

First patient treated in OneChain Immunotherapeutics' CAR T trial for cortical T-cell acute lymphoblastic leukemia

- **OneChain Immunotherapeutics announces the treatment of the first patient in the CARxALL clinical trial evaluating its most advanced product, OC-1. The trial, conducted in Barcelona at Hospital Clínic and Hospital Sant Joan de Déu, is open to both pediatric and adult patients worldwide.**
- **Cortical T-cell acute lymphoblastic leukemia accounts for 20-30% of T-cell leukemias and has a poor prognosis in patients who do not respond to standard treatments.**
- **OC -1 is a CAR T cell therapy targeting antigen CD1a, a protein almost exclusively present on tumor cells, potentially reducing severe immunosuppression risks associated with competing CAR T treatments. It has received orphan drug designation by both EMA and the FDA.**

Barcelona, 7th May 2024. OneChain Immunotherapeutics (OCI), a biotechnology company specializing in the development of CAR T cell therapies for oncological diseases, announced today the **first patient dosed** in the **CARxALL clinical trial**, a study evaluating its most advanced product, OC-1, in patients with **cortical T-cell acute lymphoblastic leukemia (coT-ALL)**. The trial, open to pediatric and adult patients worldwide, is being conducted in Barcelona at **Hospital Clínic** and **Hospital Sant Joan de Déu**, under the direction of Dr. Núria Martínez and Dr. Susana Rives, principal investigators for the study.

The CARxALL study (ClinicalTrials.gov identifier NCT05679895), is a dose-escalation trial, aiming to **evaluate for the first time in humans** the **safety and tolerability** of a **CAR T therapy (OC-1)** in patients with coT-ALL, a **subtype of leukemia** that accounts for 20% of T-cell leukemias and is characterized by a **poor prognosis** in those patients who do not respond to existing therapies. The **first patient treated at Hospital Clínic**, a young man who had previously undergone several treatment lines without success, has **received the full dose with no major issue**.

“This treatment offers hope for patients who have exhausted all available options”, explains Nuria Martínez, Principal Investigator at Hospital Clínic. It is essential that we do everything we can to ensure that as many patients as possible can access these innovative therapies. **We are very grateful to OneChain for all their support** with the clinical trial and hope to establish a long-lasting relation with them. **Their pipeline has a lot to offer to patients and families”**.

CAR T therapies are a type of immunotherapy that involves the genetic modification of immune cells called T-cells in the laboratory, to enhance and target their ability to recognize and attack cancer cells. This strategy has already shown promising results in other forms of leukemia and lymphoma. However, applying these therapies to T-cell leukemias such as coT-ALL presents **significant challenges** because tumor and healthy T cells exhibit almost the same molecules on their surface. As a result, competing

CAR T therapies aimed at T-ALL destroy both type of cells, potentially leading to severe immunosuppression in patients.

OC-1, the product being evaluated in the trial, aims to overcome these obstacles by **targeting CD1a**, a specific **protein found almost exclusively in the tumor cells** of patients with coT-ALL. "Our laboratory was the first to develop and validate a CAR T specific to this therapeutic target", says Dr. Pablo Menéndez, founder of OCI and director of the stem cell biology, developmental leukemia, and immunotherapy group at the Josep Carreras Leukemia Research Institute (IJC). "**Seeing now how academic work reaches patients is a dream come true for all of us**".

This is an **important milestone** and a very proud moment for OneChain and all our partners," said Dr. Stefanos Theoharis, CEO of the company. "Their unending support and commitment to our company and the patients has finally come to bear fruit. My heartfelt thanks go to all those individuals and organizations who have helped us achieve this milestone, including the **joint effort** of the IJC, the OneChain team, the staff at Hospital Clínic and Hospital Sant Joan de Déu, the Josep Carreras Foundation, our main investor, Invivo Partners, the Unoentrecienmil Foundation, the Banc de Sang I Teixits (BST), the CDTI Innvierte program, and the Spanish Association Against Cancer.



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About OneChain Immunotherapeutics (OCI)

OCI was **founded** by the Josep Carreras Leukemia Research Institute, ICREA and Dr. Pablo Menéndez **in Barcelona in June 2020**. It is currently supported by a partnership that includes the venture capital firm **Invivo Partners**, the **Center for Technological Development and Innovation** (Ministry of Industry), the venture capital firms **Nara Capital** and **Clave Capital**, and the **Josep Carreras Leukemia Foundation**.

The company, **based at the Barcelona Science Park (PCB)**, is focused on the **development of immunotherapy-based treatments for malignant neoplasms**, based on the research results of the group led by Dr. Pablo Menéndez, ICREA research professor and researcher at the Josep Carreras Leukemia Research Institute.

Currently, OCI is developing **five projects that include** 1) the treatment of **T-cell precursor cortical acute lymphoblastic leukemia (coT-ALL)** with a CAR T already in clinical phase (OC-1). 2) A **dual CAR T cell therapy (OC-1d)** that could treat up to 80% of patients with **T-ALL**. 3) A **CAR T cell candidate (OC-2)** for the treatment of **B-cell acute lymphoblastic leukemia**, for which the company is seeking partners 4) A platform in development of **CAR V δ 1 gammadelta T cells for allogeneic application (OC-3)**, poised to deliver ready-to-use treatments at a lower cost than current autologous CAR T treatments. And, finally, 5) a **dual CAR cell T therapy** for the treatment of **glioblastoma multiforme**, a highly aggressive brain tumor with fatal prognosis.

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