# Study of intravenous PRO 140 or placebo in adult patients with HIV

Submission date Recruitment status Prospectively registered 11/02/2008 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 15/02/2008 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 30/12/2020 Infections and Infestations

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

### Type(s)

Scientific

#### Contact name

Dr Stephen Morris

#### Contact details

Progenics Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown United States of America 10591

# Additional identifiers

### Protocol serial number

PRO140 1302

# Study information

#### Scientific Title

A phase Ib, double-blind, randomized, dose-cohort escalation study of intravenous PRO 140 or placebo in adult patients with HIV-1 infection

### **Study objectives**

The primary efficacy measure is the maximal change from baseline in viral load.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Western Institutional Review Board, 3535 Seventh Ave., SW, Olympia, Washington 98502-5010, USA. Date of approval: 10/04/2005 (ref: 1071726)

### Study design

Multi-center, double-blind, randomised, placebo-controlled study.

### Primary study design

Interventional

### Study type(s)

Treatment

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

HIV-1 infection

#### **Interventions**

Participants were randomly allocated to the following four groups (three intervention and one control groups):

Intervention - PRO 140, 10 mg/mL solution for intravenous injection:

Group 1: 0.5 mg/kg single dose Group 2: 2 mg/kg single dose Group 3: 5 mg/kg single dose

#### Control treatment:

Group 4: Placebo, single dose

### Intervention Type

Drug

### Phase

Phase I

### Drug/device/biological/vaccine name(s)

**PRO 140** 

### Primary outcome(s)

To evaluate the tolerability of a single, intravenous dose of PRO 140 within 59 days

### Key secondary outcome(s))

- 1. To assess the effect on viral load of ascending single doses of PRO 140 within 59 days
- 2. To determine the pharmacokinetics of PRO 140 within 59 days

### Completion date

08/02/2007

# **Eligibility**

### Key inclusion criteria

- 1. Males and females, at least age 18 years
- 2. Screening plasma HIV-1 RNA at least 5,000 copies/mL
- 3. CD4+ count at least 250 cells/mm3 and no documented count equal to or below 200 cells/mm3
- 4. Subject has not taken any antiretroviral therapy within three months of the screening visit
- 5. CCR5-tropic virus based on viral tropism assessment at screening visit
- 6. Normal resting 12-lead electrocardiogram at screening visit
- 7. Females of childbearing potential must have a negative serum pregnancy test result at screening and a negative urine pregnancy test result recorded within 72 hours prior to the first dose of study drug, and be non-lactating

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

Αll

### Total final enrolment

39

### Key exclusion criteria

- 1. Females who are pregnant or lactating
- 2. CXCR4-tropic virus or dual-tropic (R5X4) virus based on the Trofile™ assay at the screening visit
- 3. Previous participation in an experimental drug trial(s) within 30 days of the screening visit
- 4. History of hepatitis within the previous six months
- 5. Any prior treatment with any entry, attachment, co-receptor, or fusion inhibitor, investigational or approved

### Date of first enrolment

08/12/2005

#### Date of final enrolment

08/02/2007

# Locations

### Countries of recruitment

United States of America

Study participating centre Progenics Pharmaceuticals, Inc.

Tarrytown United States of America 10591

# Sponsor information

# Organisation

Progenics Pharmaceuticals, Inc. (USA)

### **ROR**

https://ror.org/023ka9926

# Funder(s)

# Funder type

Industry

### Funder Name

Progenics Pharmaceuticals, Inc. (USA)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008	30/12/2020	Yes	No