



Interim Results in a Phase 2b/3 Pivotal Study of PRO 140 in Treatment Experienced HIV-1 Patients with Multiple ARV Class Resistance

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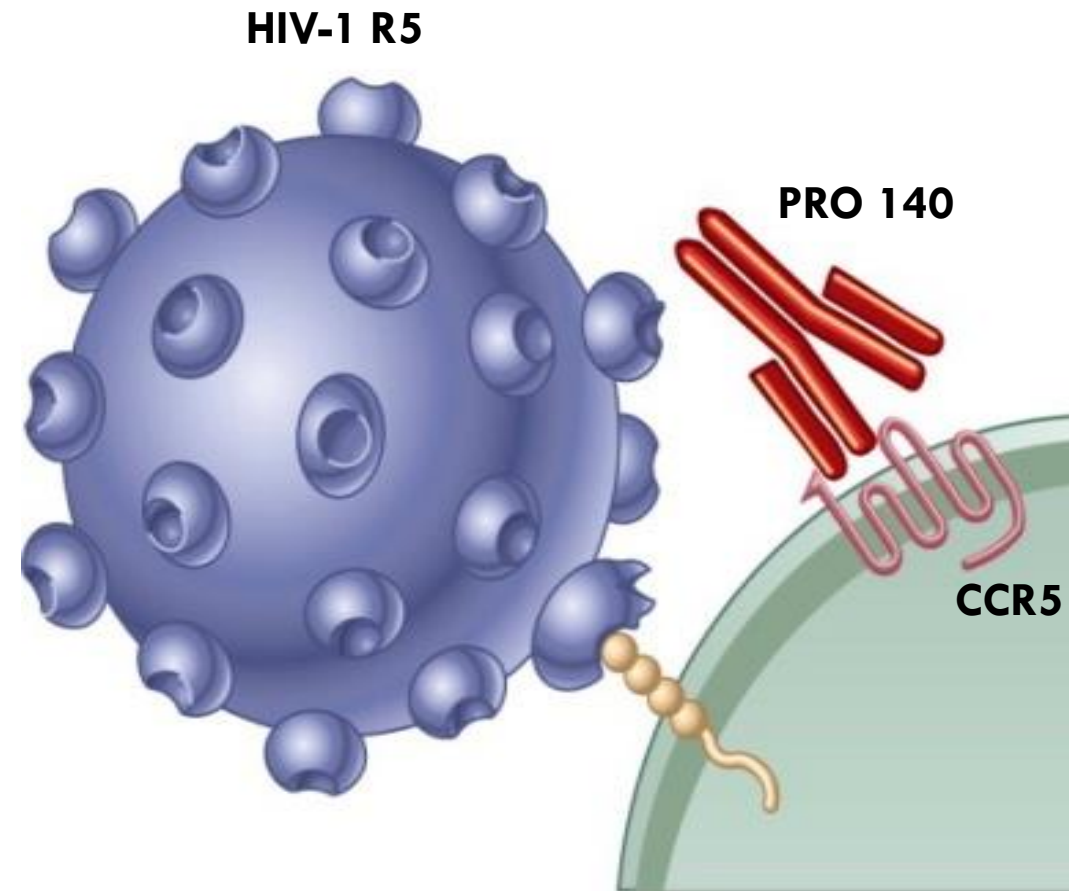
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PRO 140: Overview

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- PRO 140 is a humanized IgG4 monoclonal antibody that blocks HIV-1 from entering and infecting immune cells by binding to CCR5 with high affinity
 - High genetic barrier to virus resistance
- PRO 140 broadly inhibits genotypically diverse viruses
 - Wild-type and multidrug-resistant HIV-1
 - Viruses resistant to SELZENTRY® (maraviroc)
- No dose-limiting toxicity in animals and generally well tolerated in clinical studies
- Potent, long-term antiviral activity
- Designated FDA Fast Track drug



□ **Study Title:**

A Randomized, Double-blind, Placebo-controlled, Multi-center Trial of PRO 140; Followed by Single-arm combination of PRO 140 with **O**ptimized **B**ackground **T**herapy in Treatment-Experienced HIV-1 Patients.

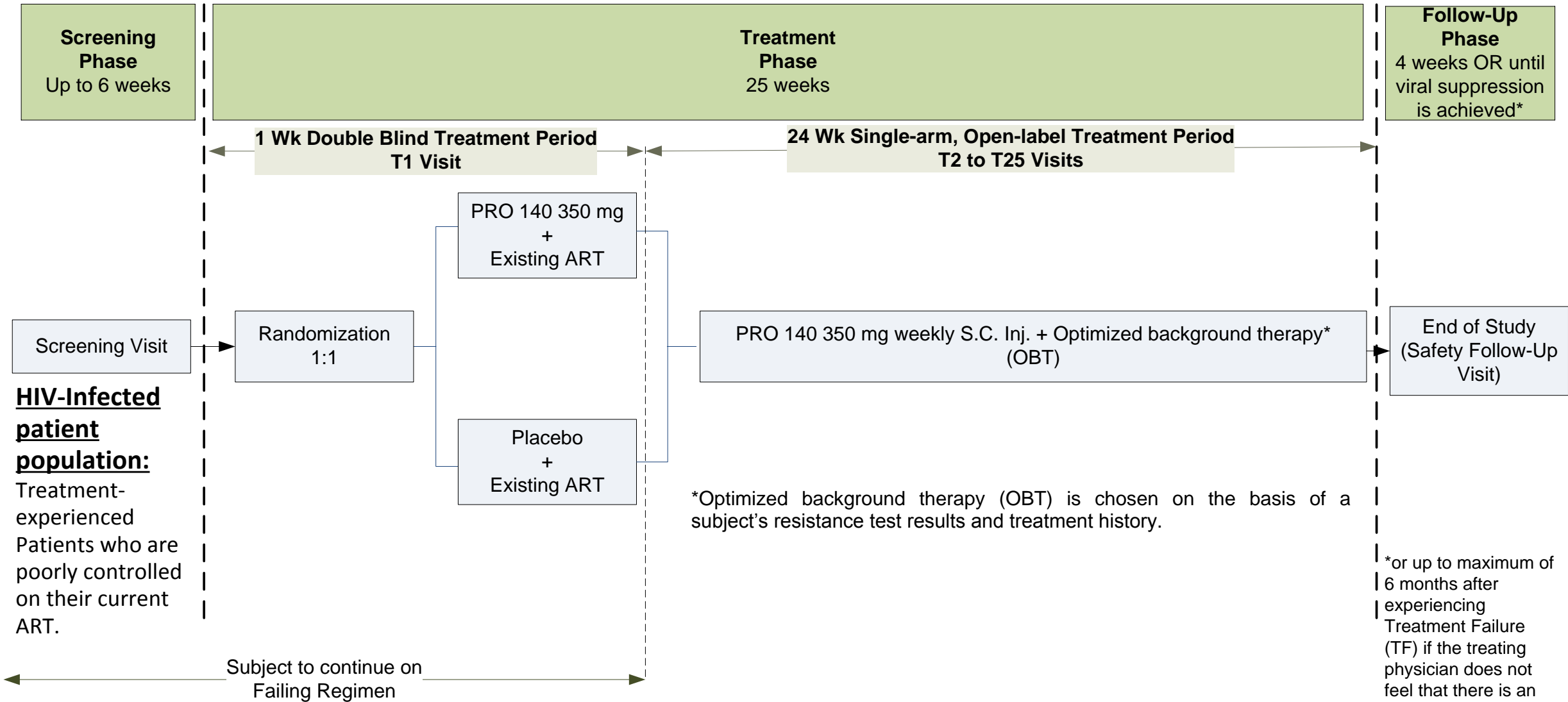
□ **Patient Population:**

- Exclusive CCR5-tropic virus
- Failing on ongoing antiretroviral therapy
- Have documented genotypic or phenotypic resistance within three drug classes (or within two drug classes with limited treatment options)

□ **Study Design:** Two-part Study

- Part 1 – Patients who are failing on existing ART will receive a single dose of PRO 140 or placebo plus their failing ART and the viral load assessed at one week [Week 1]
- Part 2 – All patients will then begin an optimized background regimen (OBT) along with weekly doses of PRO 140 for 24 weeks

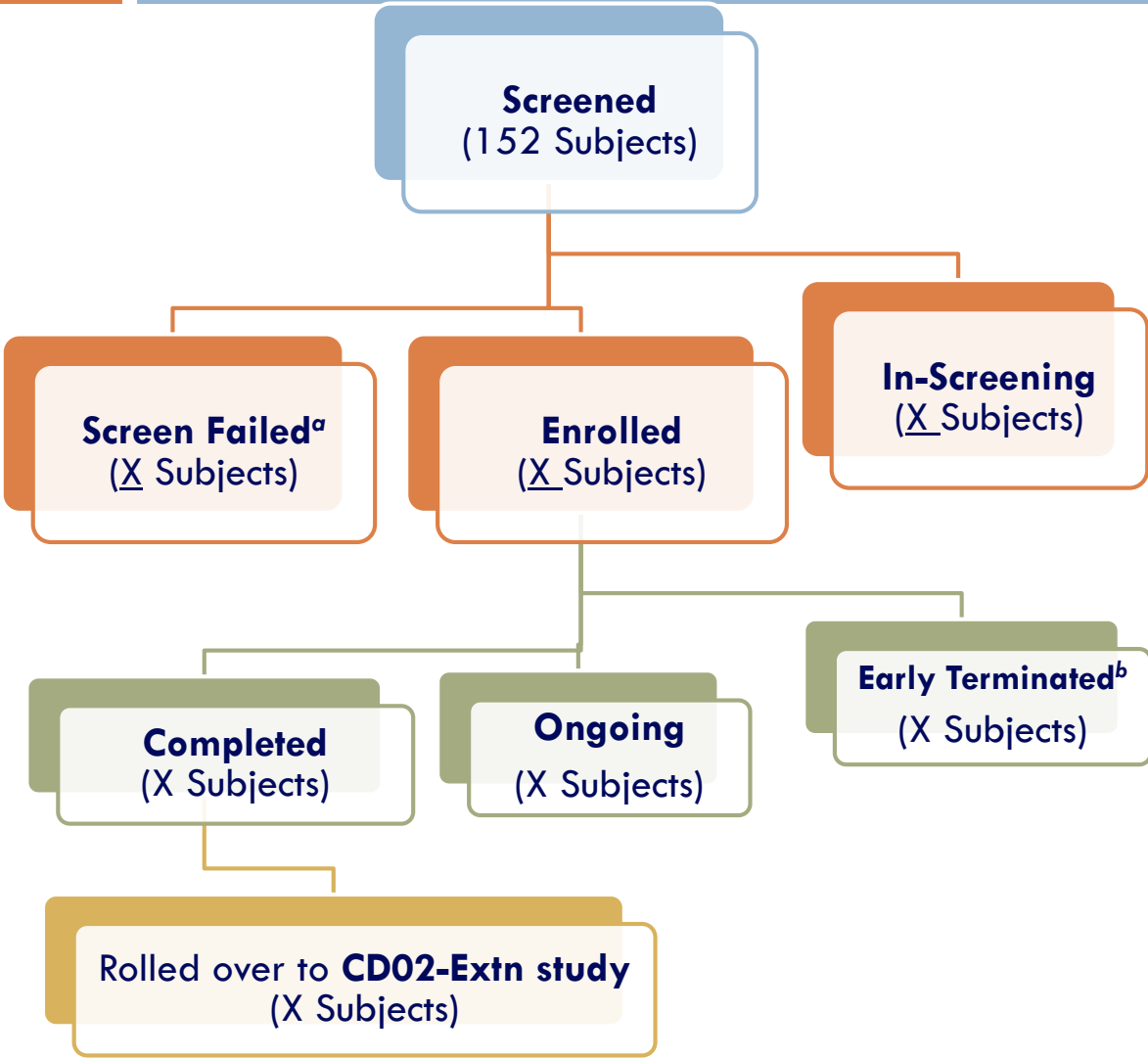
PRO 140_CD02 Study Design Schematic



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PRO 140_CD02 Study: Disposition and Baseline Characteristics

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Characteristic	Statistic	PRO 140_CD02 Study (N = X)
Age (years)	Median	54.0
	Min - Max	33-63
Time since HIV Diagnosis (yrs)*	Median	23
	Min - Max	5-36
Baseline CD4 cell count	Median	246
	Min - Max	10-1133
Gender	Male, n (%)	XX (78.2)
Race	Non-Caucasian, n (%)	X (30.4)
Ethnicity	Hispanic or Latino, n (%)	X (21.7)

N = number of eligible subjects within the population and the denominator for percentages

n = number of subjects (or observations) within the population and the numerator for percentages

* data missing for 2 subjects

Foot Notes:

^aScreen failure rate mainly attributed to d/m tropism, insufficient resistance and viral load

^bOne subject withdrew consent; one subject withdrawn due to d/m tropism

PRO 140_CD03, Phase 2b/3 Monotherapy Study

- **Study Title:** A Multicenter Study to Assess the Safety and Efficacy of PRO 140 as Long-Acting Single-Agent Maintenance Therapy for 48 Weeks in Patients with CCR5-tropic HIV-1 infection
- **Target Enrollment:** 300 subjects
- **Study Population:** Virally suppressed HIV-infected patients with CCR5-tropic virus
- **Study Design:** Patients who are on stable highly active antiretroviral therapy (HAART) for at least 6 months will receive PRO 140 monotherapy for up to 48 weeks
- **Study Status:** Enrollment target of 100 patients by end of 2Q17 & 300 by 4Q17
- **Safety Data:** Provides the safety data for the Pivotal Combination Trial CD02

PRO 140: Safety Analysis from Ongoing Clinical Trials

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- **PRO 140 350mg SC** was generally well-tolerated
- No drug-related SAEs
- No discontinuation due to AEs
- No pattern of toxicity
- Injection site reactions
 - Most common AE which occurred in <10% of patients
 - Infrequent, mild, transient, and self-resolving
- No dose-limiting toxicity in preclinical or clinical studies

PRO 140: Conclusions and Path Forward

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- **PRO 140_CD02 Phase 2b/3 Pivotal Study**
 - Ongoing Pivotal Combination study
 - Enrollment target of 30 patients by end of 2Q17
 - PRO 140 in combination with other ARV agents, in treatment-experienced patients infected with CCR5-tropic virus who have documented multi-ARV class resistance and evidence of HIV-1 replication despite ongoing therapy

- **Two Other PRO 140 Monotherapy studies are ongoing:**
 - PRO 140 CD03 Phase 2b/3 Monotherapy Study

Enrollment target of 100 patients by end of 2Q17 & 300 by 4Q17 with leading subject completed 24 weeks on PRO 140 Monotherapy
 - PRO 140 CD01-Extension Study

Nine (9) patients ongoing with leading subject completed 142 weeks on PRO 140 Monotherapy
Eight of 9 patients have completed over 2.5 years on PRO 140 monotherapy