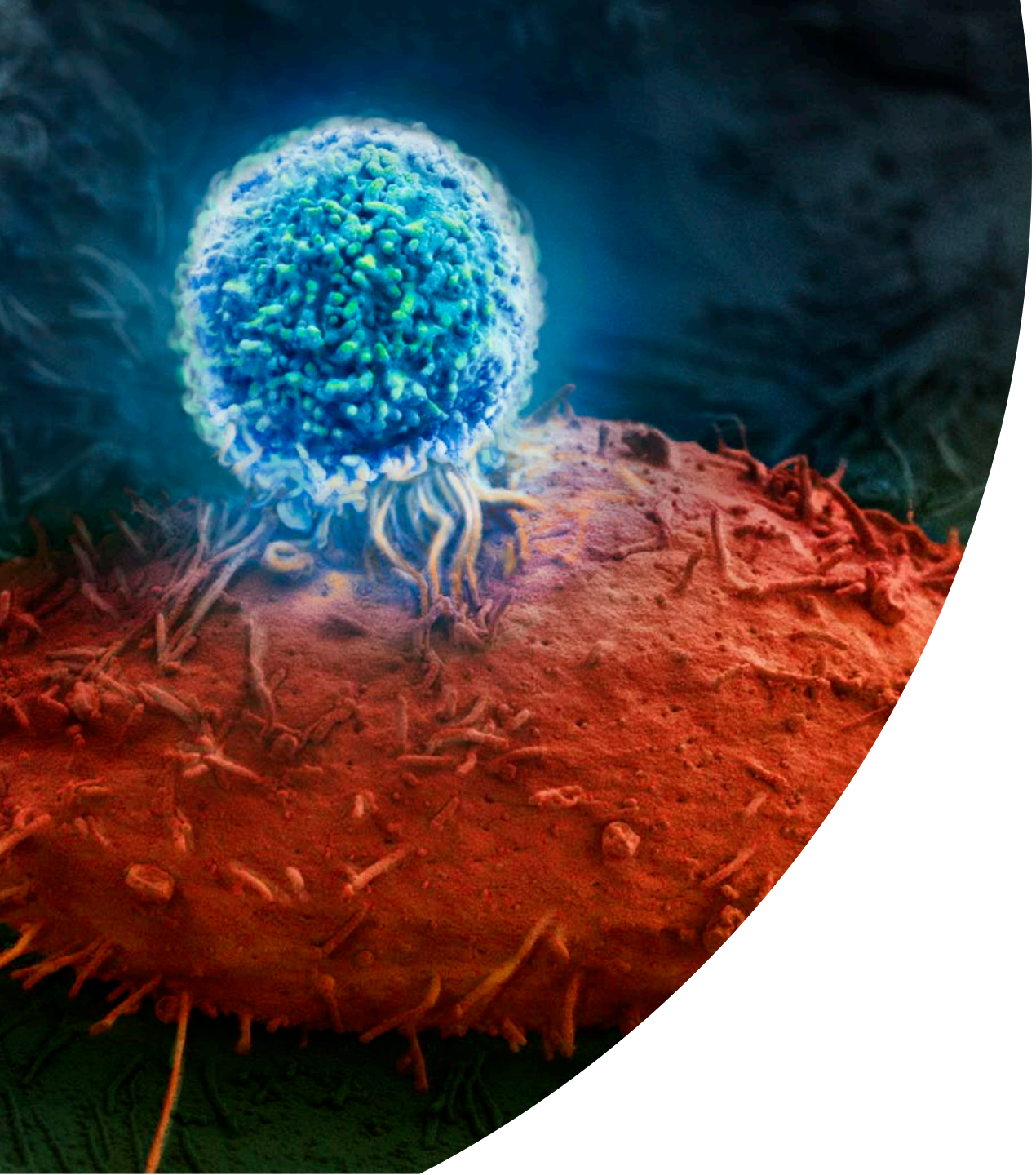

ESTRELLA

Estrella Immunopharma

Treating Both Blood and Solid Tumors with CD19 ARTEMIS® T-Cell Therapy

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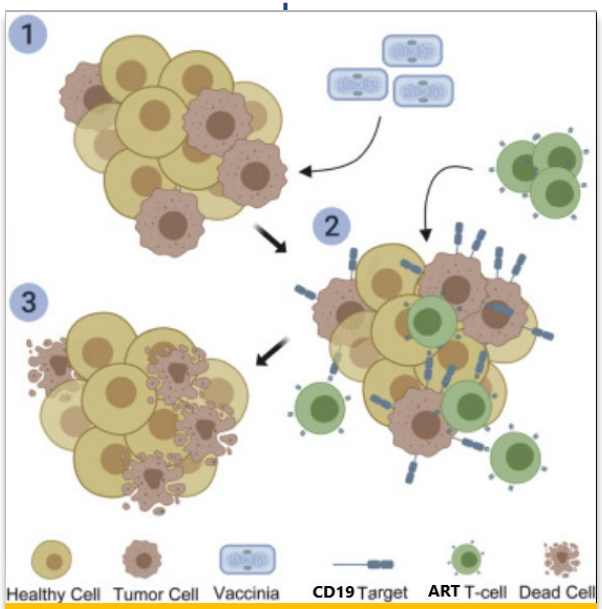
Executive Summary: Background and Opportunity

Recent success treating blood cancers with T-cell immunotherapy

- Juno Therapeutics (Juno) and Kite Pharma (Kite) were leaders in developing T-cell immunotherapy targeting CD19
- FDA approved T-cell immunotherapy targeting CD19 for blood cancer in 2017.
- A cycle of treatment costs around $400,000 per patient
- Juno and Kite acquired by Bristol-Myers Squibb(Nasdaq: BMY) and and Gilead Science (Nasdaq: GILD) for $9 billion and $11.9 billion in 2018 and 2017, respectively.

Opportunity remains for 2nd generation CD19-targeted T-cell therapies with less toxicity, and solid tumors market is wide-open

- Current CD19 T-cell therapy has severe side effects including ***Cytokine release syndrome (CRS) and neurotoxicity***
- ***Solid tumors***, which account for >90% of all cancers, have NOT been successfully treated by T-cell immunotherapy



ARTEMIS® vs. CAR-T

Superior efficacy

Enhanced tumor infiltration

Less T-cell exhaustion

Reduced cytokine release syndrome (CRS) and cytokine released toxicities

- ***Estrella's EB103***, which utilizes ARTEMIS® T-cell engineering technology, has been validated preclinically and clinically to be superior to current FDA-approved CD19 T-cell therapy in both safety and efficacy.
- The ***"Mark and Kill"*** approach by combining specially designed oncolytic viruses that label solid tumor cells with CF33-CD19t ("Mark") and EB103 ("Kill") is a potential breakthrough for treating solid tumors with T-cell therapy.

Estrella Immunopharma

A preclinical-stage biopharmaceutical company developing T-cell therapies with the potential to more effectively treat patients with blood cancers and, in partnership with Imugene, solid tumors.

Our Mission

Harness the evolutionary power of the human immune system to transform the lives of patients fighting cancer.

Our Product

- Lead product candidate, EB103, the next-generation ***CD19-targeted ARTEMIS® T-cell therapies*** with superior efficacy, enhanced tumor infiltration, and less T-cell exhaustion.
- EB104, a ***CD19/22 Dual-Targeting ARTEMIS® T-cell therapies*** with more efficacy, reducing relapse due to CD19 antigen loss.

ARTEMIS®

Our Partnership

In partnership with Imugene, our ***ARTEMIS® technology*** may be used in EB103, utilizing Imugene's product candidate, the Oncolytic Virus "CF33-CD19t", to treat solid tumors in a ***"Mark and Kill"*** strategy.

IMUGENE
Developing Cancer Immunotherapies

Estrella Immuonpharma's World Class Experts

Randy Schekman, PhD

- Cell Biologist at UC Berkeley
- Former editor-in-chief of Proceedings of the National Academy of Sciences & Annual Review of Cell and Development Biology
- 2013 Nobel Prize of Medicine Winner

Stephan Grupp, MD, PhD

- Chief of the Cell Therapy and Transplant Section in the Division of Oncology and Director of Cancer Immunotherapy Program at Children's Hospital of Philadelphia
- Principal Investigator for CD19 CAR-T Kymriah by Novartis

W. Michael Kavanaugh, MD

- Associate Clinical Professor of Medicine at University of California, San Francisco.
- Former CSO and Head of Research and Non-Clinical Development of CytomX.
- Former Senior VP and CSO of Five Prime Therapeutics.
- Former VP of Novartis Vaccines & Diagnostics, and ED of Oncology Biologics in Novartis Institutes of Biomedical Research.

Cheng Liu, PhD

- CEO of Estrella and inventor of ARTEMIS® and CD19 antibody
- Principal Scientist in antibody drug discovery at Chiron/Novartis from 1997 to 2006
- Awarded Special U.S. Congressional Recognition for contributions to improving human health in 2007

David Scheinberg, MD, PhD

- Physician, scientist, drug developer, entrepreneur, and pioneer of targeted alpha particle therapies.
- Memorial Sloan Kettering Cancer Center, Former Chairman of Leukemia Service

Gainpietro Dotti, MD

- Research Professor of microbiology and immunology at University of North Carolina
- Director of the Lineberger Comprehensive Cancer Center Immunotherapy Program at University of North Carolina at Chapel Hill.

Estrella Immunopharma Licensed Patents on CD19-ARTEMIS®

CD19

Issued patents in the US and have 23 applications worldwide


US010301388B2

(12) **United States Patent**
Liu et al.

(10) **Patent No.: US 10,301,388 B2**
(45) **Date of Patent: May 28, 2019**

(54) **ANTIBODY AGENTS SPECIFIC FOR HUMAN CD19 AND USES THEREOF**

(71) Applicant: **Eureka Therapeutics, Inc.**, Emeryville, CA (US)

(72) Inventors: **Hong Liu**, Emeryville, CA (US); **Jingwei Lu**, Emeryville, CA (US); **Zhiyuan Yang**, Emeryville, CA (US); **Li Long**, Emeryville, CA (US); **Neal Cheng**, Emeryville, CA (US)

(73) Assignee: **Eureka Therapeutics, Inc.**, Emeryville, CA (US)

USPC 530/387.1, 387.3; 435/325; 424/93.21
See application file for complete search history.

(56) **References Cited**

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ARTEMIS®

Four issued patents in the US and 62 applications pending worldwide

(12) **United States Patent**
Lu et al.

(10) **Patent No.: US 10,098,951 B2**
(45) **Date of Patent: Oct. 16, 2018**

(54) **ANTIBODY/T-CELL RECEPTOR CHIMERIC CONSTRUCTS AND USES THEREOF**

(71) Applicant: **EUREKA THERAPEUTICS, INC.**, Emeryville, CA (US)

(56) **References Cited**

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4,199,022	A	4/1980	Senkan et al.

(12) **United States Patent**
Lu et al.

(10) **Patent No.: US 10,464,988 B2**
(45) **Date of Patent: *Nov. 5, 2019**

(54) **ANTIBODY/T-CELL RECEPTOR CHIMERIC CONSTRUCTS AND USES THEREOF**

(71) Applicant: **EUREKA THERAPEUTICS, INC.**, Emeryville, CA (US)

C07K 2319/00 (2013.01); *C07K 2319/03* (2013.01); *C07K 2319/33* (2013.01); *C07K 2319/74* (2013.01)

(58) **Field of Classification Search**
CPC A61K 39/39558; A61K 35/17

(12) **United States Patent**
Liu et al.

(10) **Patent No.: US 10,822,413 B2**
(45) **Date of Patent: Nov. 3, 2020**

(54) **CELLS EXPRESSING CHIMERIC ACTIVATING RECEPTORS AND CHIMERIC STIMULATING RECEPTORS AND USES THEREOF**

(71) Applicant: **EUREKA THERAPEUTICS, INC.**, Emeryville, CA (US)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,753,357 A 8/1973 Schwartz

(12) **United States Patent**
Lu et al.

(10) **Patent No.: US 10,822,389 B2**
(45) **Date of Patent: *Nov. 3, 2020**

(54) **ANTIBODY/T-CELL RECEPTOR CHIMERIC CONSTRUCTS AND USES THEREOF**

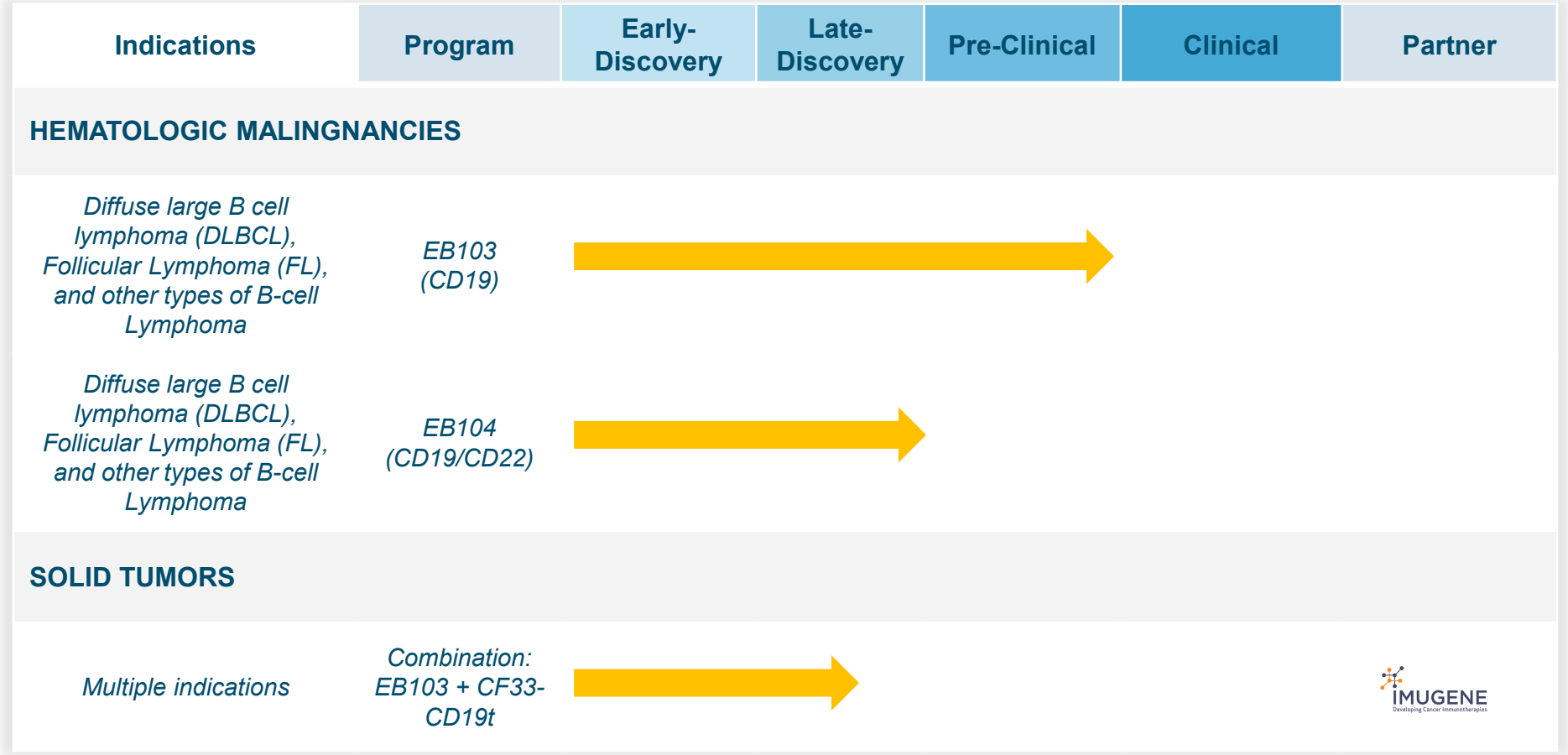
(71) Applicant: **EUREKA THERAPEUTICS, INC.**, Emeryville, CA (US)

2317/56 (2013.01); *C07K 2317/622* (2013.01); *C07K 2317/73* (2013.01); *C07K 2319/00* (2013.01); *C07K 2319/03* (2013.01); *C07K 2319/33* (2013.01); *C07K 2319/74* (2013.01)

(58) **Field of Classification Search**

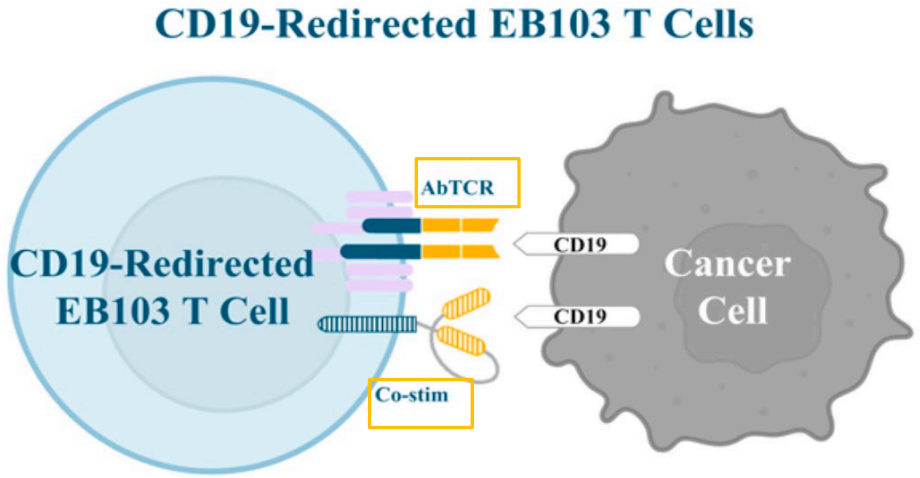
Estrella Pipeline and Strategy

- Our approach is to rapidly advance our lead product candidate EB103, ***CD19-Redirected ARTEMIS® T-Cell programs*** in relapsed/refractory and high-risk ***blood cancers first***.
- We are also developing EB104, ***CD19/22 Dual Targeting ARTEMIS® T-Cell Therapy*** to treat patients with lower surface CD19 density or a greater prevalence of CD22.
- Meanwhile, in partnership with Imugene we are developing EB103+ CF33-CD19t using the ***"Mark-and-Kill"*** approach to address various types of ***solid tumors***.



Lead Product: EB103 (CD19-Redirected ARTEMIS® T-Cell Therapy)

EB103 T-Cells



EB103 CD19-Redirected ARTEMIS® T Cells

EB103 Engineered to express ARTEMIS® cell receptors (i.e., the AbTCR and co-stimulatory molecule) on cell surfaces.

Once infused, EB103 T-cells(cell receptors) recognize and bind the CD19-positive cancer cells.

Cell receptors, AbTCR/CD3 complex-mediated signal transduction within the EB103 T-cell is initiated, leading to the activation of the EB103 T-cell.

The second “enhancement” signal is generated when the co-stimulatory molecule expressed on the EB103 T-cells binds to its target, CD19.

EB103 T-cells seek out CD19-positive cancer cells, bind to and destroy them.

Key Unit – AbTCR and Co-stim

The key units of our novel, proprietary CD19-Redirected ARTEMIS® T Cells comprised of an **antibody-T-cell-receptor (AbTCR) and a co-stimulatory molecule**:

The Antibody-T-Cell Receptor (AbTCR) serves as the core component featuring:

- A target-binding domain derived from an antibody fragment antigen-binding (Fab) region
- An effector domain derived from portions of a human gamma/delta (γδ) T-cell receptor (TCR)

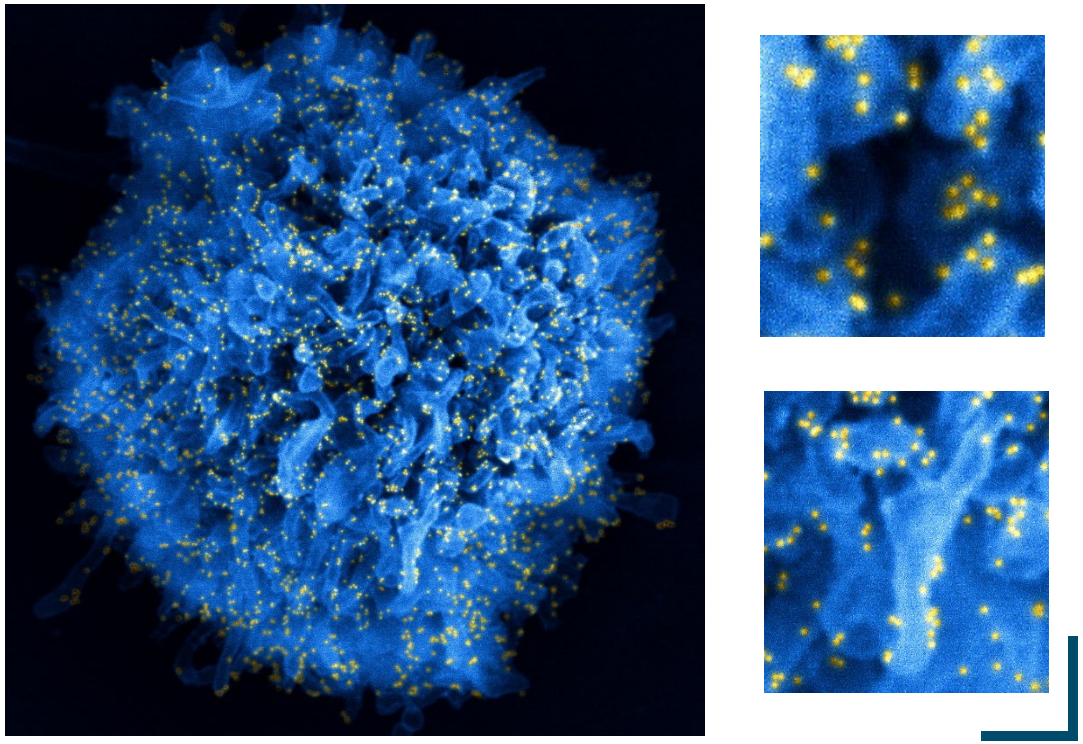
The Co-Stimulatory Molecule is an additional key component featuring:

- A target-binding domain derived from a single-chain variable fragment (scFv)
- A co-stimulatory domain derived from portions of a human co-stimulatory receptor

Both the AbTCR and the co-stimulatory molecule bind to the **CD19 antigen**, a well-validated target commonly overexpressed on blood cancer cells.

Proprietary ARTEMIS® Technology

ARTEMIS®



ARTEMIS® receptor is primarily localized in microvilli.

(Collaboration: Alice Liang, Ph.D. Director of Microscopy Laboratory, NYU Langone Health NYU School of Medicine)

Superiority to Conventional CAR-T

- ARTEMIS T-cell therapy is **clinically validated in patients**
- ARTEMIS® vs. CAR-T
  - ✓ **Superior** efficacy
  - ✓ **Enhanced** tumor infiltration
  - ✓ **Less** T cell exhaustion
  - ✓ **Reduced** Cytokine release syndrome (CRS) and cytokine related toxicities

Better Safety and Potent Anti-tumor Efficacy

Stephan A. Grupp, MD, PhD

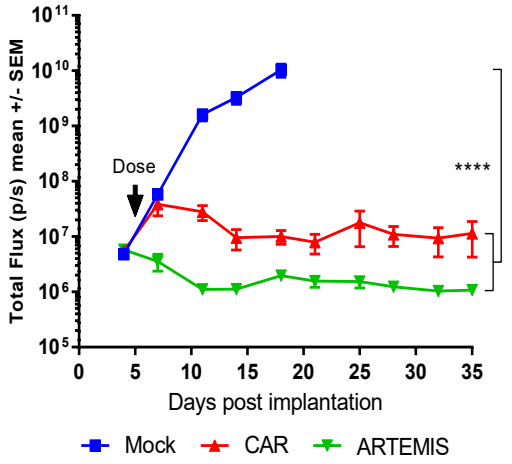
- Delivered CAR T-cell therapy to the first pediatric patient in the world (Emily Whitehead)
- Led the first multicenter global study of Kymriah®, which became the first CAR-T therapy to receive approval from the FDA

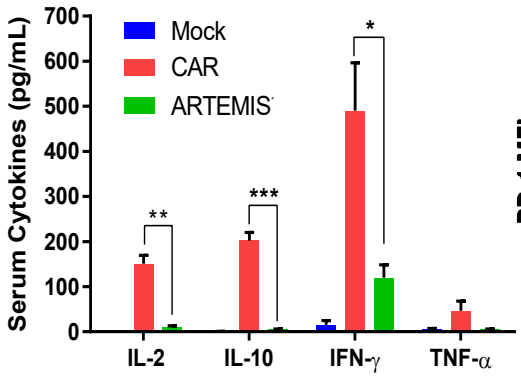
Children's Hospital of Philadelphia℠

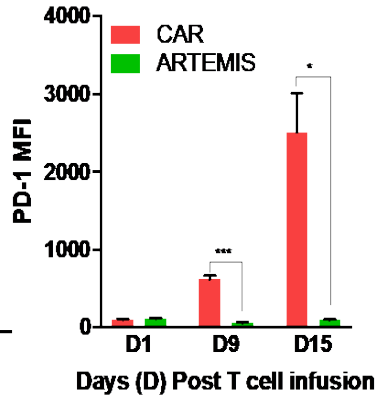
- **Collaboration research with Dr. Grupp's team showed CD19 ARTEMIS® T-cell Therapy demonstrated better safety and anti-tumor efficacy.**
- **The research paper *Xu et al. Cell Discovery (2018) 4:62* published in *Nature* in 2018.**

ARTEMIS vs. CAR-T cells

- Potent anti-tumor activity
- Better safety profile
- Longer durability with less exhausted phenotype







Snapshots of Estrella CD19 Therapy in Lymphoma Patients

- **Collaboration research with the First Affiliated Hospital of Xi'an Jiaotong University for exploratory, single-arm, open-label, non-randomized early investigator initiated study ("IIS").**

Abstract # 2870 — 61th ASH Annual Meeting 2019

Summary

- As of Sep 11th, 2019, 9 adult r/r DLBCL patients received autologous ET019003 ARTEMIS ™ T cells at the dose of 3x10^6/kg/infusion. Their clinical responses were followed up for at least 1 month after infusion.
- Repeat dosing of ET019003 T cells is well tolerated.
- Robust expansion of ET019003 T cells in peripheral blood was observed in all subjects. Peak expansion did not correlate with adverse event and response.
- ET019003 T cell therapy demonstrated a favorable safety profile. No more than grade-2 CRS was observed and no patient shows neurotoxicity.
- ET019003 T cells achieved excellent clinical efficacy (ORR: 8/9, best response: CR: 4/9, PR: 4/9).

A novel antibody-TCR (AbTCR) T-cell therapy is safe and effective against CD19-positive relapsed/refractory B-cell lymphoma

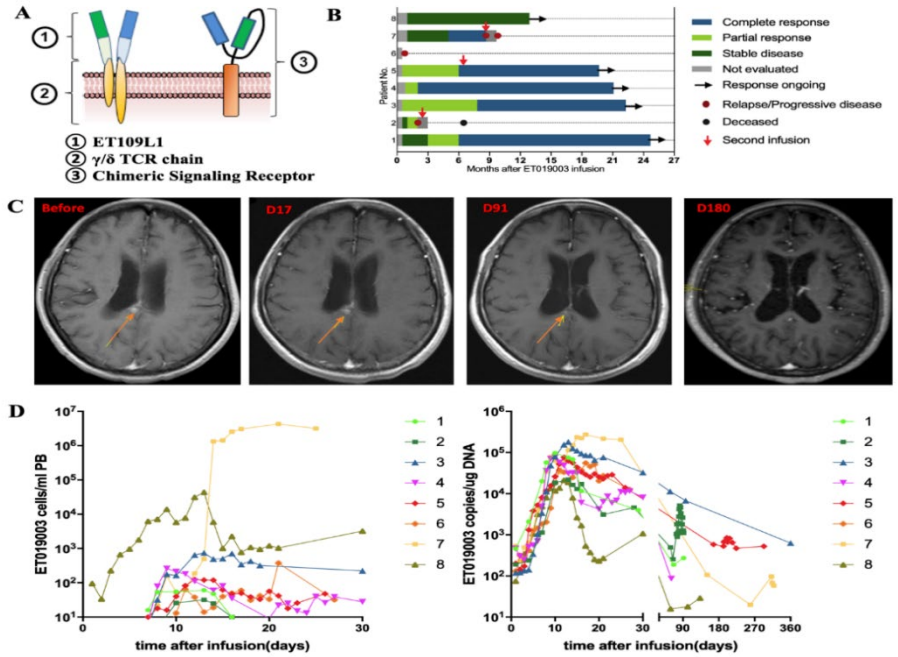
Pengcheng He[1] · Haibo Liu[1] · Bryan Zimdahl[2] · Jie Wang[1] · Minna Luo[1] · Qi Chang[2] · Fangzhou Tian[2] · Fan Ni[2] · Duo Yu[2] · Huasheng Liu[1] · Limei Chen[1] · Huaiyu Wang[1] · Mei Zhang[1] · Stephan A. Grupp[3,4] · Cheng Liu[2]

Received: 19 April 2022 / Accepted: 10 June 2022

ASH | Annual Meeting & Exposition 2021

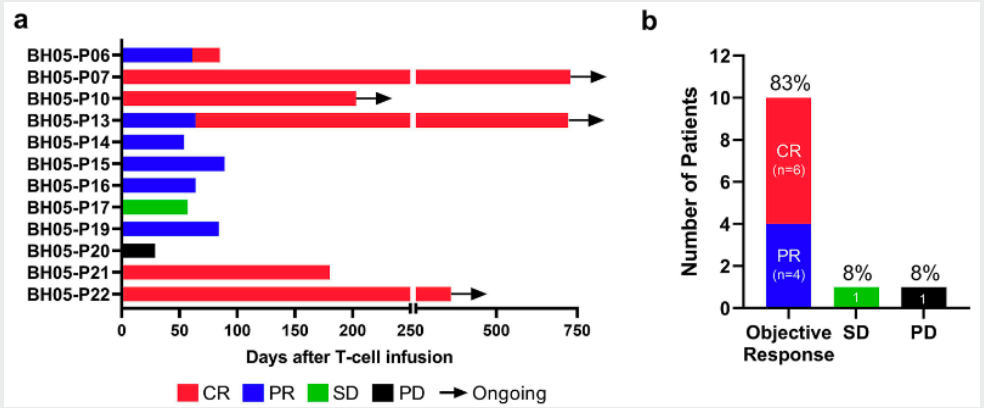
826 Novel CD19-Specific γ/δ TCR-T Cells in Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Oral presentation Monday, December 13, 2021: 5:15 PM

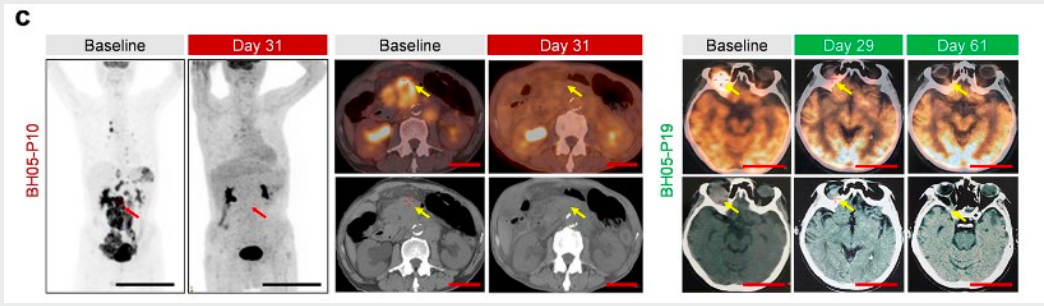


EB103 Clinical Studies

- **This IIS study [1] provides data that indicates that EB103 has anti-tumor activity and an attractive safety profile in patients with CD19-positive r/r B-cell lymphoma.**



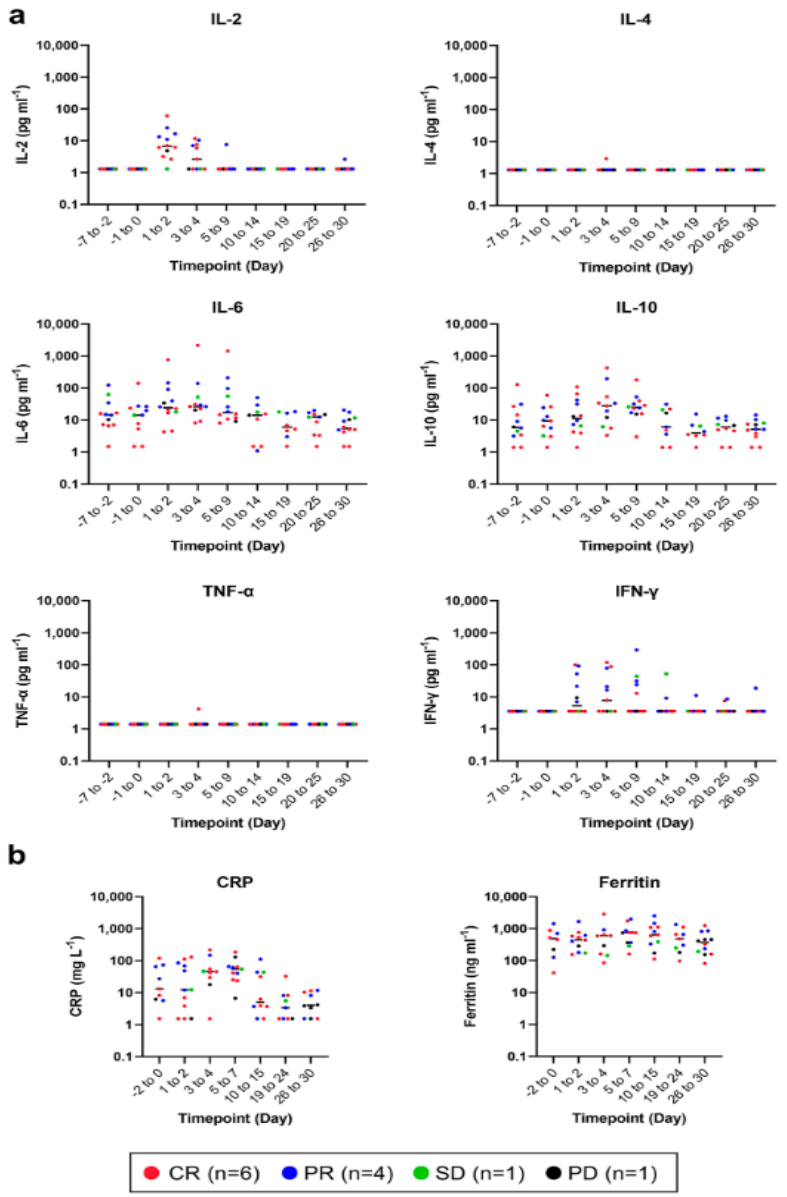
(a) Treatment response and duration of response after initial infusion of EB103 T-cells. Black arrows indicate ongoing remission and follow-up.
(b) Best response for the 12 patients. Best response was defined as the best response (i.e., CR > PR > SD > PD) the patient achieved at any time after receiving EB103. CR - complete response, PR - partial response, SD - stable disease, PD - progressive disease.



(c) Representative radiographic images of two responders (BH05-P10 and BH05-P19) at baseline and the indicated time points after EB103. Red or yellow arrows mark the tumor lesions. Full body images are PET-CT scans. Cross-sectional images are PET scans (top rows) and CT scans (bottom rows). Scale bars: black, 20 cm; red, 6 cm.

(1) Reference: He et al. Journal of Cancer and Clinical Oncology 10 June 2022
A novel antibody-TCR(AbTCR) T-cell therapy is safe and effective against CD19-positive relapsed/refractory B-cell Lymphoma

EB103 Clinical Studies



- **This IIS study [1] provides data that indicates that EB103 has anti-tumor activity and an attractive safety profile in patients with CD19-positive r/r B-cell lymphoma.**
  - The study enrolled patients from November 2018 to January 2020 [1] 16 patients were enrolled, and 12 patients were treated.
  - Of the 12 patients treated, six patients (50%) achieved a complete response ("CR"), and four (33%) achieved a partial response ("PR"), with a best objective response rate of 83%.
  - CRs were durable, including two patients with ongoing CRs for 22.7 months and 23.2 months. EB103 was well-tolerated with an attractive safety profile.
  - **No patients experienced severe (grade > 3) CRS, and only one patient experienced ICANS of any grade.** Significant elevations of cytokine levels were not seen, even in patients with marked expansion of EB103 T-cells.

- **Levels of cytokines and serum inflammatory markers after EB103 T-cell infusion**

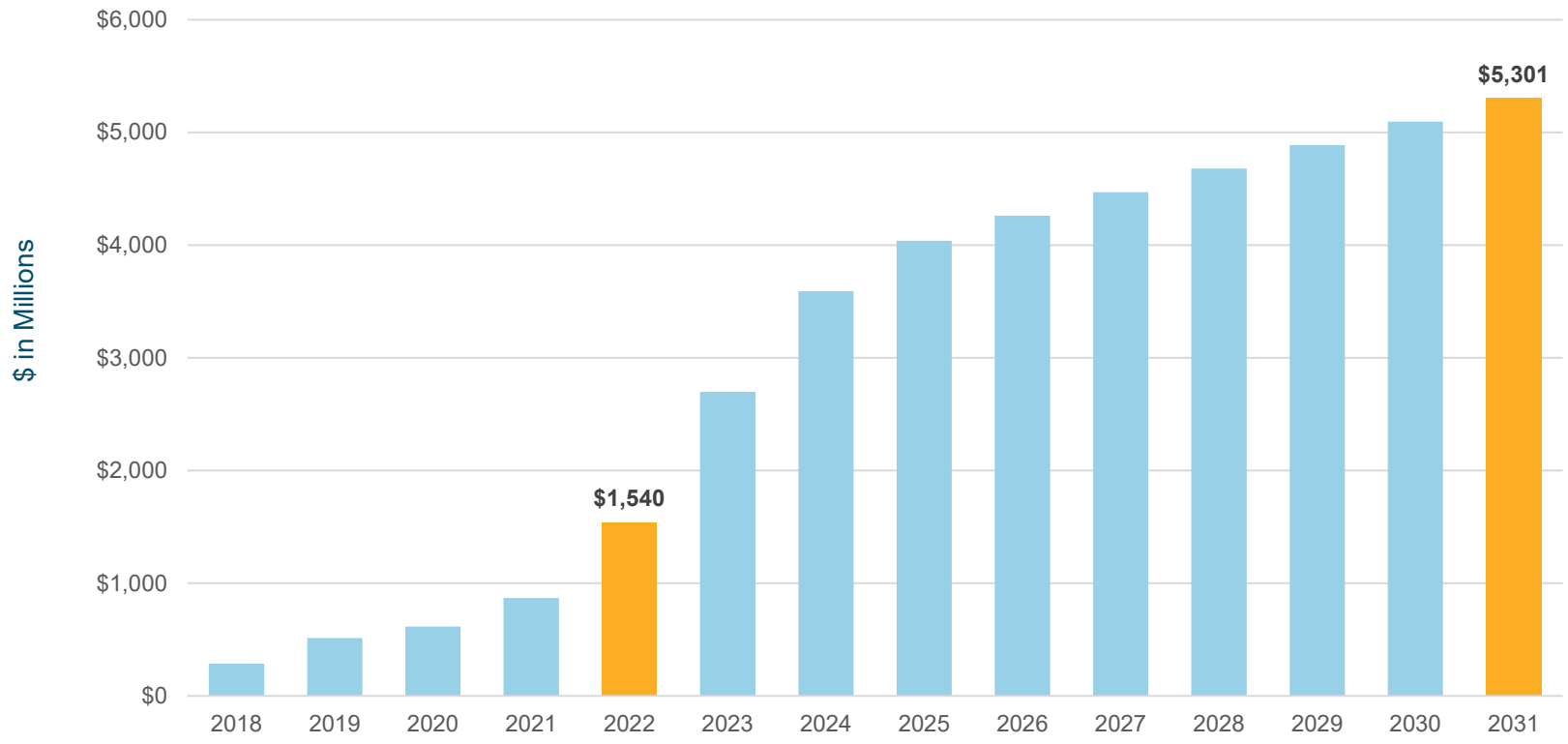
  (a) Cytokine levels

  (b) Serum c-reactive protein (CRP) and ferritin levels in patients during the first month of EB103. Horizontal lines denote median values. Patients' best responses are denoted by color of the symbols: CR (red), PR (blue), SD (green), and PD (black).
  Values less than the limit of detection were recorded as half the lower limit

(1) This IIS was conducted at The First Affiliated Hospital of Xi'an Jiaotong University in China and was registered at www.clinicaltrials.gov as #NCT03642496
Reference: He et al. Journal of Cancer and Clinical Oncology 10 June 2022
A novel antibody-TCR(AbTCR) T-cell therapy is safe and effective against CD19-positive relapsed/refractory B-cell Lymphoma

CD-19 Targeted CAR-T Therapies Market

Currently approved CD-19 targeted CAR-T therapies projected sales in lymphoma: *$5+ billion (2031)*



CD19 CAR-T Product Sales Projection (2018-2031)

Source: Datamonitor, June 2022

CD-19 CAR-T Company Acquisitions

- *1st Generation CD-19 CAR-T Companies Valued at $9-12B at the Time of Acquisition*

FDA approved T-cell therapies are limited to hematologic malignancies

Kite, A GILEAD Company

$11.9 billion In 2017 by Gilead

JUNO THERAPEUTICS

$9 billion in 2018 by Celgene

- *Three FDA approved CAR-T therapies historical sales from 2017 to 2021, and projected sales in 2022 and 2027*

Kymriah ($MM) (Novartis)	2017A	2018A	2019A	2020A	2021A	2022E	2027E
USA	$6	$76	$159	$205	$62		
Worldwide	$6	$76	$278	$474	$298	$806	

Yescarta ($MM) (Gilead/Kite)	2017A	2018A	2019A	2020A	2021A	2022E	2027E
USA	--	$263	$373	$362	$200		
Worldwide	--	$264	$456	$563	$338	$794	$1,973

Breyanzi ($MM) (BMS/Juno)	2017A	2018A	2019A	2020A	2021A	2022E	2027E
USA	--	--	--	--	$46		
Worldwide	--	--	--	--	$48	$368	

Treatment	Price (WAC)	Treatment	Price (WAC)
Kymriah (Novartis)	$373,000-$475,000	Yescarta (Gilead/Kite)	$373,000

Treatment	Price (WAC)
Breyanzi (BMS/Juno)	$410,300

Note: WAC, wholesale acquisition costs
Source: Datamonitor, January 2022

Highlights of EB103 Program

- Potentially best 2nd generation CD19 T-cell therapy with Proprietary ARTEMIS® T-cell engineering technology that is superior to CAR-T technology with decreased risks of side effects and superior safety.
- IND clearance in Q1 2023, Phase I trials in 1H 2024.

Antibody-based target recognition

- The ability to achieve **high specificity and binding affinity** to intended cancer target when compared to TCRs.

AbTCR includes portions of a human TCR

- The AbTCR associates with the endogenous CD3 complex enabling the AbTCR to use the same activation and regulatory signaling pathways employed by **natural TCRs**.
- This feature may lead to **improved safety** in patients.

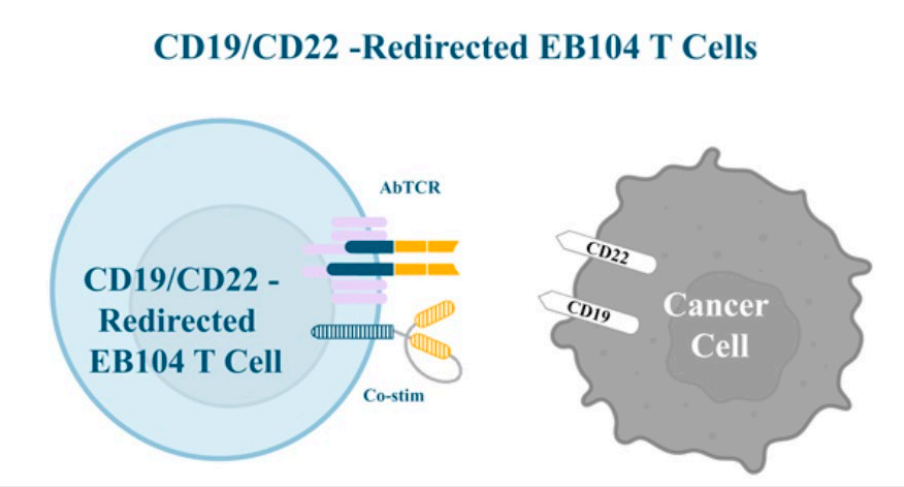
Co-stimulation provided as a separate molecule

- The AbTCR construct does not include an intracellular signaling domain covalently-linked to a co-stimulatory domain, and thus has the potential to eliminate T-cell hyperactivation and consequently, **lower the risk of CRS and ICANS** commonly observed with CAR-T therapy.

EB104 (CD19/22 Dual-Targeting ARTEMIS® T-Cell Therapy)

EB104

CD19/CD22-Redirected EB104 T Cells



EB104 Engineered to express ARTEMIS® cell receptors (i.e., the AbTCR and co-stimulatory molecule) on cell surfaces. **AbTCR in EB104** recognize and binds to **both CD19 and CD22 antigen**.

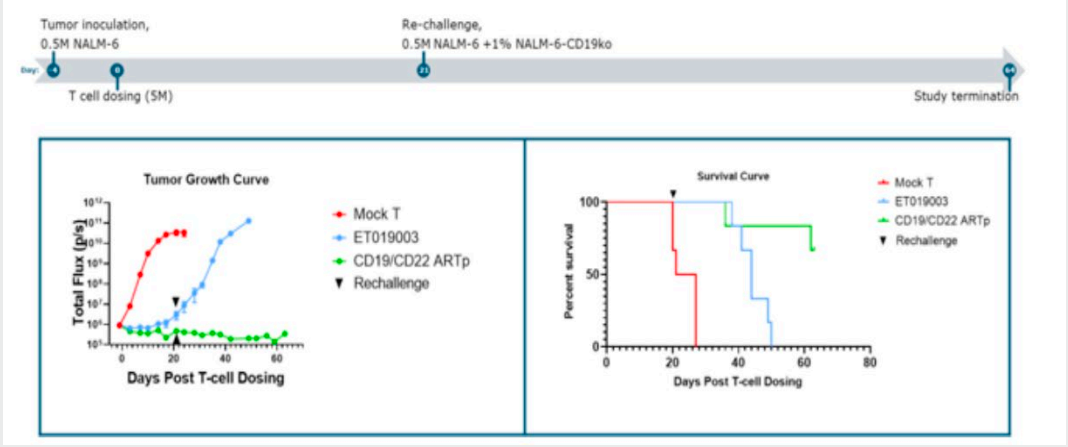
Once infused, EB104 T-cells(cell receptors) recognize and bind the CD19-and CD22-positive cancer cells.

Cell receptors, AbTCR/CD3 complex-mediated signal transduction within the EB104 T-cell is initiated, leading to the activation of the EB104 T-cell.

The second “enhancement” signal is generated when the co-stimulatory molecule expressed on the EB104 T-cells binds to its target, CD19.

EB104 T-cells seek out CD19- and CD22-positive cancer cells, bind to and destroy them.

EB104 Preclinical Data

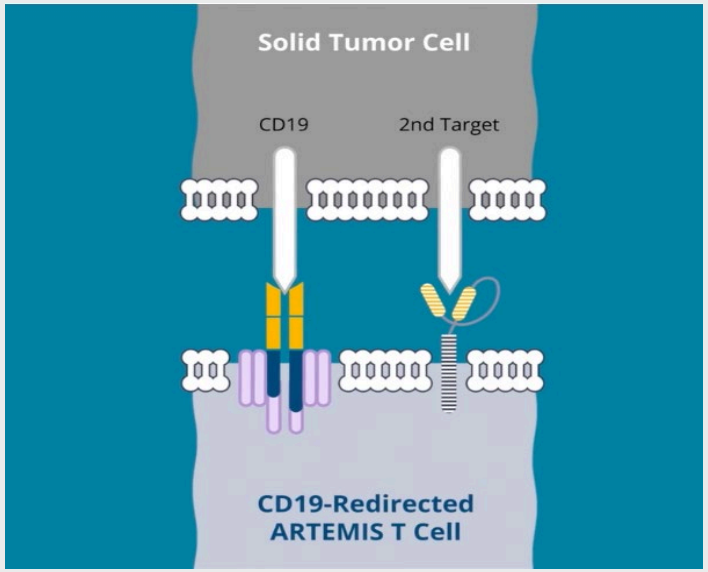


- Results showed that EB104 T-cells have the potential to eradicate Nalm-6 Primary Tumors and Nalm-6-CD19ko re-challenge tumors in the xenograft model, suggesting that EB104 T-cells have the potential to control the growth of tumor cells that do not express CD19.
  - A Nalm- 6-CD19ko cell line constructed, with the “knockout” of CD19 gene expression to tested the activity of EB104 in mice using NSGTM xenograft models.
  - Inoculated NSGTM mice, that were CD19 positive four days before receiving (i) mock control T-cells, (ii) EB103 T-cells, and (iii) EB104 T-cells. The Primary Nalm-6 Tumors in EB103 and EB104 groups resulted in remission.
  - Then inoculated the NSGTM mice with 1% Nalm-6-CD19ko to mimic diminished CD19 surface expression, creating “re-challenge” tumors.
    - EB103 T-cells not able to control the re-challenge tumors in the EB103 T-cell group, the re-challenge tumors in the EB104 T-cell group resulted in remission.

CF33-CE19t and EB103 (Collaboration with Imugene)

CF33-CE19t and EB103

The Mark-and-Kill Approach



To address the lack of solid tumor-specific targets currently available, we use *CF33-CD19t*, an *oncolytic virus,* to force solid tumor cells to express the CD19 protein on the cell surface.

The **CD19-Redirected ARTEMIS T Cells** can then pursue and kill the **CD19-labeled solid tumors**, offering a potential treatment solution to cancers where there are no inherently abundant solid tumor-specific targets available.

Highlights

- Estrella Immunopharma has developed a 2nd generation CD19 T-cell Immunotherapy in a "Mark and Kill" strategy
  - In a partnership with Imugene "CF33-CD19t", the same product has potential to be used to treat ***solid tumors*** in a "**Mark and Kill"** strategy

Partnership with Imugene (AUX: IMU)

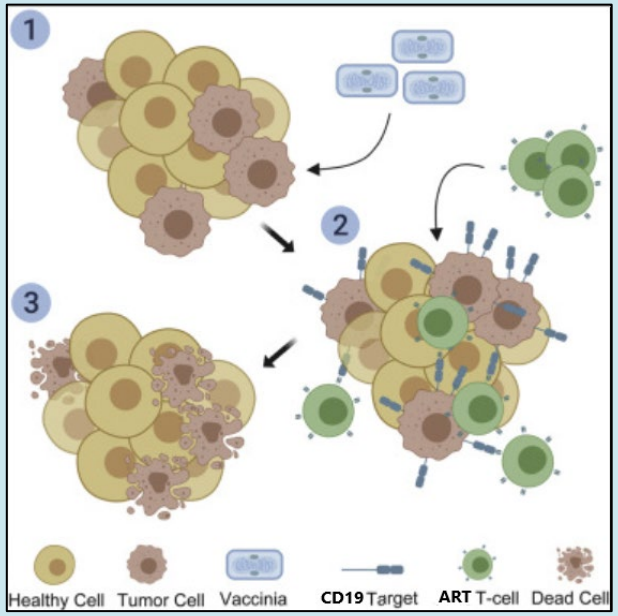
- Founded: 2012
- Headquarter: Melbourne, Australia
- Market Cap: AUD 1.29 billion (1)
- Key People:
  - Paul Hopper (Serial bioentrepreneur)
  - Leslie Chong (CEO; former clinical program lead at Genentech)

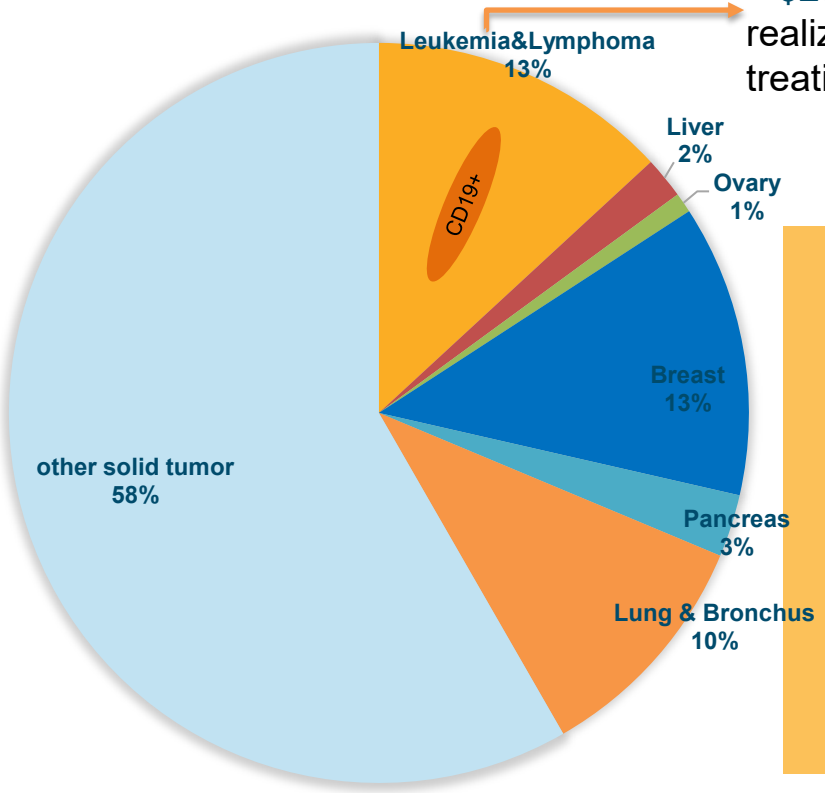
(1) As of November 1st 2022.

Solid Tumor Market Potentials

Treating Solid Tumor with Estrella's CD-19 T-cell Therapies: "Mark and Kill Strategy"

- CF33 Oncolytic Virus ("Mark" the Tumor-Imugene)
- T-Cell Therapy ("Kill" the Tumor - Estrella)





~ $20 billion combined market capitalization realized by *Juno* and *Kite* with T-cell therapies treating **CD19+** liquid tumors

Solid tumors represent:

1.6 million new cases and

90% of total diagnoses in US each year.

0 FDA approved CAR-T/TCR (T-Cell Receptor) therapies

Estimated New Cancer Cases in United States, 2022(1)

(1)Source: American Cancer Society, *Cancer Facts & Figures 2022*

Summary

Estrella Expects to Achieve High Return with Decreased Risk

High Return

- CD19 T cell product average price of $400K per treatment is expected to covered by insurance
- Juno and Kite acquisition of $9 billion and $11.7 billion respectively, provide the reference for potential company value for blood cancer market
- Success to treat solid tumors would expand sales and potentially drive Estrella Immunopharma valuation beyond those of Juno and Kite

Decreased Risk

- Proven safety of targeting CD19; four CD19 CAR-T therapies have been approved by FDA to date
- Target large blood cancer market: $2 billion in sales for CD19+ in lymphoma alone as of 2021
- ARTEMIS® technology has been verified by third party to be superior to FDA-approved products
- Estrella's CD19-targeted T-cell therapy has been validated in patients in multiple clinical studies
- Potential for expansion into solid tumor market (>$10B) with same CD19-targeted T-cell therapy

Estrella Immunopharma

Treating Both Blood and Solid Tumors with CD19 ARTEMIS® T-Cell Therapy

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