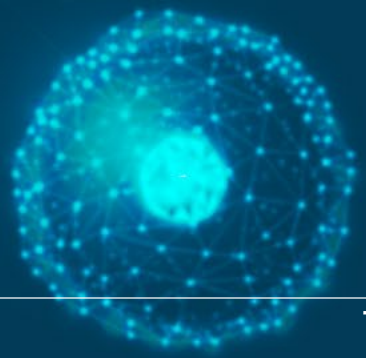
TEVOGEN BIO®

A healthier world is possible when lifesaving innovations are within the reach of all



Forward-Looking Statements

This presentation contains certain forward-looking statements, including without limitation statements relating to: Tevogen's plans for its research and manufacturing capabilities; expectations regarding future growth; expectations regarding the healthcare and biopharmaceutical industries; and Tevogen's development of, the potential benefits of, and patient access to its product candidates for the treatment of infectious diseases and cancer. Forward-looking statements can sometimes be identified by words such as "may," "could," "would," "expect," "anticipate," "possible," "potential," "goal," "opportunity," "project," "believe," "future," and similar words and expressions or their opposites. These statements are based on management's expectations, assumptions, estimates, projections and beliefs as of the date of this press release and are subject to a number of factors that involve known and unknown risks, delays, uncertainties and other factors not under the company's control that may cause actual results, performance or achievements of the company to be materially different from the results, performance or other expectations expressed or implied by these forward-looking statements.

Factors that could cause actual results, performance, or achievements to differ from those expressed or implied by forward-looking statements include, but are not limited to: changes in the markets in which Tevogen competes, including with respect to its competitive landscape, technology evolution, or regulatory changes; changes in domestic and global general economic conditions; the risk that Tevogen may not be able to execute its growth strategies or may experience difficulties in managing its growth and expanding operations; the risk that Tevogen may not be able to develop and maintain effective internal controls; the failure to achieve Tevogen's commercialization and development plans and identify and realize additional opportunities, which may be affected by, among other things, competition, the ability of Tevogen to grow and manage growth economically and hire and retain key employees; the risk that Tevogen may fail to keep pace with rapid technological developments to provide new and innovative products and services or make substantial investments in unsuccessful new products and services; that Tevogen will need to raise additional capital to fully realize its business plans; risks related to the ability to develop, license or acquire new therapeutics; the risk of regulatory lawsuits or proceedings relating to Tevogen's business; uncertainties inherent in the execution, cost, and completion of preclinical studies and clinical trials; risks related to regulatory review, approval and commercial development; risks associated with intellectual property protection; Tevogen's limited operating history; and those factors discussed or incorporated by reference in Tevogen's Annual Report on Form 10-K and subsequent filings with the SEC.

You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Tevogen undertakes no obligation to update any forward-looking statements, except as required by applicable law.

Executive Summary

Executive Summary

TEVOGEN BIO

Tevogen Bio is a clinical-stage specialty immunotherapy company:

Harnessing highly enriched scalable *genetically unmodified* allogeneic CD8+ cytotoxic T lymphocytes

- To produce off-the-shelf and personalized T cell therapies
- For treatment of cancers and viral infections that may cause disruption in cancer care

Aiming to address the significant unmet needs of large patient populations

- And offer commercially attractive and economically viable therapeutics
- And plan a short path to positive cashflow

EXACTCELL™ TECHNOLOGY

Proprietary technology with broad applications for convenient and affordable cellular immunotherapies with disease target specificity; highly enriched, scalable, *genetically unmodified* allogeneic T cells for the treatment of acute viral infections, long-term consequences of viral infections, viral and non-viral induced cancers.

PIPELINE

TVGN 489, a clinical-stage product, is being developed for the treatment of SARS-CoV-2 infection in patients with B cell hematologic cancers, other cancers, and Long COVID.

Preclinical stage products include: TVGN 920 for HPV-related cervical cancer; TVGN 930 for EBV-associated Lymphomas; TVGN 960 for HPV-related mouth and throat cancer.

INTELLECTUAL PROPERTY

Three *wholly owned*, granted U.S. patents; Twelve pending U.S. patents, including two in AI.

LEADERSHIP

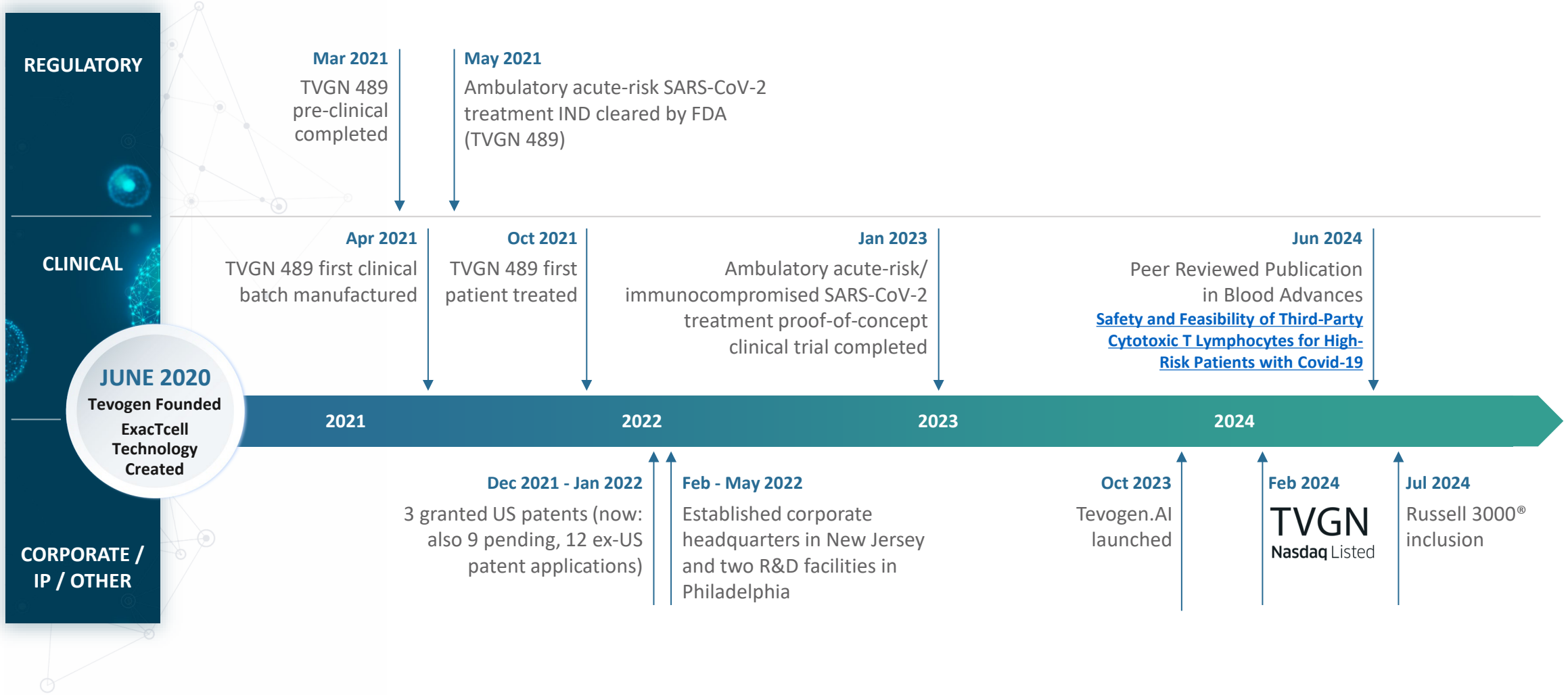
Industry leaders and scientists with drug development, alliance management, and global product launch experience.

CLINICAL TRIAL

Proof-of-concept clinical trial completed with positive results of first clinical product candidate, for treatment of acute high-risk SARS-CoV-2 patients.

Key Achievements

Tevogen moved its first product from discovery to clinical phase within 18 months of inception



Planned Priorities

Reflects management's current assumptions, estimates, projections and beliefs

SHORT TERM

- Expand R&D and clinical manufacturing capacity
- **TVGN 489** pivotal trial for treatment of SARS-CoV-2 infection in patients with:
  a. B cell malignancies and
  b. Solid tumors and other non B-cell malignancies
- Identify and execute collaboration agreement with commercialization partner(s)
- Establish Medical Affairs function and initiate market development campaign

MID TERM

- Expand manufacturing capacity to match the forecasted demand
- Prepare organization for commercialization, marketing, sales, fulfilment, and HLA testing
- Seek BLA approval for **TVGN 489** for treatment of SARS-CoV-2 infection in patients with B cell malignancies
- Launch **TVGN 489** in oncology followed by other indications
- Phase I clinical trial **TVGN 920** for HPV related cervical cancer
- Phase I clinical trial **TVGN 960** for HPV related mouth and throat cancer
- **TVGN 489** pivotal trial for the treatment of SARS-CoV-2 infection in immunosuppressed patients with autoimmune diseases
- Phase I clinical trial **TVGN 930** for EBV-Associated Lymphomas

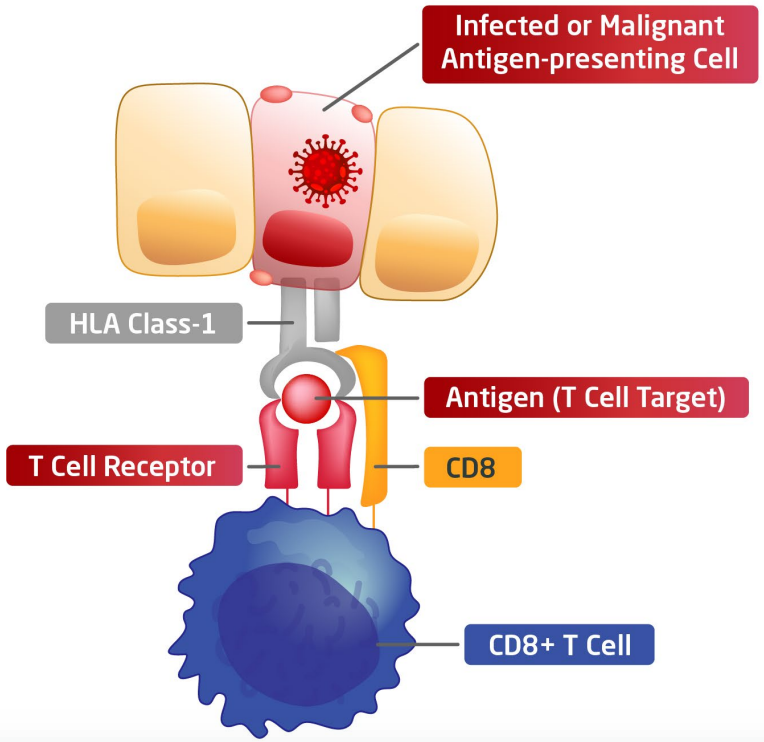
Our Science and ExacTcell™ Technology

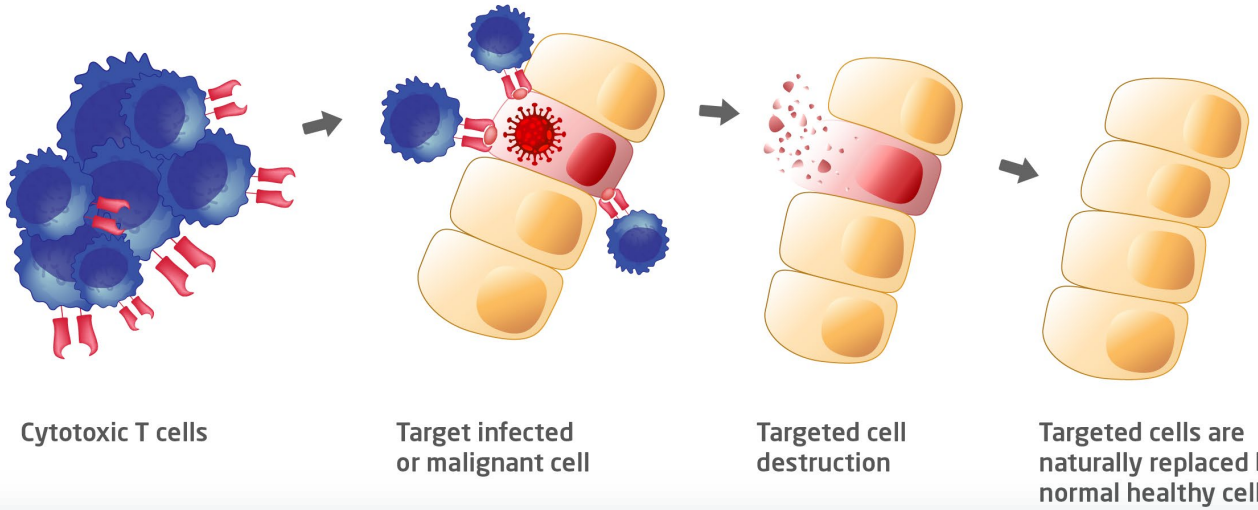
- Naturally occurring T cells enriched and expanded for precision targeting restricted by a single HLA molecule
- A unique approach focused on administering allogeneic, personalized, and economically sustainable T cell therapeutics

ExacTcell – Mode of Action

Focuses on the selection and expansion of naturally occurring, **genetically unmodified T cells** to target multiple, distinct, preselected proteins present *only* on virus-infected or malignant cells and to kill those cells.

VIEW ANIMATION ON YouTube



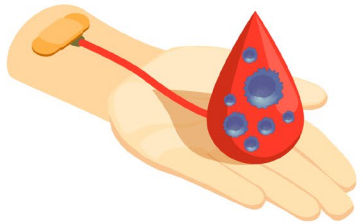


Human Leukocyte Antigens (HLA) show foreign protein to T cells. HLA varies from person to person.
For this reason, a panel of T cells is necessary to match a variety of HLA types.

ExacTcell – Tevogen's T Cell Therapy

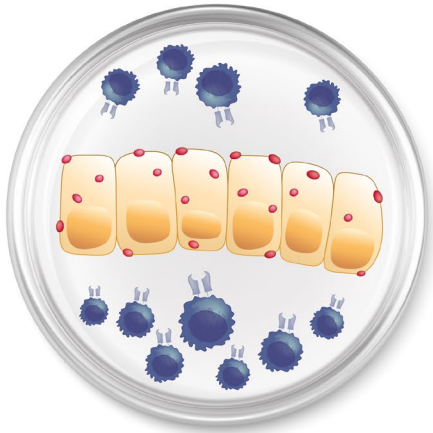
Tevogen’s commercial scale ready manufacturing process yields a highly efficient ratio of doses per cell donor

VIEW ANIMATION ON YouTube



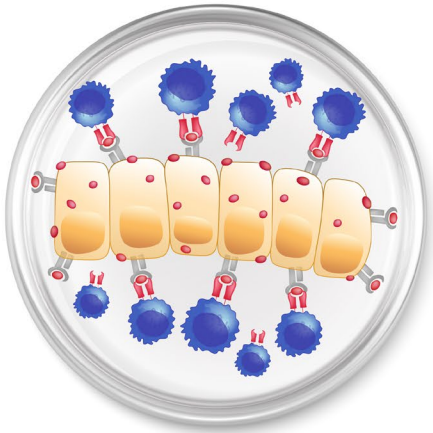
1

T cells donated by a single donor.



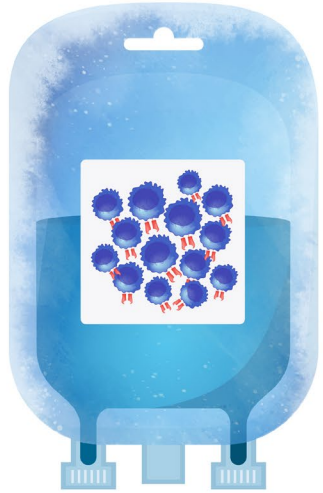
2

T cells exposed to artificially made proteins of the virus or cancer of interest.



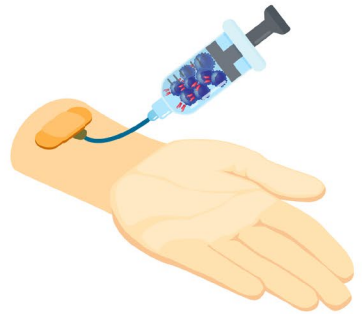
3

T cells that naturally engage the proteins of interest are selected and nourished.



4

The selected T cells expand to yield hundreds of doses from single cell donor and stored for outpatient use.



5

After infusion T cells engage the viral proteins, they were trained to recognize. HLA-matched off-the-shelf therapy can be infused in minutes.

ExacTcell – Benefits and Uniqueness

A technology that enables potentially safe, effective, and easy to administer cell therapy

	ExacTcell	Autologous CAR-T	Allogeneic CAR-T	Tumor Infiltrating Lymphocytes (TILs)	Bispecific T cell Engager (BiTE®)
Designed to attack only diseased cells and spare normal healthy counterparts	✓	✗	✗	✓ May cause vitiligo after melanoma Rx	✗
Genetically unmodified cells	✓	✗	✗	✓	N/A
Lacks frequent serious side effects	✓	✗	✗	✗	Sometimes
		Common to observe CRS, neurologic toxicity, significant low white blood cell count, low blood pressure			
Designed for outpatient treatment and follow up	✓	✗	✗	✗	Not For First Dose
Avoids preparatory chemotherapy	✓	✗	✗	✗	✓
Off-the-shelf administration limiting risk of disease progression during product manufacture	✓	✗	✓	✗	✓
			Avoiding gaps in cancer treatment increases the chances of success		
Hundreds of doses produced from a single donor/batch	✓	✗	?	✗	N/A
			For some treatments, one lot made for each patient		
Number of doses administered	One	One	One	Typically One	Several

References available on Slide 29

Advantages of Using TVGN 489 to Treat Cancer Patients with SARS-CoV-2

Avoiding prolonged gaps in cancer treatment increases chances of cancer treatment success

- Cancer is typically treated in repetitive fashion. The time interval between cancer treatments allow the body to recover more so than the cancer can recover.
- With prolonged gaps in cancer treatment, there is more time for the cancer to re-grow, allowing resistant cells to become a larger part of the tumor.
- Even a 4-week delay in treatment is associated with higher risk of death across surgical, chemotherapy, and radiation therapy treatments in 7 common cancers[1]. With a longer treatment gap, a higher risk exists of cancer cells becoming resistant and cancer treatment failing.

After TVGN 489 therapy, patients were able to move rapidly to stem cell transplant, which ablates virtually all immunity, without any resurgence in SARS-CoV-2 symptoms or other activity.

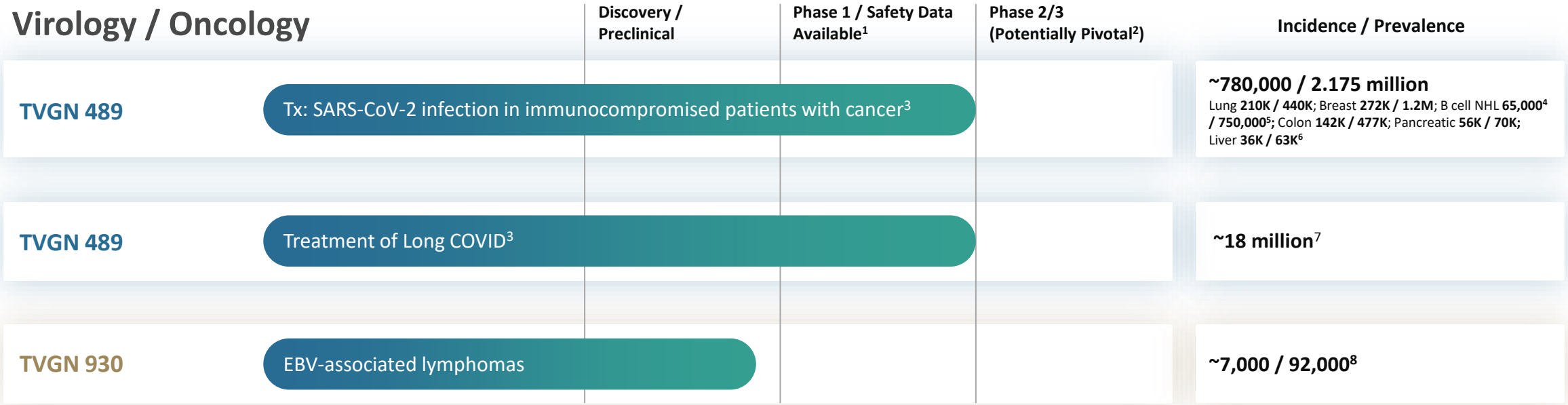
Patients should thus be consistently more likely to resume their cancer treatment more quickly after TVGN 489.[2]

1. Hanna, T. et al. British Medical Journal, 2020. https://doi.org/10.1136/bmj.m4087
2. Study Details | Transfer of Infection Fighting Immune Cells Generated in the Laboratory to High Risk Patients With COVID-19 Infection | ClinicalTrials.gov

Pipeline & Strategy

- Tevogen Bio is developing therapeutic products that not only treat cancer but also enable oncology patients to maintain uninterrupted therapy.
- Addition of non-oncology products to the pipeline is an opportunistic approach to maximize ROI from our proprietary ExacTcell technology

Pipeline



References available on Slide 30 and Slide 31

Pipeline

Oncology

		Discovery / Preclinical	Phase 1 / Safety Data Available[1]	Phase 2/3 (Potentially Pivotal[2])	Incidence / Prevalence
TVGN 920	Cervical Cancer Prevention with High-Risk HPV Infection				**5.5 million** women per year have HPV 16/18[4] and of these, **200,000** women per year are diagnosed with high grade dysplasia[8]
TVGN 960	Mouth and throat cancer (HPV-related)				**~32,000 / 110,000[5]**
TVGN 116	Liver Cancer Prevention with High-Risk Chronic Hepatitis B Infection				**Prevalence: ~850,000 to 2.2M[6]**

Future Considerations

- SARS-CoV-2 infection in patients under treatment for rheumatoid and psoriatic arthritis
- EBV-related Multiple Sclerosis

References available on Slide 32

TVGN 489 in Long COVID

- Recent studies[1] have detected persistent Spike and Nucleocapsid proteins in some Long COVID patients suggesting the existence of a viral reservoir in these patients.
- None of the patients treated with TVGN 489 developed Long COVID during the 6-month study follow up period[2]. This suggest that effectively clearing the virus could prevent Long COVID by stopping the formation of a viral reservoir.
- Future acute SARS-CoV-2 studies are expected to build on the observation about Long COVID prevention.
- The finding of a viral reservoir suggests that CTLs can be used to eliminate this reservoir, hopefully eliminating the symptoms of Long COVID along with it.

1. Long COVID: major findings, mechanisms and recommendations | Nature Reviews Microbiology
2. Study Details | Transfer of Infection Fighting Immune Cells Generated in the Laboratory to High Risk Patients With COVID-19 Infection | ClinicalTrials.gov

Leadership & Board

Key Executive Leadership

Leadership with diversified experience across all sectors of the healthcare ecosystem and a successful track record in drug development

> When affordability of lifesaving medications is paired with a profitable business model, society prospers
>
> **- Ryan Saadi, June 2020**

Ryan Saadi, MD, MPH
Chief Executive Officer
Yale University

Neal Flomenberg, MD
Chief Scientific Officer and Global R&D Lead
Thomas Jefferson University

Sadiq Khan, MBA
Chief Commercial Officer
University of Illinois Chicago

Kirti Desai, CPA
Chief Financial Officer
University of Mumbai
Member: American Institute of Certified Public Accountants

Johnson & Johnson · CSL Behring · sanofi aventis (Because health matters.) · Sidney Kimmel Cancer Center Jefferson Health | NCI – designated

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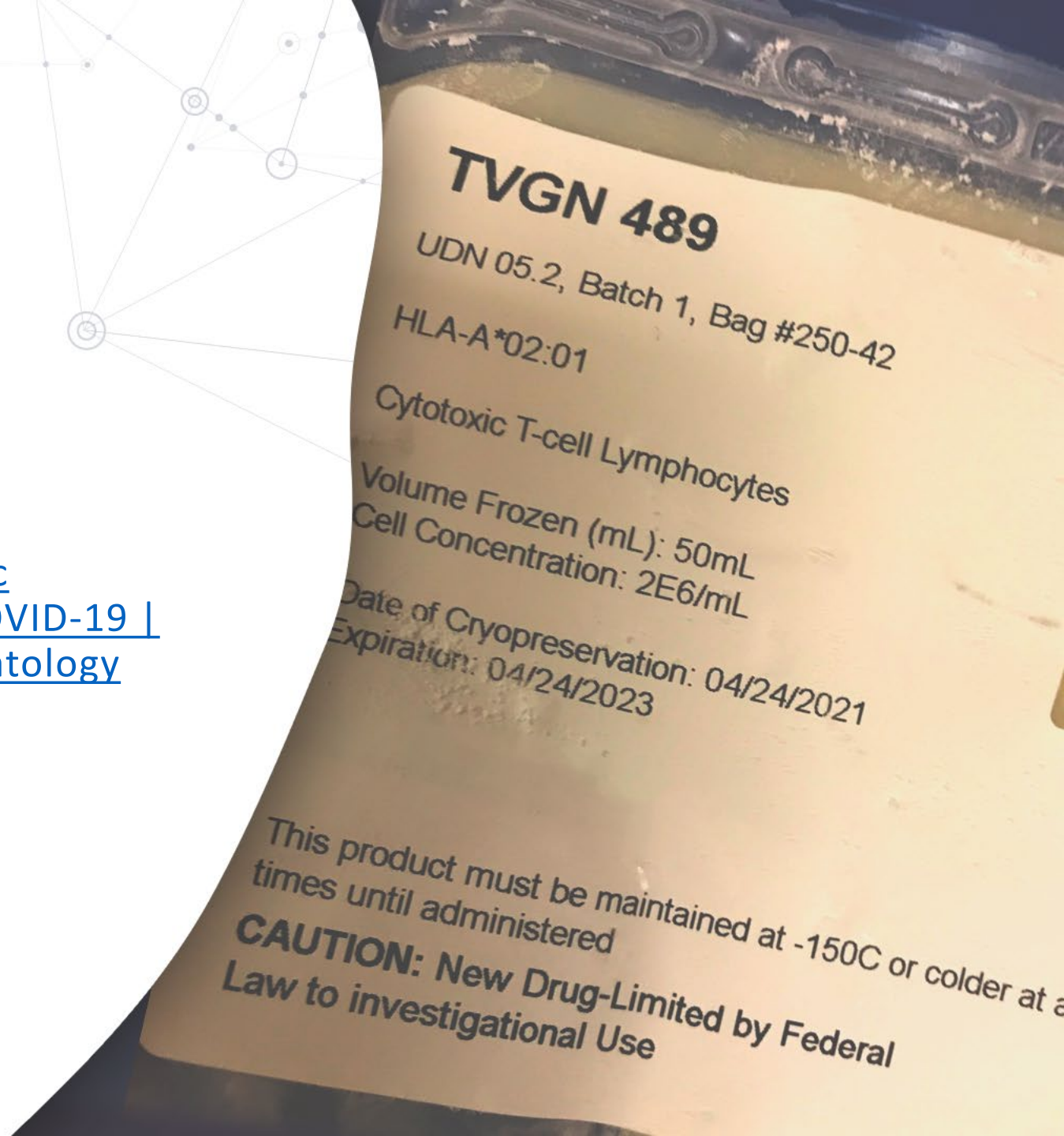
Clinical Trial

[Safety and feasibility of third-party cytotoxic T lymphocytes for high-risk patients with COVID-19 | Blood Advances | American Society of Hematology](#) (ashpublications.org)



Clinical Trial – Design and Objectives

DESIGN

Patient Assignment

Assignment to the Interventional versus Observational Arm was based on the subject's HLA type. Rapid HLA typing was obtained at the time of enrollment.

- Patients positive for HLA-A*02:01 received the CTLs (Interventional Arm). Protocol specified that maximum time to treatment after SARS-CoV-2 diagnosis was 4 days
- Patients negative for HLA-A*02:01 were enrolled on an Observational Arm with follow-up of symptoms at time points mirroring patients on the Interventional Arm as part of the Exploratory Objective

Interventional Study Arm

- Ambulatory patients were treated with TVGN 489 (Day 0) and observed for 4 days (Days 1-4) after treatment
- The 4 testing doses were based on data regarding anti-viral T-cell therapy in hematopoietic transplant patients
- After discharge, patients were contacted or seen in the office daily x 10 additional days after the infusion and at 1, 2, 3, and 6 months after infusion
- Dose limiting toxicity (DLT) monitoring period was 14 days after TVGN 489 CTLs infusion

OBJECTIVES

Primary Endpoints (Interventional Arm)

Assess the safety of TVGN 489 when given at 4 escalating dose levels. Safety defined as the absence of:

- ≥ Grade 3 acute infusion reaction
- Signs of cytokine release syndrome as commonly seen after CAR-T therapy (Hypoxia and/or Hypotension)
- Neurotoxicity
- Graft versus host disease
- Grade 4 or higher adverse events related to the CTLs

Secondary Endpoints (Interventional Arm)

- Reduction of viral load and symptoms in patients (up to 14 days)
- Assurance that TVGN 489 did not interfere with patients' own development of T cell and B cell immunity to SARS-CoV-2 (up to 6 months)
- Determine persistence of TVGN 489 (up to 6 months)

Exploratory Endpoint

- Examine the symptomatic control of SARS-CoV-2 in Interventional Arm versus patients in Observational Arm

Clinical Trial – Target & Size of Population

Dose-finding study with four dosing levels of SARS-CoV-2-Specific Cytotoxic T Lymphocytes (TVGN 489)

TARGET POPULATION

Ambulatory patients with newly diagnosed SARS-CoV-2 infection at acute risk for complications due to one or more of the following conditions:

- Hypertension
- Obesity
- Diabetes
- Cardiovascular Disease
- Age ≥ 65
- Chronic Lung Disease
- Chronic Liver Disease
- Malignancy (treated within previous 24 months)
- Lack of Response to SARS-CoV-2 Vaccine
- History of Stroke
- Chronic Kidney Disease
- Requiring Nursing Home Support/Poor Performance Status
- Not on Supplemental Oxygen
- Sickle Cell Disease

12 **Interventional arm enrolled**

18 **Observational arm enrolled**

30 **Total Patients**

Each of the four dosing levels completed with the minimum required number of three patients, for a total of twelve patients. This was due to the absence of appreciable toxicities across all dose levels. The observational arm, which was designed to end enrollment when interventional arm enrollment was completed, concluded with **18** patients, appreciably less than what would have occurred if the interventional group required additional enrollment.

Clinical Trial – Patient Characteristics

50% of patients in the Interventional Arm were on active cancer or lupus treatment

	Interventional Arm	Observational Arm
Median Age (Range)	**59** (24 – 83)	**57** (26 – 85)
Ethnicity	C – 66% AA – 17% H – 17%	C – 67% AA – 28% H – 5%
Gender	Males – 42% Female – 58%	Males – 44% Female – 56%
Immunocompromised due to active cancer treatment or therapy for autoimmune diseases	**50%**	**6%**
Comorbid Conditions Median (Range)	**3** (2 – 5)	**2.5** (1 – 3)
Baseline Antibody Status	**33.3%** Unvaccinated or no response to vaccination (Immunocompromised)	**11.1%** Unvaccinated
Treatment	TVGN 489	Standard of care including mAbs

Dosing Level	Patient Ethnicity / Gender	Age	Comorbidities	Vaccination Status	Variant
Dosing Level 1 (1×10^5 cells/kg)	African Amer Male	24	Obesity, HTN, DM, Asthma	Unvaccinated	Delta
	Caucasian Female	73	Obesity, HTN, Age	Vaccinated	Delta
	Hispanic Female	47	HTN, DM, CV Disease, Stroke, Lupus	Vaccinated	Delta
Dosing Level 2 (3×10^5 cells/kg)	Caucasian Male	56	Obesity, Colon cancer on active treatment	Vaccinated	Omicron BA.1
	Hispanic Female	44	Obesity, Lymphoma on active treatment	Unvaccinated	Omicron BA.1
	Caucasian Female	73	HTN, Pancreatic Cancer on active treatment, Age	Vaccinated x 1 Dose	Omicron BA.1.1
Dosing Level 3 (1×10^6 cells/kg)	Caucasian Male	58	HTN, DM	Vaccinated	Omicron BA.2.9
	Caucasian Female	83	HTN, Lymphoma on active treatment, Age	No vaccine response	Omicron BA.2
	African Amer Female	63	HTN, Obesity, Lymphoma on active treatment	No vaccine response	Omicron BA.2.12
Dosing Level 4 (3×10^6 cells/kg)	Caucasian Male	67	Obesity, HTN, DM, Age, Heart Disease	Vaccinated	Omicron BA.2
	Caucasian Female	60	Obesity, HTN, DM	Hx of SARS-CoV-2, Unvaccinated	Omicron BA.5
	Caucasian Male	49	Obesity, HTN, DM	Vaccinated	Omicron BA.5.2

Study Details | Transfer of Infection Fighting Immune Cells Generated in the Laboratory to High Risk Patients With COVID-19 Infection | ClinicalTrials.gov

Clinical Trial – Key Observations

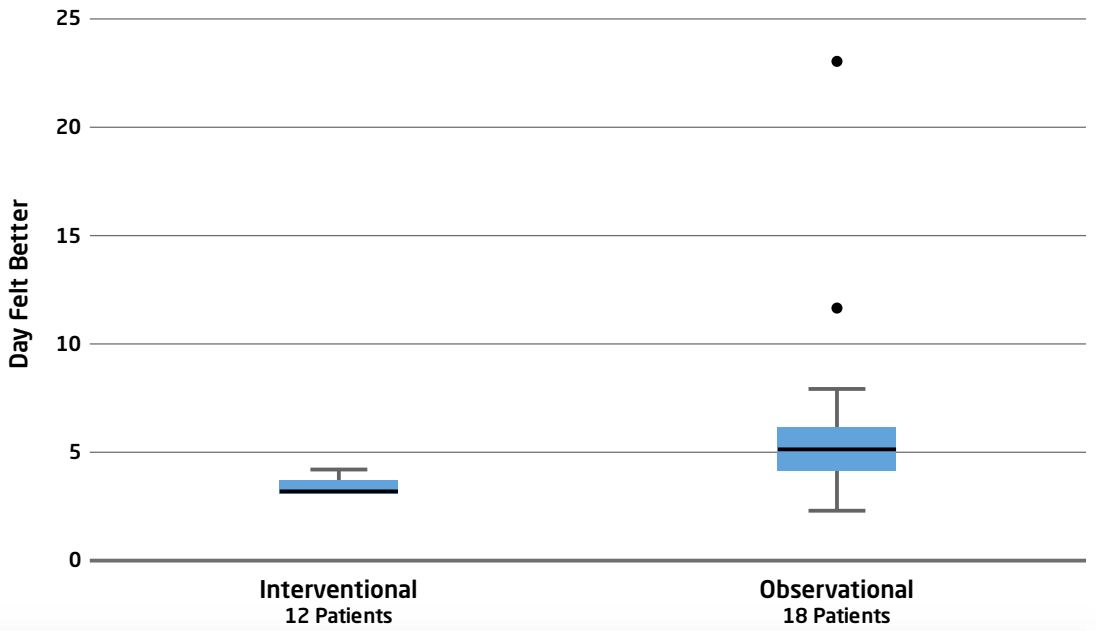
Therapy well-tolerated at all dose levels, no dose limiting toxicities observed

PRIMARY ENDPOINT

Dose-Limiting Toxicity Criteria	Trial Result
≥ Grade 3 acute infusion reaction	None
Cytokine release syndrome (Hypoxia and/or Hypotension)	None
Neurotoxicity	None
Graft versus Host Disease	None
Grade 4 or higher adverse events	None

Institutional data safety monitoring committee and external medical monitor reviewed results and **deemed therapy well-tolerated at all dose levels**

EXPLORATORY ENDPOINT



No incidence of **SARS-CoV-2 reinfection** or **Long COVID** was observed in any treated patient at the time of the six month follow up

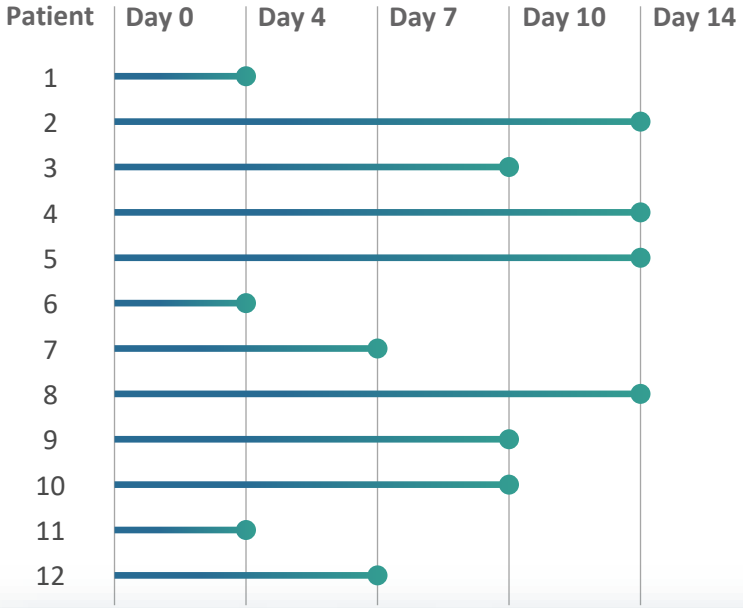
Study Details | Transfer of Infection Fighting Immune Cells Generated in the Laboratory to High Risk Patients With COVID-19 Infection | ClinicalTrials.gov

Clinical Trial – Key Observations

Rapid viral load reduction after TVGN 489 treatment; documented persistence of TVGN 489

SECONDARY ENDPOINTS

Time to Eliminate 99-100% of Viral Load

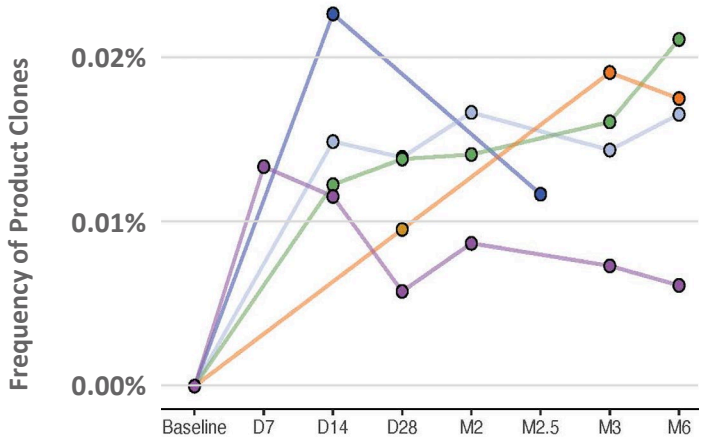


SARS-CoV-2 viral presence was assessed by PCR.

Viral clearance was far more rapid than what would have been expected, particularly given that 50% of the patients were immune compromised.

Baseline assessment revealed a substantial SARS-CoV-2 burden in at least 10 of the 12 patients. Despite this, 11 of 12 patients demonstrated prompt and significant reduction in viral load (>85%) by day 4. And all were negative or reduced (>99%) by day 14

Persistence of CTLs



TVGN 489 SARS-CoV-2 reactive CD8+ T cells could still be detected in all patients tested at 6 months.

Immunosequencing by:

Adaptive biotechnologies

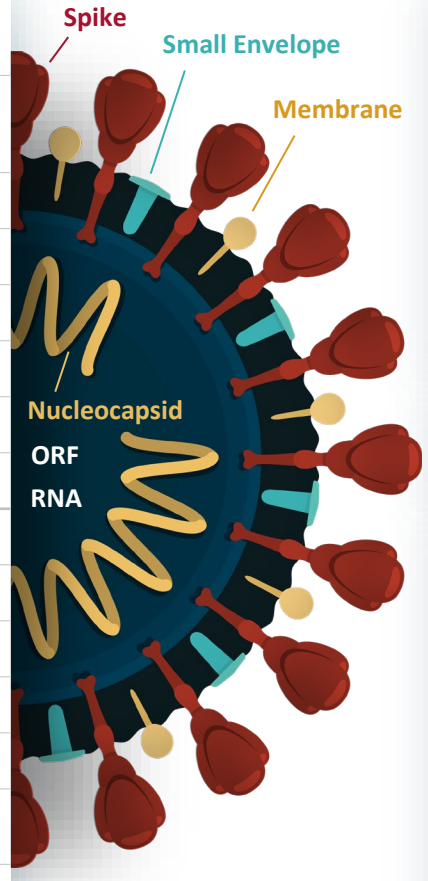
"Product-only clone" refers to any T cell expressing a T cell receptor with a DNA sequence found in the investigational product (TVGN 489) but ***not*** found in a treated patient's sample before infusion

ExacTcell – Ongoing Efficacy Against SARS-CoV-2 Strains as of Sep 2024

Tevogen's targets have been preserved throughout the pandemic; vaccines and mAbs target the quickly mutating Spike protein, leading to a potential sudden loss or reduction in efficacy

HLA Restriction	Peptide #	Peptide Source	Percentage of Isolates with Preserved Target by Variant			
			BA.1	BA.2	JN.1	KP.2 (FLiRT)
HLA-A*02:01	1	Nsp7	99.91%	99.96%	99.95%	99.99%
	2	ORF3a	99.74%	94.19%	99.23%	99.41%
	3	Spike	96.29%	99.95%	99.71%	99.71%
	4	ORF3a	99.80%	92.24%	99.68%	99.62%
	5	Nsp8	99.94%	99.93%	99.77%	99.90%
	6	Nsp3	99.88%	99.88%	99.93%	99.81%
HLA-A*01:01	1	ORF3a	99.86%	99.81%	99.5%	99.06%
	2	Nsp3	99.32%	99.76%	99.26%	99.11%
	3	Nsp3	99.77%	99.17%	99.91%	99.94%
	4	Membrane	90.60%	99.68%	99.83%	99.70%
	5	nsp9	99.94%	99.92%	99.93%	99.97%
	6	RNA-dependent RNA polymerase	99.90%	99.45%	99.77%	99.76%
	7	3C-like proteinase	99.99%	99.90%	99.98%	99.99%

Above TVGN targets selected in 2020 and preserved in thousands of samples from NIH database



TVGN 489

- Targets multiple internal and external proteins across the entire viral genome which are preserved across variants.
- Not limited to the spike protein like vaccines and monoclonal antibodies.
- As of Sep 2024, Tevogen Bio confirms preservation of TVGN 489 targets in dominant FLiRT strains of SARS-CoV-2.

Vaccine requires reformulation at least yearly to address predominant variants; vaccine protection can be lost rapidly.

Monoclonal antibodies (mAbs) were compromised due to the virus' rapid mutation rate and sole focus on the spike protein. As a result, majority of mAbs have had their EUA revoked.

Monoclonal	Target	Status
Bamlanivimab	Spike protein	EUA revoked – Apr 16, 2021
Etesevimab	Spike protein	EUA revoked - Jan 24, 2022
Casirivimab/imdevimab (REGEN-COV)	Spike protein	EUA revoked – Jan 24, 2022
Sotrovimab	Spike protein	EUA revoked – Apr 05, 2022
Bebtelovimab	Spike protein	EUA revoked – Nov 30, 2022
Tixagevimab/cilgavimab (Evusheld)	Spike protein	EUA revoked – Jan 26, 2023

TEVOGEN.AI

Artificial Intelligence

TEVOGEN.AI

Enhancing Patient Access by Utilizing Artificial Intelligence-powered Tools

Target Detection: We are exploring ways to deploy AI-powered target detection to further accelerate our product development pace, either internally or in collaboration with others.

Reducing Failure Rates: AI could use data patterns to foresee potential adverse drug reactions early on, potentially averting costly trial failures. It might also flag efficacy concerns, guiding timely adjustments to enhance the probability of success.

Optimizing Clinical Trials: AI algorithms could analyze data to identify patients who would be most likely to respond to the investigational therapy.

FAILURE IN PRECLINICAL

69%

of programs never succeed in delivering an IND [1]

FAILURE IN CLINICAL

90%

of drug candidates in clinical trials fail [2]

1 Biotech Valuation Best Practices | Toptal®
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TEVOGEN.AI Microsoft databricks

Tevogen.AI will leverage Microsoft's digital infrastructure, scientific research, and AI expertise, along with Databricks' data engineering capabilities, to power the development of its proprietary technologies.

- **PredicTcell™:** A suite of AI algorithms that predict immunologically active peptide-T cell receptor interactions to enhance precision immunotherapy. Continuously refined through reinforcement learning, PredicTcell accelerates in-vivo processes and expands Tevogen Bio's pipeline. Its growing terabyte-scale database analyzes millions of protein-peptide interactions across diseases and the human genome.

- **AdapTcell™:** AI-driven algorithms decoding human leukocyte (HLA) antigens and T cell interactions to deepen immune system insights and reveal new therapeutic paths. As understanding grows, AdapTcell models conduct in-silico experiments that inform genetics, proteomics, and build a high-resolution HLA specificity map.

Tevogen.AI continues to build a data pipeline and curate data across numerous virology areas of development (table below). These datasets enable us to offer precise guidance for lab testing, where we can validate HLA-to-protein binding based on specific target identification, speeding up development process.

Virus	Number of Isolates
SARS-CoV-2	3,915,366
Hepatitis B	10,046
Human Papillomavirus	11,755
Influenza	75,874
Respiratory Syncytial Virus	2,517
MPox	10,631

Thank You

Please contact us with investor inquiries at: **ir@tevogen.com**
For all other inquiries: **info@tevogen.com**

1 877-TEVOGEN

Appendix

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TIL Therapy

1. Tumor-Infiltrating Lymphocyte (TIL) Therapy | Dana-Farber Cancer Institute
2. TIL Therapy | Treatment for Melanoma | OHSU Knight Cancer
3. NIH cost of TIL therapy, in First Cancer TIL Therapy Gets FDA Approval for Advanced Melanoma, Lifileucel First Cellular Therapy Approved for Cancer – NCI
4. Zhao Y, Deng J, Rao S, Guo S, Shen J, Du F, Wu X, Chen Y, Li M, Chen M, Li X, Li W, Gu L, Sun Y, Zhang Z, Wen Q, Xiao Z, Li J. Tumor Infiltrating Lymphocyte (TIL) Therapy for Solid Tumor Treatment: Progressions and Challenges. Cancers (Basel). 2022 Aug 27;14(17):4160. doi: 10.3390/cancers14174160. PMID: 36077696; PMCID: PMC9455018

CAR-T

1. Cancer Research UK: CAR T-cell therapy, CAR T-cell therapy | Cancer Research UK
2. American Cancer Society: CAR T-cell Therapy and Its Side Effects CAR T-cell Therapy and Its Side Effects | American Cancer Society
3. WEB MD-Navigating the Financial Aspects of CAR T-Cell Therapy. CAR T-Cell Therapy: How to Manage Costs and Get Financial Assistance (webmd.com)
4. Luo Jingming and Zhang Xianwen. Challenges and innovations in CAR-T cell therapy: a comprehensive analysis. Frontiers in Oncology, 14,2024. doi=10.3389/fonc.2024.1399544
5. CAR-T Reimbursement Updates Proposed for FY 2024 | Avalere
6. Challener, C. Moving from Autologous to Allogeneic Cell Therapies: Drivers and Hurdles. Pharma's Almanac. Moving from Autologous to Allogeneic Cell Therapies: Drivers and Hurdles (pharmasalmanac.com)

TVGN 489

1. Grosso, et al. Safety and feasibility of third-party cytotoxic T lymphocytes for high-risk patients with COVID-19. Blood Advances, Volume 8, Issue 15,13 August 2024, Pages 4113-4124. Safety and feasibility of third-party cytotoxic T lymphocytes for high-risk patients with COVID-19 | Blood Advances | American Society of Hematology (ashpublications.org)

Appendix

Slide 13

1. Phase 1 clinical trials are designed in part to generate proof of concept data and safety-related data on tolerability and side effects.
2. A pivotal trial is a trial designed to generate data sufficient to support the filing of an application for regulatory approval. A pivotal trial may not necessarily be denoted as a Phase 3 clinical trial, and instead may be a Phase 2 or Phase 2/3 clinical trial. We believe that Phase 2, Phase 2/3, or Phase 3 clinical trials may serve as pivotal trials for TVGN 489.
3. We believe that the safety data from our completed Phase 1 clinical trial should be sufficient to serve as the basis for one or more later stage, potentially pivotal trials in acute SARS-CoV-2 patients with B-cell cancer immune suppression, other B cell immune suppressed acute SARS-CoV-2 patients with a B cell cancer indication, and for Long COVID prevention and treatment. We cannot be certain whether we will be permitted to move from a Phase 1 trial directly to a pivotal trial covering any specific target population until the FDA reviews and concurs with or rejects our proposed plans, and the FDA may require us to conduct further trials to generate additional safety and efficacy data prior to approval.
4. Based on the recent references below, there are >65,000 new cases of adult B cell lymphoma diagnosed in the US each year.
   80,620[2] -1% (1% to exclude pediatric[3]) = 79,814 x (85% of the B cell type[1]) = 67,842
   1. Most people with NHL have a B-cell type of NHL (about 85 percent). Leukemia & Lymphoma Society. Lymphoma | Learn About Lymphatic System Blood Cancers | LLS
   2. 80,620 people will be diagnosed with non-Hodgkin Lymphoma in 2024. How Common is Lymphoma? | Key Statistics for Non-Hodgkin Lymphoma | American Cancer Society
   3. The rate of pediatric NHL to adults is just over 1% of adults. El-Mallawany et al. Mature B-cell lymphomas in adolescents and young adults - PMC (nih.gov)
5. Leukemia and Lymphoma Society Blood Cancer Statistics | LLS
6. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; USCS Data Visualizations - CDC, released in June 2024.
7. Products - Data Briefs - Number 480 - September 2023 (cdc.gov)

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8. Top lymphomas associated with EBV are[1]:	Annual Incidence:	Prevalence:
1. Burkitt Lymphoma (Sporadic) (Incidence of EBV association is 10%)	1,200[3] x 10% = 120	<5,000[4] x 10% = 500
2. Classical Hodgkin Lymphoma (Incidence of EBV association is 31%)	8,570[5] x 31% = 2,657	228,081[5] x 31% = 70,705
3. Diffuse Large Cell Lymphoma (Incidence of EBV association is 10%)	18,000[6] x 10% = 1,800	63,883 to 142,889[7] (avg of 103,386) x 10% = 10,339
4. NK and T cell Lymphoma (Incidence of EBV association is 25%)	61[8] or 99[9] (avg of 80) x 25% = 20	
5. Gastric Cancer (Incidence of EBV association is 8-10%[2])	26,500 x 9% = 2,385	Prevalence of 116,000 x 9% = 10,440
	Total annual incidence EBV+ lymphoma = 6,982	**Total prevalence EBV+ lymphoma = 91,984**

References:

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2. National Cancer Institute, EBV-Associated Gastric Cancer, 2024. Downloaded on 10.2.24 at: https://dceg.cancer.gov/research/cancer-types/stomach-gastric/ebv-associated-gastric-cancer
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4. National Center for Advancing Translational Sciences, GARD-Genetic and Rare Diseases Information Center. 2024. Downloaded on 10/1/24 at: https://rarediseases.info.nih.gov/diseases/5973/burkitt-lymphoma
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6. Lymphoma Research Foundation, Diffuse large B Cell Lymphoma, Fact Sheet. 2024. Downloaded on 10/1/24 at https://lymphoma.org/understanding-lymphoma/aboutlymphoma/nhl/dlbcl/#:~:text=Diffuse%20large%20B%2Dcell%20lymphoma%20(DLBCL)%20is%20the%20most,part%20of%20the%20lymphatic%20system.
7. Chihara, D. et al. Clinical Lymphoma, Myeloma and Leukemia, 22 (12),e1092-e1099, 2022. https://www.clinical-lymphoma-myeloma-leukemia.com/article/S2152-2650(22)00260-9/pdf#:~:text=DLBCL%20prevalence%20was%20estimated%20to,patients%20living%20with%20active%20disease.
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Appendix

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4. United States of America Human Papillomavirus and Related Cancers, Fact Sheet 2023(2023-03-10) https://hpvcentre.net/statistics/reports/USA_FS.pdf
5. HPV and Oropharyngeal Cancer | Cancer | CDC
6. HBV Epidemiology - Core Concepts