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PragmaTIL Receives Approval to Advance Safer Cell Therapy for Cancer Patients

PragmaTIL, a project funded by the European Union, has received regulatory approval to launch its clinical trial at two hospitals: Vall d'Hebron Institute of Oncology (VHIO) in Spain and Herlev Hospital in Denmark. Approval for the Netherlands Cancer Institute (NKI) in the Netherlands is pending and expected soon. These hospitals will independently produce Tumor-Infiltrating Lymphocytes (TIL), according to a unified set of standards. The trial aims to explore novel methods for conducting **Tumor-Infiltrating Lymphocyte Adoptive Cell Therapy (TIL-ACT)** to reduce toxicity while maintaining treatment efficacy for patients with melanoma, lung cancer, and cervical cancer.

Breakthrough in TIL-ACT Therapy: PragmaTIL's Clinical Trial Approval

PragmaTIL is an EU-funded research project under the HORIZON-MISS-2022-CANCER-01-03 initiative, focused on optimizing treatment for patients with refractory cancers through pragmatic clinical trials. The study explores innovative approaches to Tumor-Infiltrating Lymphocyte Adoptive Cell Therapy (TIL-ACT), specifically aiming to reduce toxicity while preserving therapeutic efficacy for patients with melanoma, lung cancer, and cervical cancer.

In September 2024, the protocol submitted by TIL-producing hospitals in Denmark (Herlev Hospital), the Netherlands (Netherlands Cancer Institute, NKI), and Spain (Vall d'Hebron Institute of Oncology, VHIO) was approved by the European Medicines Agency (EMA). This approval is critical for starting the study and ensuring consistency in how clinical trials will be conducted across the participating centers and future sites involved: Karolinska Institutet and the Sheba Medical Center. In addition to the clinical procedures, the protocol outlines essential aspects such as data collection, patient involvement, and the measurement of quality of life (QoL) during the trial.

A Unique, Decentralized Multi-Center Approach

For the first time in Europe, each center involved in the PragmaTIL trial will independently produce its own Tumor-Infiltrating Lymphocytes (TILs) under the same clinical protocol, marking a significant milestone in cancer research. This decentralized approach to **TIL production** and administration sets a new precedent for clinical trials across multiple academic hospitals.

Silvia Martin Lluesma, Head of VHIO's Advanced Therapies Program and member of PragmaTIL, highlighted the innovative nature of the trial: "This model could shape the future of clinical trials."

On a logistical level, each hospital will manage its own processes for TIL production and patient treatment, providing a unique regulatory framework for multi-center trials conducted within academic environments.

Reducing Toxicity with an Innovative Therapy

Scientists are currently researching modified interleukin-2 to reduce toxicity in treatments. "The current standard treatment for patients undergoing TIL-ACT causes significant toxicity. For this reason, we decided to study a new molecule aimed at reducing toxicity and improving patients' quality of life during treatment", explains **Elena Garralda**, PragmaTIL Coordinator and Director of VHIO's Research Unit for Molecular Therapy of Cancer (UITM)-CaixaResearch. Under this context, the PragmaTIL trial will compare this high-dose IL-2 therapy with a modified IL-2 product developed by **Anaveon,** a clinical-stage biopharmaceutical company. Anaveon's product, ANV419, is designed to minimize the toxic side effects associated with traditional IL-2 therapy.

The trial will be divided into two groups: one group will receive the standard high-dose IL-2, while the other will receive Anaveon's ANV419. This comparison aims to determine whether ANV419 can effectively reduce treatment toxicity while maintaining therapeutic efficacy, potentially improving patient outcomes. The innovative biopharmaceutical IL-2 analogue molecule may represent a breakthrough in making TIL-ACT safer and more tolerable for patients.

Patient Engagement at the Heart of PragmaTIL

Patient involvement is central to the PragmaTIL project. From the start, a Patient Advisory Committee was established to integrate patient insights into the protocol design. Patient-reported outcomes, including feedback on toxicity and quality of life (QoL), are a key focus of the study, and were co-selected with patients.

Patients continue to be involved in the subsequent phases of the trial, including its implementation. Currently, supportive care resources to improve communication and informational needs as well as access to supportive care strategies are being co-designed with patients and providers to improve their experience during the trial and to inform clinical pathways for toxicity management during and after TILs therapy.

In addition, PragmaTIL is part of the EU's "Diagnosis and Treatment-Refractory Cancer" Cluster (DCT), a collaborative hub of 12 EU projects working together to advance cancer research. The DCT cluster focuses on enhancing the overall quality of life for cancer patients, improving early detection, and optimizing treatment.

WeShare: A Platform for Patient Engagement

The PragmaTIL trial will utilize the WeShare platform, a digital infrastructure funded by the French National Research Agency (ANR) and coordinated by **UNICANCER**. This platform is designed to support digitally enabled clinical trial procedures, facilitating patient engagement and the collection of patient-generated data, while also focusing on equity, inclusion, and diversity in clinical research. Developed to support quality of life and social sciences research in oncology, WeShare enables longitudinal data collection from patients, including patient-reported outcomes and biosensor data tracking physiological and behavioral parameters customized according to the needs of each clinical study.

Available in multiple languages (Spanish, English, Swedish, Danish, and Dutch), the platform will allow patients across different countries to report treatment-related toxicities, quality of life, and behavioral data both actively and passively, throughout the trial.

Contact Information

For more information, visit **www.pragmatil.eu** or contact the project's Communication and Dissemination Officer at pragmatil@vhio.net

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