

# Autologous TLPLDC vaccine (tumor lysate, particle loaded, dendritic cells)

<b>Submission date</b> 15/02/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/11/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to determine the safety and effectiveness of a vaccine, made from the patient's own tumor tissue and blood, to prevent cancer recurrence in patients with solid tumors.

### Who can participate?

Patients aged over 18 with solid tumors

### What does the study involve?

Tumor tissue is collected during standard of care surgery along with a blood sample. The vaccine (prepared from components of the tumor and the blood) is given for a total of four times over a period of three months. The patient will continue to see their treating medical oncologist for standard of care follow up. Any adverse events and tumor response are assessed at each study visit and standard of care visit.

### What are the possible benefits and risks of participating?

Patients may develop an immune response that may prevent recurrence of cancer or treat an existing tumor.

### Where is the study run from?

Perseus Cayman Limited (Cayman Islands)

### When is the study starting and how long is it expected to run for?

November 2012 to January 2018

### Who is funding the study?

Perseus PCI (USA)

### Who is the main contact?

Dr George Peoples

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr George Peoples

**Contact details**

110 E. Houston Street  
San Antonio  
United States of America  
78205

**Additional identifiers****Protocol serial number**

N/A

**Study information****Scientific Title**

Autologous TLPLDC vaccine (tumor lysate, particle loaded, dendritic cells): a single-arm open-label trial

**Study objectives**

Autologous TLPLDC vaccine prevents recurrences in resected stage III/IV or to treat stage IV solid tumors

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Cayman Island Health Practice Commission, 25/01/2013, registration number: HPC/HCF/129

**Study design**

Single-arm open-label interventional

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Resected stage III/IV solid tumor or to stage IV solid tumors

**Interventions**

A vaccine is made from the patient's own tumor tissue (collected during standard of care surgery) and blood. Patients will be seen for a total of four months to receive the initial vaccine and then three follow up visit vaccine inoculations (1/month). Safety and efficacy will be assessed for each patient. Follow up will be continued as per standard of care dictated by the

patient's treating medical oncologist for a continual assessment of disease free status/tumor response and any adverse events. This information will be collected from the electronic medical record. Patients will be followed up to 2 years for disease progression and overall survival.

### **Intervention Type**

Biological/Vaccine

### **Primary outcome(s)**

Safety of of the autologous TLPLDC vaccine at baseline, month 1, 2, 3 and at each standard of care visit to the treating medical oncologist. Safety data will be collected on local and systemic toxicities and graded and reported per the Common Terminology Criteria for Adverse Events (CTCAE) v4.03.

### **Key secondary outcome(s)**

Efficacy of the autologous TLPLDC vaccine at baseline, month 1, 2, 3 and at each standard of care visit to the treating medical oncologist. Disease-free status/tumor response will be monitored per standard of care as dictated by the patients' treating medical oncologist. This information will be obtained from the patient and/or the referring medical oncologist. Follow-up scans will be assessed for tumor response per RECIST v1.1.

### **Completion date**

01/01/2018

## **Eligibility**

### **Key inclusion criteria**

1. Stage III/IV (resected) solid tumor malignancy
2. Stage IV solid tumor malignancy with accessible tumor
3. Approximately 1 mg (1 cm<sup>3</sup>) of accessible and dispensable tumor that will not interfere with pathologic staging
4. ECOG 0-1 performance
5. Not involved in other clinical trials
6. Capable of giving informed consent
7. Age 18 to 99

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

## Key exclusion criteria

1. ECOG >2
2. Insufficient tumor available to produce vaccine
3. Immune deficiency disease or HIV, active HBV, or active HCV
4. Steroids or other immunosuppressants

## Date of first enrolment

26/11/2012

## Date of final enrolment

01/01/2017

## Locations

### Countries of recruitment

Cayman Islands

### Study participating centre

Perseus Cayman Limited

Cayman Islands

KY1-1206

## Sponsor information

### Organisation

Perseus PCI (USA)

### ROR

<https://ror.org/03mfyst18>

## Funder(s)

### Funder type

Industry

### Funder Name

Perseus PCI (USA)

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	31/05/2018		Yes	No