Tevogen Bio Announces Positive Proof-of-Concept Clinical Trial Results of Its Off-The-Shelf, Allogeneic Cytotoxic CD8+ T Cell Therapy for Treatment of Acute High-Risk COVID Patients, First Clinical Product of Company's Precision Cell Therapy Platform

- **The primary study endpoints were related to safety. No dose-limiting toxicities or significant adverse events related to TVGN 489, including Cytokine Release Syndrome, were observed in any patient at any dose level.**
- **Secondary endpoints measuring the reduction of viral load and the presence of cellular and humoral anti-COVID-19 responses after treatment were met.**
- **Fifty percent (50%) of treatment arm patients were immunocompromised versus six percent (6%) of observational arm patients.**
- **Treatment arm patients were infected by a variety of COVID variants ranging from Delta through Omicron BA.5.2.**
- **Observational arm patients were treated with standard of care including monoclonal antibodies.**
- **Key observational findings: All treatment arm patients returned to their baseline level of health within 14 days of treatment. No incidence of COVID reinfection or Long COVID was observed in any treated patient at the time of the six (6) month follow up.**

WARREN, N.J., January 23, 2022 – Tevogen Bio today announced positive topline results from its Proof-of-Concept (POC) clinical trial designed to evaluate the safety and feasibility of TVGN 489, the company's first clinical product of its precision T Cell therapy platform, for the treatment of acute high-risk COVID-19 patients. TVGN 489 is a genetically unmodified, off-the-shelf, allogeneic cytotoxic CD8+ T lymphocyte (CTL) product with precise targets across the SARS-CoV-2 genome, not just the Spike protein. To date, TVGN 489 targets, identified early in the pandemic, persist in the most recent SARS-CoV-2 variants. The open label comparative trial was conducted at Thomas Jefferson University Hospital in Philadelphia to assess the safety and feasibility of TVGN 489 when given at one of four escalating doses. Twelve ambulatory patients with newly diagnosed COVID-19 infection who were at higher risk for infection-related complications due to advanced age or CDC-defined comorbid conditions such as heart, lung, liver, and kidney disease, hypertension, diabetes, cancer, or obesity were treated on the trial. Eighteen patients, who also met these criteria but did not receive TVGN 489 because of lack of HLA matching, were enrolled on an observational arm in the study and treated with standard of care including monoclonal antibodies.

The treated patients had between 2 to 5 comorbidities each and 6 out of 12 (50%) were immunocompromised due to treatment for cancer or autoimmune disease. Multiple COVID-19 variants were detected in the group. Safety endpoints included infusion reactions, grade 4 adverse events, GVHD, marrow aplasia, neurotoxicity and CRS.

Table 1. Treatment arm (n=12)

Safety Criteria as Defined in the Study Protocol	**Trial Result**
Infusion Reactions (≥ Grade 3)	0/12
Cytokine release syndrome, (Grade ≥ 2)	0/12
Neurotoxicity (Grade ≥ 2)	0/12
Graft versus Host Disease	0/12
Grade ≥4 Adverse Events (Related to the CTL therapy & outside the spectrum of identified COVID related adverse events)	0/12

Safety endpoints were reviewed after each dose level and confirmed by an independent Data and Safety Monitoring Committee at Jefferson and by both internal and external Medical Monitors who provided permission to escalate to the next dose level. Based on the data in Table 1, safety was confirmed with the minimum required number of patients per dosing level. In addition to safety endpoints, secondary endpoints measuring the reduction of viral load and the presence of cellular and humoral anti-COVID-19 responses after treatment were also met.

Enrollment was completed in nine months, and six-month follow-up for all patients concluded on January 19, 2023. In the treatment arm, no patient experienced progression of their COVID-19 infection and all patients returned to their baseline level of health within 14 days of treatment. There were no incidences of COVID-19 reinfection or Long COVID observed in any treated patient through the 6-month follow-up period. While patients in the treatment group experienced COVID-19 symptom relief in a rapid, consistent timeframe as self-reported and confirmed by the investigators, patients on the observation arm showed improvement in a less consistent, and in some cases, longer time frame.

The study investigators plan to submit the full data for publication in a peer-reviewed journal in the upcoming weeks.

“The highly encouraging data of TVGN 489 allows us to turn our attention to the critical unmet need in the COVID-19 landscape. Immunocompromised and the elderly and infirm usually do not benefit from currently available prevention or treatment strategies for COVID-19 and remain highly vulnerable to poor outcomes with a COVID-19 infection. These patients, as well as those individuals with Long COVID, urgently require new treatment options,” said Dr. Dolores Grosso, DNP, the Principal Investigator of the trial.

“I’m greatly encouraged by the POC trial experience of TVGN 489 and hopeful that our investigational COVID-19 therapy will eventually offer hope to a substantial segment of patients.” said Dr. Neal Flomenberg, MD, Tevogen’s Chief Scientific Officer.

“Tevogen’s goal is to provide access to the vast and unprecedented potential of personalized immunotherapies for large patient populations impacted by common cancers and viral infections. The ability to administer TVGN 489 in the outpatient setting and the ongoing work by Tevogen scientists to use this product in diverse patient populations, highlights Tevogen Bio’s commitment to patient accessibility”, said Tevogen founder and CEO Dr. Ryan Saadi, MD, MPH.

Tevogen’s research pipeline includes treatment for other serious viral infections and cancers using their precision T Cell platform.

About Tevogen’s Next Generation Precision T Cell Platform

Tevogen’s next generation precision T-cell platform is designed to provide increased immunologic specificity to eliminate malignant and virally infected cells, while allowing healthy cells to remain intact. Multiple, precise candidate targets on viral or malignant cells are selected in advance for T cell sensitization and effector functions with the goal of overcoming the mutational escape capacity of cancer cells and viruses while limiting cross-reactivity.

Tevogen is investigating its technology’s potential to overcome the primary barriers to the broad application of personalized T cell therapies: potency, purity, production-at-scale, and patient-pairing, without the limitations of current approaches. Tevogen’s goal is to provide access to the vast and unprecedented potential of developing personalized immunotherapies for large patient populations impacted by common cancers and viral infections. The ability to administer TVGN-489 in the outpatient setting and the ongoing work by Tevogen scientists to use this product in diverse patient populations, highlights Tevogen Bio’s commitment to patient accessibility.

About Tevogen Bio

Tevogen Bio is driven by a team of highly experienced industry leaders and distinguished scientists with drug development and global product launch experience. Tevogen’s leadership believes that accessible personalized immunotherapies are the next frontier of medicine, and that disruptive business models are required to sustain medical innovation in the post-pandemic world.

Forward Looking Statements

This press release contains certain forward-looking statements relating to Tevogen Bio™ Inc (the “Company”) and its business. These statements are based on management’s current expectations and beliefs as of the date of this release and are subject to several factors which involve known and unknown risks, delays, uncertainties, and other factors not under the Company’s control that may cause actual results, performance or achievements to be materially different from the results, performance or other expectations implied by these forward-looking statements. Forward-looking statements can sometimes be identified by terminology such as “may,” “will,” “should,” “intend,” “expect,” “believe,” “potential,” and “possible,” or their negatives or comparable terminology, as well as other words and expressions referencing future events, conditions, or circumstances. In any forward-looking statement in which the Company

expresses an expectation or belief as to future results, there can be no assurance that the statement or expectation or belief will be achieved. Various factors may cause differences between the Company's expectations and actual results, including, among others: the Company's limited operating history; uncertainties inherent in the execution, cost, and completion of preclinical studies and clinical trials; risks related to regulatory review, and approval and commercial development; risks associated with intellectual property protection; and risks related to matters that could affect the Company's future financial results, including the commercial potential, sales, and pricing of the Company's products. Except as required by law, the Company undertakes no obligation to update the forward-looking statements or any of the information in this release, or provide additional information, and expressly disclaims any and all liability and makes no representations or warranties in connection herewith or with respect to any omissions therefrom.

Contacts

Tevogen Communications
T: 1 877 TEVOGEN, Ext 701
Communications@Tevogen.com