

## **Tevogen Bio Announces Positive Safety Data from Second Cohort in Ongoing Proof-of-Concept Clinical Trial of TVGN-489, its Investigational T cell Therapy for Treatment of COVID-19 in High-Risk Patients**

- **No dose-limiting toxicities reported in first or second cohorts (n=6)**
- **The dosing of patients on dose levels one and two marks the midway point of the trial's planned four dosing levels**
- **All patients in the second cohort infected with Omicron variant as opposed to the first cohort of patients who were infected with the Delta variant**

February 3, 2022

METUCHEN, N.J. Tevogen Bio, a clinical stage biotechnology company specializing in developing cell and gene therapies in oncology and viral infections, today announced it has completed dosing of the second cohort of patients (n=3) in the proof-of-concept clinical trial of TVGN-489, its investigational allogeneic SARS-CoV-2 specific Cytotoxic CD8+ T lymphocytes (CTL) immunotherapy for treatment of COVID-19 in high-risk patients. The dosing of patients on dose levels one and two marks the midway point of the trial's planned four dosing levels. Trial details are available at [Clinical Trials – Tevogen](#).

This single center, open-label clinical trial, conducted at Jefferson University Hospitals in Philadelphia, is designed to study the safety and optimal dosage of TVGN-489 when given to adult patients (age ≥ 18 years) with a SARS-CoV-2 infection. The trial is enrolling participants at high risk of severe COVID-19 progression due to advanced age or other underlying health conditions. The outcomes of participants receiving the investigational therapy (Arm A) are being compared to patients receiving standard of care (Arm B).

Each of the patients in the second cohort received a single infusion (3 x 10<sup>5</sup> cells/kg) of TVGN-489, a higher dosing level than the first cohort (1 x 10<sup>5</sup> cells/kg). No dose limiting toxicities or treatment-related adverse events, including Cytokine Release Syndrome (CRS), have been observed to date in either cohort. Investigators are currently enrolling the third cohort of patients who will receive a higher dose level of TVGN-489 via infusion. The enrollment is expected to conclude early in the second quarter of 2022.

“Our observations regarding the safety of this investigational T cell immunotherapy in the second cohort of patients are very encouraging and provide the basis for continued optimization of dosing in future cohorts. We remain optimistic about the possibility of TVGN-489 serving as a useful tool in the fight against COVID-19 and its emerging variants,” said the Principal Investigator of the trial, Dr. Dolores Grosso, who is the recipient of last year's award in Clinical Research from the Sidney Kimmel Cancer Center – Jefferson Health. Dr. Grosso added that genomic sequencing revealed that all patients in the second cohort were infected with Omicron variant, as opposed to the first cohort of patients who were infected with Delta variant.

Tevogen CEO Ryan Saadi, M.D., M.P.H., said, “Tevogen's off-the-shelf allogeneic T cell technology overcomes the primary barriers to the broad application of personalized T cell

therapies: potency, purity, production-at-scale, and patient-pairing. Our breakthrough innovation opens the possibility of bringing the benefits of T cell therapeutics to large patient populations at unprecedented speed, without the need for specialized medical facilities, such as those required for CAR-T.”

## **About TVGN-489**

TVGN-489 is a highly purified, SARS-CoV-2-specific cytotoxic CD8+ T lymphocyte (CTL) product, which is designed to detect targets spread across the entire viral genome. These targeted CTLs are designed to recognize and kill off virally infected cells, hopefully allowing the body to replace them with healthy, uninfected cells. TVGN-489 demonstrated strong activity against SARS-CoV-2 targets in preclinical studies.

## **About Tevogen Bio**

Tevogen Bio is driven by a team of distinguished scientists and highly experienced biopharmaceutical leaders who have successfully developed and commercialized multiple franchises. 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.’s (the “Company”) development and patient access of its innovations in infectious diseases and oncology. These statements are based on management’s current expectations and beliefs as of the date of this release and are subject to a number of factors which involve known and unknown risks, delays, uncertainties and other factors not under the company’s control which may cause actual results, performance or achievements of the company to be materially different from the results, performance or other expectations implied by these forward-looking statements. In any forward-looking statement in which the Company expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. These factors include results of current or pending clinical trials, risks associated with intellectual property protection, financial projections, sales, pricing and actions by the FDA/EMA. 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 make no representations or warranties in connection herewith or with respect to any omissions herefrom.

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