TRANSPLANT RECIPIENTS
INTERNATIONAL ORGANIZATION, INC.

POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD) AFTER SOLID ORGAN TRANSPLANTATION

PTLD is a rare complication that can arise after solid organ transplantation (SOT) and is often associated with very poor outcomes. It can occur due to the immune suppression following transplant. The primary cause of PTLD is the Epstein-Barr virus (EBV) which remains in a latent state with a normal immune system but becomes active when the immune system is suppressed.[1]

THIS FACT SHEET COVERS:

- Standard treatment for PTLD
- A Phase 3 clinical trial for PTLD, including eligibility and contact information
- Resources to help patients pay for clinical trial travel related costs

STANDARD TREATMENT

Initial treatment typically includes:

- Reduction of immunosuppression to see if the patient's own immune system can fight the PTLD.
- Rituximab (Rituxan®) to target the patient's B cells.
- If the PTLD is unresponsive to rituximab or is highly aggressive, chemotherapy may be employed.
- Other treatments in development, available through clinical trials.[1]

The Food and Drug Administration (FDA) has not yet approved any therapies to treat PTLD.

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References:

1. Nagle SJ, Reshef R, Tsai DE. Posttransplant Lymphoproliferative Disorder in Solid Organ and Hematopoietic Stem Cell Transplantation. *Clinics in Chest Medicine. 2017; 38(4):771-783.*

CELLULAR THERAPY CLINICAL TRIAL

Title: Tabelecleucel (tab-cel™) to treat EBV-associated PTLD after solid organ transplant – (NCT03394365)

Type: Multicenter, open label, single-arm, phase 3 trial

Goal: To assess the efficacy and safety of tabelecleucel for the treatment of Epstein-Barr Virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) in the setting of SOT after failure of rituximab or rituximab plus chemotherapy.

Who can join: Patients who have:

- EBV-positive PTLD after solid organ transplant (liver, kidney, heart, lung, pancreas, small bowel or any combination of these)
- PTLD after failure of rituximab with or without chemotherapy; CD20 negative PTLD is eligible after failure of first line chemotherapy
- A suitably matched tab-cel product available
- Adequate organ function and blood counts as defined by the trial protocol

Treatments: Tab-cel is made with T cells from a healthy donor. Expanded, genetically unmodified donor EBV-directed T cells may find and destroy the patient's EBV-infected B cells. Tab-cel is given as an IV infusion on days 1, 8, and 15 of every 5-week cycle. Infusion can be done as inpatient or outpatient and requires monitoring of vitals for 2 hours post-infusion. Treatment continues until maximal response with up to 4 different tab-cel products, unacceptable toxicity, or initiation of non-protocol therapy.

Sponsor: Atara Biotherapeutics

Study Directors:

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Email: clinicaltrials@atarabio.com

Tabelecleucel Trial Locations:

United States, California

University of California Davis Comprehensive Cancer Center (Adults only)
Sacramento, California, United States, 95817
Contact: Mehrdad Abedi, MD 916-703-9118
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United States, Connecticut

Yale University (Adults and Pediatrics)
New Haven, Connecticut, United States, 06519
Contact: Pamela Valentino, MD 203-785-4649
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Lombardi Comprehensive Cancer Center (Adult and Pediatrics)
Washington, District of Columbia, United States, 20007
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University of Florida (Adults and Pediatrics)
Gainesville, Florida, United States, 32610
Contact: John Fort, MD 352-273-9120 john.fort@ufl.edu

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Miami, Florida, United States, 33136
Contact: Amer Beitinjaneh, MD, MPH, MSc 305-243-6626
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Contact: Susan Prockop, MD 212-639-6715
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Levine Cancer Institute (Adult and Pediatrics)
Charlotte, North Carolina, United States 28204
Contact: Dr. Philip Roehrs 704-381-9900
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United States, Ohio

Nationwide Children's Hospital (Pediatrics only)
Columbus, Ohio, United States, 43205
Contact: Anthony Audino, MD 614-722-3550
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The Ohio State University - Arthur G. James Cancer Center Hospital (Adults and Pediatrics)
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Contact: Ashok Srinivasan, MD 901-595-4720
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Vanderbilt - Ingram Cancer Center (Adult and Pediatrics)
Nashville, Tennessee, United States, 37232
Contact: Gowri Satyanarayana, MD 615-875-6138
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United States, Texas

University of Texas MD Anderson Cancer Center (Adults and Pediatrics)
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United States, Wisconsin

Froedtert Hospital & the Medical College of Wisconsin (Adults only)
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GRANTS FOR CLINICAL TRIAL TRAVEL COSTS

The Drs. Jeffrey and Isabel Chell Clinical Trials Travel Grant helps qualified patients pay for travel expenses for eligible clinical trials, including the trial described here.

- **Call:** 1 (888) 814-8610
- **Email:** clinicaltrials@JCCTP.org
- **Visit:** JCCTP.org

