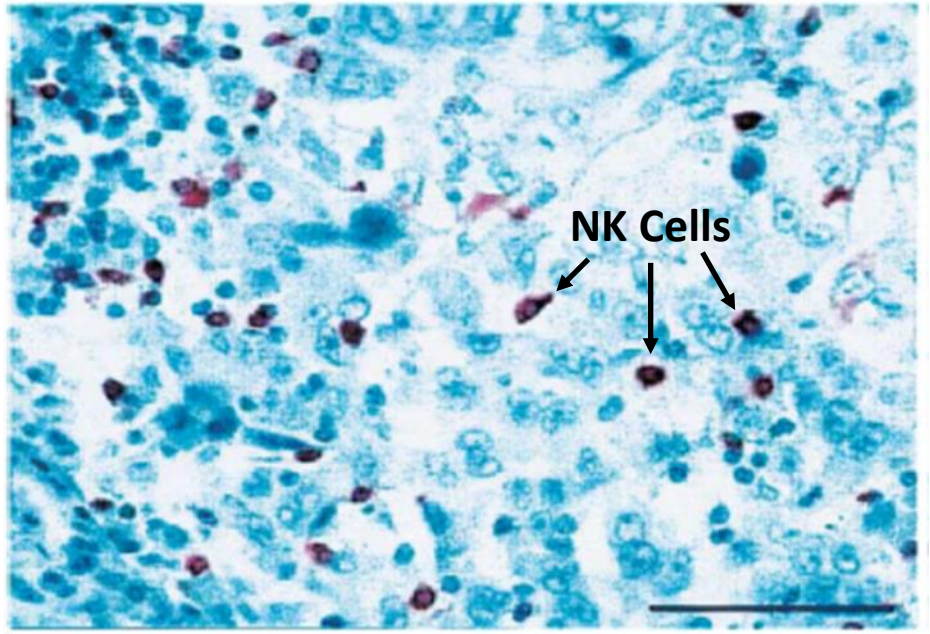
NK Cells Infiltrate Tumors

Low NK Cell Infiltration



Male, 74 years of, ex-smoker. Peripheral squamous cell lung cancer, stage IB. Time survival at follow-up of 37 months (died).

High NK Cell Infiltration

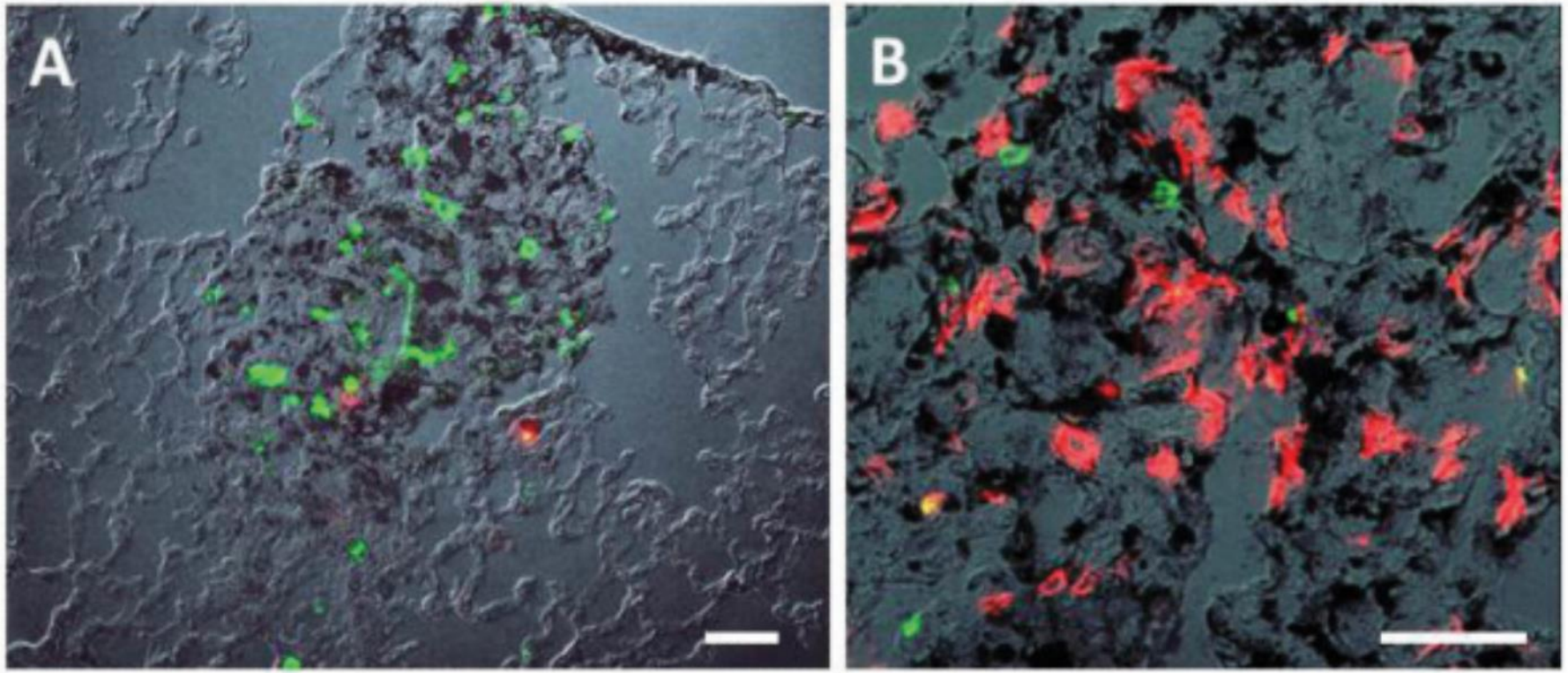


Male, 75 years old, ex-smoker. Central squamous cell lung cancer, stage IB. Time survival at follow-up of 139 months (still alive).

NK cell infiltration of tumors improves patient outcomes and survival.

F.R. Villegas et al., Lung Cancer 35 (2002) 23–28

THERAPEUTIC STRATEGY



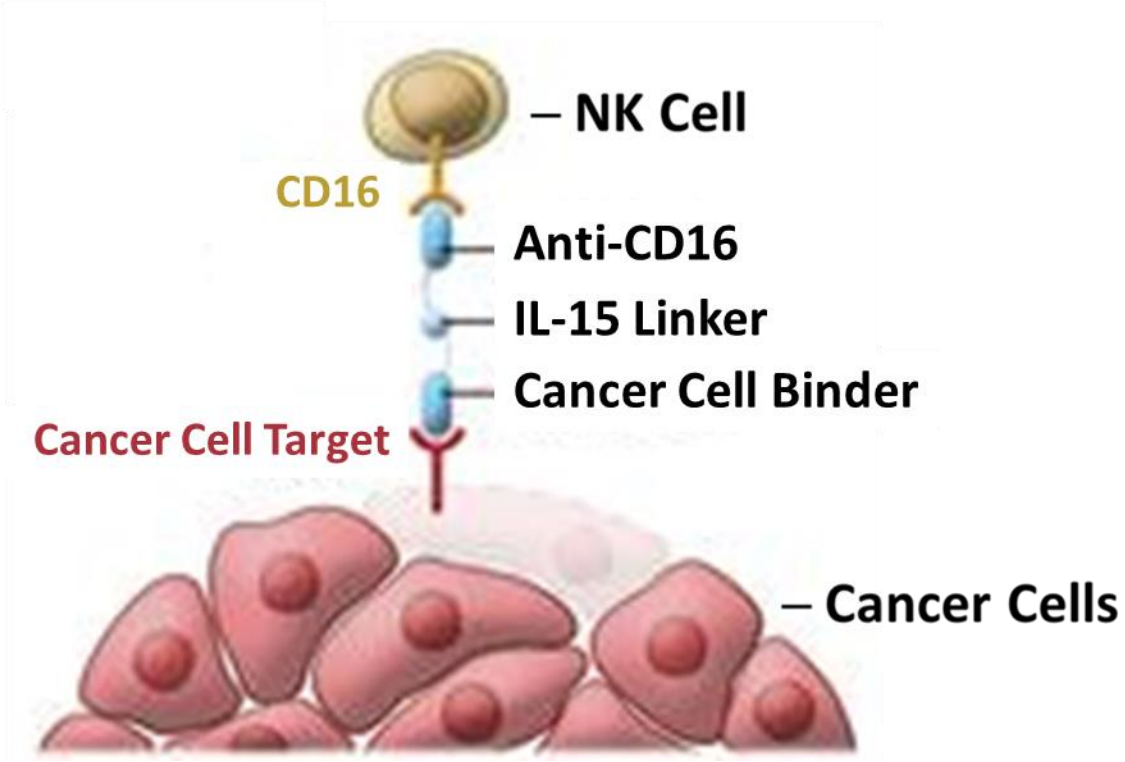
A: No NK cell proliferation within the TME.

B: NK cell (red) proliferation within the TME.

Enhance tumor cell killing by increasing the number of ADCC activated, target-directed cytotoxic NK cells within the tumor microenvironment.

Larsen, S., Crit Rev Oncog. (2014) 19(0): 91–105

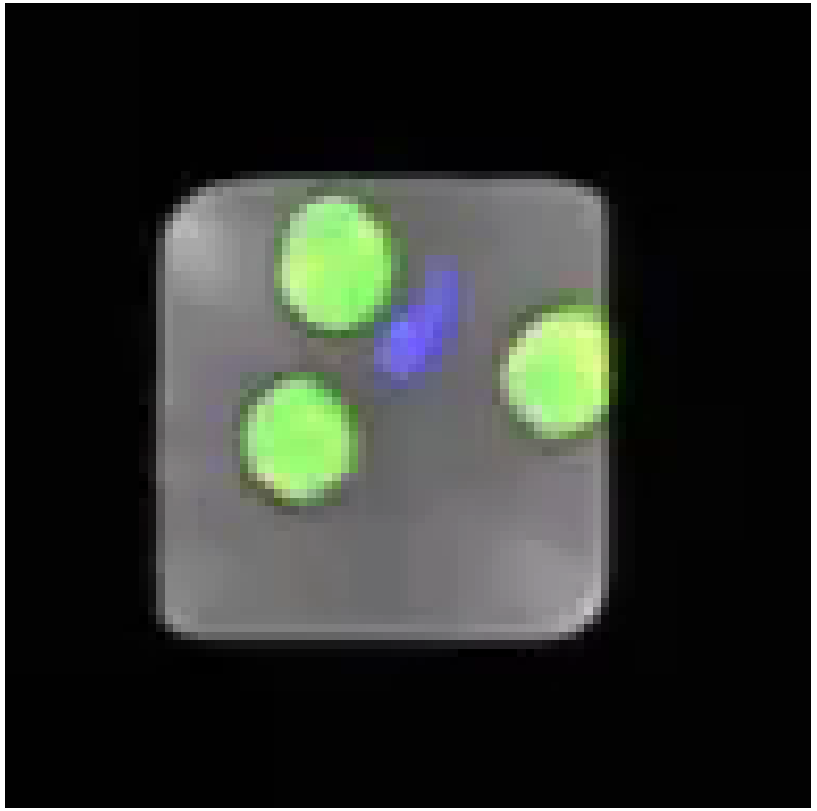
WHAT IS A TRIKE™ THERAPEUTIC?



Key Therapeutic Features:

- Target-directed ADCC killing.
- Integrated cytokine support within the TME.
- Simultaneous NK cell ADCC activation, proliferation and persistence.
- First-in-Class modular therapeutic platform technology.

TriKE™ Directed NK Cell Serial Killing of Tumor Cells



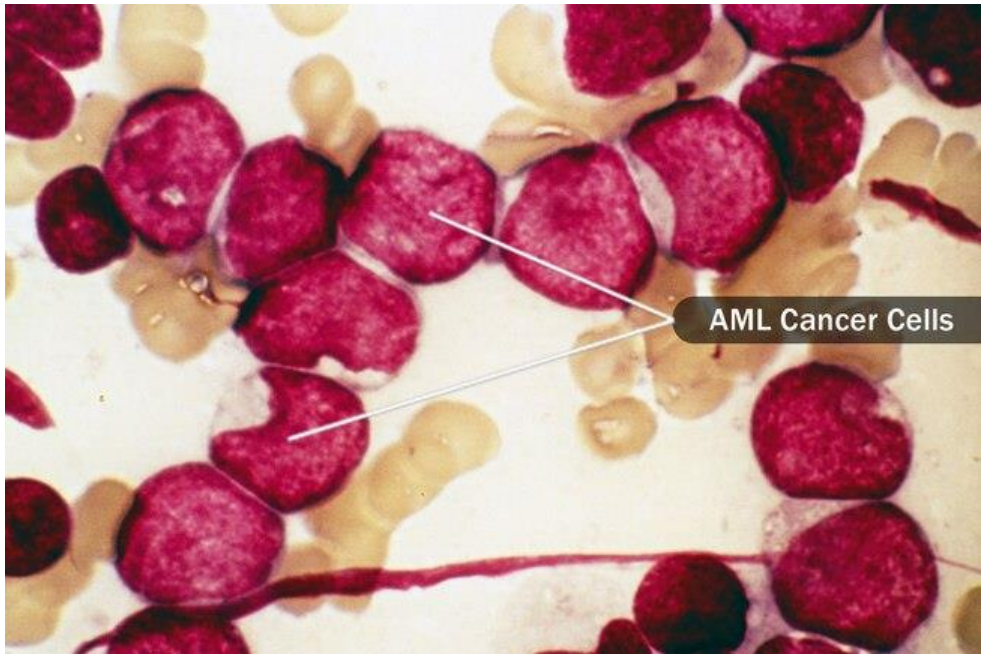
Enhanced Serial Killing of Cancer cells (green) by TriKE directed NK cell (blue).

- Integrated CD16 and IL-15 in TriKE drives NK cell ADCC activation to enhance serial killing, proliferation and minimize toxicities resulting from hyperactivation of T cells causing CRS.
- TriKE therapeutics can be used to treat solid tumors and hematologic tumors.
- TriKE is an immune oncology therapeutic – not a cell therapy.

TriKE™ Product Candidate Pipeline

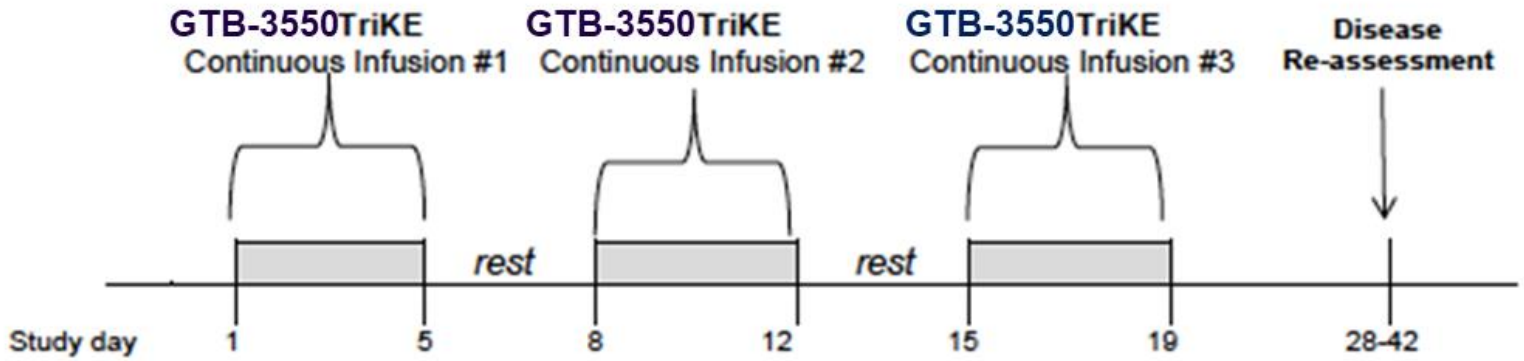
TriKE™ Product Candidates (Indication)	Pre-clin	GMP Manufacturing	Phase I	Phase II	Anticipated Time to Next Milestone
GTB-3550 TriKE (Leukema - AML and other CD33+ Cancers)					2Q21 End of Phase I
GTB-4550 (PD-L1 / Solid Tumor Cancers)					4Q20
GTB-5550 (B7H3 / Solid Tumor Cancer)					4Q20

GTB-3550 TriKE™ Product Candidate



- 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 I/II Expansion clinical trial.

GTB-3550 TriKE™ First-in-Human Clinical Trial Design



Phase 1: Dose Finding (at least 12 evaluable patients)

Patients will receive GTB-3550 at the assigned dose level. Each patient will receive a bolus test dose (20% of the daily continuous infusion dose) to assess pharmacokinetics/pharmacodynamics. If no unacceptable reactions occur after 4 hours, the patient will receive GTB-3550 at the assigned dose for three consecutive weekly 96 hour continuous infusions separated by a 72 hour rest.

GTB-3550 Dose daily continuous infusion dose (µg/kg/day)
5
10
25
50
100
200

Primary Objective: To identify the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of GTB-3550 defined as the dose level that most closely corresponds to a dose limiting toxicity rate (DLT) of 20%.

Phase 2: Efficacy at RP2D (max 30 patients)

Patients will receive three consecutive blocks of four 24 hour continuous infusions of GTB-3550 TriKE at the Phase I RP2D separated by a 72 hour rest.

Primary Objective: To determine preliminary efficacy as measured by the rates of "best" clinical response by Day 42 day after the start of the 1st infusion.

Stage 1: Enroll 13 patients, including all patients treated at the MTD during Phase 1. If 3 or more of these 13 patients have a clinical response to GTB-3550 the trial moves to Stage 2.
Stage 2: Enroll an additional 17 patients.

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

- Four patients treated to date:
  - Two patients treated at the 5 mcg/kg/day, and two patients treated at the 10 mcg/kg/day cohorts.
  - Currently enrolling patients at the 25mcg/kg/day dose label.
- One patient at the 5 mcg/kg/day with stable disease after first course of therapy was retreated with a second course of 3 weeks of GTB-3550 therapy.
- No observed adverse events – no fevers, tachycardia or constitutional symptoms – even though dose of TriKE™ greatly exceeded the MTD of continuous infusion of IL-15 of 2 mcg/kg/day.
- Significant increase in NK cell proliferation, and NK cell activation observed in all patients.
- No hyperactivation of patient T-cell population – no cytokine release syndrome (CRS).
- Subsequent patients enrolled in the clinical trial will be administered higher doses of GTB-3550.

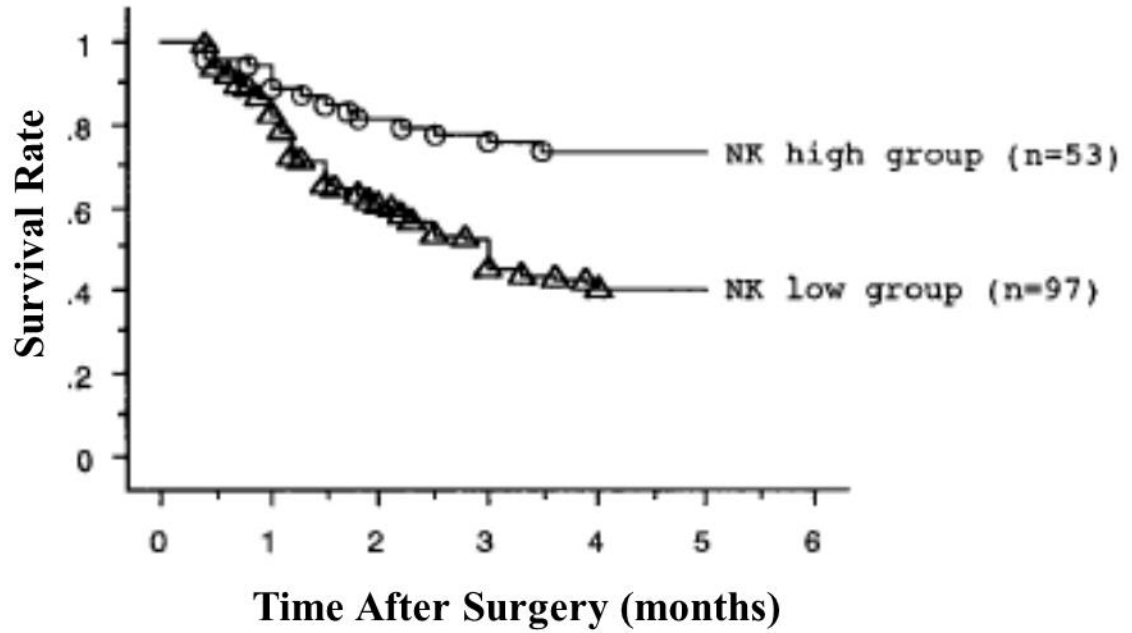
TRIKE™ FOR SOLID TUMORS

Enhance tumor cell killing by increasing the number of ADCC activated, target-directed cytotoxic NK cells within the tumor microenvironment.

Cancer type
Colorectal carcinoma
Hepatocellular carcinoma
Gastric carcinoma
Adenocarcinoma lung
Gastric carcinoma
Leukemia
Squamous cell, lung
Renal cancer
Squamous cell, esophagus
Squamous cell, vulva

Larsen, S., et al, *Crit Rev Oncog*. 2014 ; 19(0): 91–105

High vs Low NK Cell Infiltration into Tumor



Overall survival curves of patients with pulmonary adenocarcinoma on the basis of NK cell infiltration. *(P=0.0002)*

Takanami, I et al, J Thorac Cardiovasc Surg 2001;121:1058-63

TriKE™ for Treatment of Solid Tumor Cancers

Significant reduction in solid tumor burden and improvement in survival after treatment with TriKE™

- TriKE™ has been evaluated in ovarian, breast, prostate, pancreatic ductal adenocarcinoma and lung cancer models.
- TriKE™ demonstrated significant reduction in tumor burden in animal models.
- TriKE™ increased overall survival in animal models of solid tumor cancers.

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

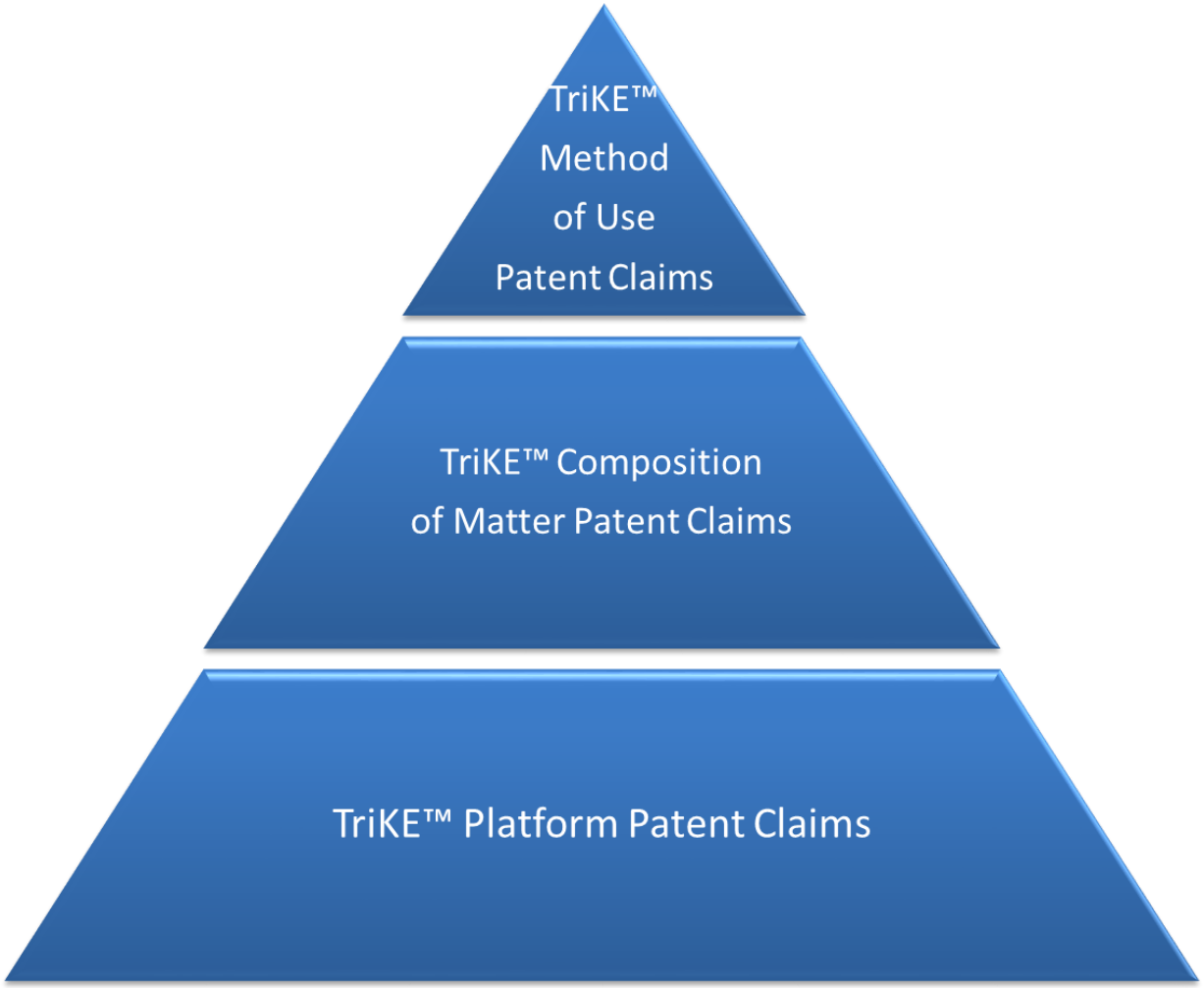
NK cell therapy. Significantly more expensive.

PARTNERSHIP HIGHLIGHTS

Cytovance® Biologics
a Hepalink Company

- Cytovance will develop GMP cell lines, and manufacture TriKE product candidates for use in GT Biopharma clinical trials.
- GT Biopharma has the option to pay Cytovance in cash or shares of GT Biopharma common stock.
- Cytovance with help develop new TriKE product candidates on a fee-for-services basis – no clinical development milestone payments or royalties on product sales.
- GT Biopharma receives fully paid nonexclusive license to use Cytovance's Keystone® E. coli bacterial and CHO mammalian expression systems for the manufacture of TriKE product candidates.

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.

MANAGEMENT TEAM

ANTHONY J. CATALDO

Chairman, Chief Executive Officer & President

Mr. Cataldo founded GT Biopharma Inc. From February 2011 to June 2013 Mr. Cataldo served as Founder and Chairman & CEO of Iovance Biotherapeutics, Inc., (IOVA). Mr. Cataldo has served as Chairman/CEO of several biotech companies including: Calypte Biomedical Corporation and Senetek, PLC.

JEFFREY S. MILLER, M.D.

Consulting Chief Medical Officer

Dr. Miller is the inventor of GT Biopharma's TriKE™ technology. Dr. Miller is currently a Professor of Medicine at the University of Minnesota, and is the Deputy Director of the University of Minnesota Masonic Comprehensive Cancer Center. Dr. Miller has more than 20 years of experience studying the biology of NK cells and other immune effector cells and their use in clinical immunotherapy with over 170 peer-reviewed publications. Dr. Miller received his M.D. degree from Northwestern University School of Medicine, and completed his internship and residency in Internal Medicine at the University of Iowa in Iowa City. After completing a post-doctoral fellowship in Hematology, Oncology and Transplantation at the University of Minnesota, he joined the faculty in 1991.

STEVEN WELDON, MBA, CPA

Chief Financial Officer & Director

Mr. Weldon has been a member of the board of directors and Chief Financial Officer since the founding of GT Biopharma. Mr. Weldon has served on the board of directors of several publicly traded companies and as chief executive officer and chief financial officer. Mr. Weldon received his bachelor of science degree and his Master's in Business Administration from Florida Southern College and is a licensed Certified Public Accountant in the State of Florida.

MARTIN SCHROEDER, M.Sc.

Consulting Chief Technology Officer

Mr. Schroeder has been Executive Vice President and Managing Director of the Emmes Group, Inc. Mr. Schroeder has also held a number of industry management and executive positions, including Chairman, President and Chief Executive Officer of AMS, Inc., a venture capital-backed molecular genomics company. Mr. Schroeder also played key roles in the founding of Intercept Pharmaceuticals, a public biotech company focused on the treatment of patients with progressive non-viral liver diseases, and the founding of Iovance Biotherapeutics, a public company developing cell therapies. Mr. Schroeder was also a Visiting Scientist at the U.S. Department of Agriculture following completion of his graduate studies in biochemistry. Mr. Schroeder holds a Bachelor of Science degree in Biochemistry from UCLA, and a Master of Science degree in Biochemistry from CSULB.

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