



## **Kyverna Therapeutics Announces First Publication of Ingenui-T, a Novel CAR T-Cell Vein-to-Vein Manufacturing Process**

January 24, 2024

*The proprietary process, called Ingenui-T, utilizes whole blood from a standard blood draw*

*The novel process is designed to elevate the CAR T cell patient experience by offering a less-invasive alternative to apheresis as well as substantial reduction of cost through a minimization of the CAR T-cell therapy vein-to-vein process*

EMERYVILLE, Calif., January 24, 2024 – Kyverna Therapeutics, Inc. (Kyverna), a patient-centered clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today announced the publication in [BioRxiv](#) of a paper describing Kyverna's proprietary manufacturing process that utilizes less than 300 ml of whole blood from a blood draw instead of apheresis for the collection of T cells from patients undergoing chimeric antigen receptor (CAR) T-cell therapy.

Leukapheresis – a specific type of apheresis – is a conventional starting material for CAR T-cell therapy. The procedure poses challenges due to its length and invasiveness, cost, limited capacity of apheresis beds, and resource constraints at the collection center.

Currently, apheresis requires patients to be connected to a cell separator to collect the T cells by centrifugation and returns the remaining blood components into the body. The procedure must be performed at specialized centers and can last up to 5 hours.

"Ingenui-T represents the culmination of significant development work and our commitment to improve the patient journey and current industry-standard processes for CAR T-cell therapies by easing the burden on patients and improving outcomes.", said Karen Walker, chief technology officer of Kyverna. "We were able to achieve a process minimization without compromising the quality of the operations or the characteristics of the resulting product."

"By eliminating the need for apheresis, we are demonstrating our focus on improving the patient experience, as well as their caregivers.", said Peter Maag, Ph.D., chief executive officer of Kyverna. "Together with our partners, like ElevateBio, we look forward to continuing to innovate."

"We congratulate the Kyverna team for continuously transforming and improving the patient experience. ElevateBio is proud to be partnering with Kyverna to drive innovation and bring these potentially life-transformative therapies to the significant number of patients suffering from autoimmune disorders.", said David Hallal, chairman and chief executive officer of ElevateBio.

CAR T-cell therapy involves modifying a patient's T cells to recognize and remove B cells in the patient's body. Kyverna's CD19 CAR T-cell therapy, KYV-101, specifically targets CD19, a protein expressed on the surface of B cells, which is involved in various types of autoimmune diseases. Kyverna plans to continue to explore additional indications for KYV-101 and develop a robust pipeline of promising product candidate immunotherapies aimed at addressing unmet medical needs in autoimmune diseases.

### **About Ingenui-T**

Ingenui-T is a proprietary, next-generation process in preclinical development for manufacturing autologous anti-CD19 CAR T-cell therapy that incorporates the same CAR construct as KYV-101. The Ingenui-T platform utilizes whole blood from a blood draw as the starting material and implements a process minimization for a more effective outcome.

### **About KYV-101**

KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate for use in B cell-driven autoimmune diseases. The CAR in KYV-101 was designed by the National Institutes of Health (NIH) to improve tolerability and tested in a 20-patient Phase 1 trial in oncology. Results were published by the NIH in *Nature Medicine*<sup>1</sup>.

Kyverna is currently conducting two trials of KYV-101 in patients with lupus nephritis, an autoimmune disease in which more than half of patients do not achieve a complete response to current therapies and are at risk of developing kidney failure. Additional clinical trials of KYV-101 in systemic sclerosis, myasthenia gravis, and multiple sclerosis are in preparation. We believe that the differentiated properties of KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

### **About ElevateBio**

ElevateBio is a technology-driven company commercializing its R&D technology platforms with BaseCamp®, its end-to-end process development and cGMP manufacturing business, to accelerate partners developing and commercializing genetic medicines.

In September 2023, Kyverna partnered with ElevateBio to leverage BaseCamp's expertise in process development and cell product manufacturing.

### **About Kyverna Therapeutics**

Kyverna is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. As our lead product candidate, KYV-101 is advancing through clinical development across two broad areas of autoimmune disease: rheumatology and neurology, including two ongoing multi-center, open-label Phase 1 trials of KYV-101 in the United States and Germany for patients with lupus nephritis.

Kyverna's pipeline includes next-generation chimeric antigen receptor (CAR) T-cell therapies in both autologous and allogeneic formats with properties intended to be well suited for use in B cell-driven autoimmune diseases.

By advancing more than one mechanism for taming autoimmunity, Kyverna is positioned to act on its mission of transforming how autoimmune

diseases are treated.

For more information, please visit <https://kyvernatx.com>.

**Kyverna Media Contact:**

Consort Partners for Kyverna  
kyvernatx@consortpartners.com

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1. Brudno et al., Nature Medicine 2020; 26:270-280.