



**TRANSPLANT RECIPIENTS
INTERNATIONAL ORGANIZATION, INC.**

CLINICAL TRIALS

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.

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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Tabelecleucel Trial Locations:

Connecticut

Yale University - New Haven (Adults and Pediatrics) **Contact:**
Pamela Valentino, MD, Tel: 203-785-4649 **Email:**
pamela.valentino@yale.edu

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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.

Tablecleucel Trial Locations (cont):

Florida

University of Florida – Gainesville (Adults and Pediatrics)
Contact: John Fort, MD, Tel: 352-273-9120
Email: john.fort@ufl.edu

Leonard M. Miller School of Medicine - Miami Transplant Institute (Adults only)
Contact: Amer Beitinjaneh, MD, MPH, MSc Tel: 305-243-6626
Email: abeitinjaneh@miami.edu

Georgia

Winship Cancer Institute of Emory University - Atlanta (Adults only)
Contact: Jonathon Cohen, MD, Tel: 404-778-3942
Email: jonathon.cohen@emory.edu

Illinois

Loyola University Medical Center - Maywood (Adults and Pediatrics)
Contact: Patrick Stiff, MD, Tel: 708-327-3148
Email: pstiff@lumc.edu

Missouri

Washington University School of Medicine - St. Louis (Adults only)
Contact: Armin Ghobadi, MD, Tel: 314-747-8439
Email: arminghobadi@wustl.edu

New York

Memorial Sloan Kettering Cancer Center - Manhattan (Adults and Pediatrics)
Contact: Susan Prockop, MD, Tel: 212-639-6715
Email: prockops@mskcc.org

Montefiore Medical Center – Bronx (Adults only) **Contact: Murali Janakiram, MD, Tel:** 718-920-4826 **Email:** mjanakir@montefiore.org

Montefiore Medical Center - Bronx (Pediatrics only)
Contact: David Loeb, MD, PhD, Tel: 718-741-2342 **Email:** dloeb@montefiore.org

Columbia University Medical Center - New York City (Adults and Pediatrics)
Contact: Ran Reshef, MD, Tel: 212-342-0530
Email: rr3036@cumc.columbia.edu

Ohio

Nationwide Children's Hospital – Columbus (Pediatrics only)
Contact: Anthony Audino, MD, Tel: 614-722-3550
Email: anthony.audino@nationwidechildrens.org

The Ohio State University - Columbus (Adults and Pediatrics)
Contact: Robert Baiocchi, MD, PhD Tel: 614-293-3196
Email: robert.baiocchi@osumc.edu

Pennsylvania

Children's Hospital of Philadelphia (Pediatrics only) **Contact: Nancy Bunin, MD, Tel:** 215-590-2255 **Email:** buninn@email.chop.edu

University of Pennsylvania - Philadelphia (Adults only)
Contact: Sunita Nasta, MD, Tel: 215-662-6933
Email: sunitanasta@uphs.upenn.edu

Texas

MD Anderson Cancer Center - Houston (Adults and Pediatrics)
Contact: Kris Michael Mahadeo, MD Tel: 713-792-6620
Email: kmmahadeo@mdanderson.org

Wisconsin

Froedtert Hospital & the Medical College of Wisconsin - Milwaukee (Adults only)
Contact: Marcelo Pasquini, MD, MS Tel: 414-805-0700
Email: mpasquini@mcw.edu

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



HERE TO HELP YOUR PATIENTS FIND CLINICAL TRIALS

Offered by NMDP/Be The Match, the Jason Carter Clinical Trials Program helps patients with blood cancers and blood disorders find and join clinical trials. This program offers one-on-one support and a simple search tool to find clinical trials.

CALL: 1 (888) 814-8610 | EMAIL: clinicaltrials@jcctp.org | WEB: JCCTP.org

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Every individual's medical situation, transplant experience, and recovery is unique. You should always consult with your own transplant team or family doctor regarding your situation. This information is not intended to replace, and should not replace, a doctor's medical judgment or advice.