CytoDyn is anticipating a 2019 BLA submission for PRO 140.

Plasma HIV

After 25 weeks of treatment:

- 92% of subjects with viral load < 400 copies/mL
- Exclusive R5

Any active infection or malignancy requiring acute treatment

The PRO 140 is a simple, long-acting, and potent anti-HIV-1 agent. PRO 140 could be a paradigm shift in the treatment of HIV-infected individuals in Phase I/II/III studies showing high genetic barrier to viral resistance.

Subject with ≥ 0.5 log10 decrease in plasma HIV RNA copies/mL

Wild-type and multidrug-resistant HIV-1

Viruses resistant to maraviroc (SELENITY®)

Both laboratory and low-passage clinical strains

No dose-limiting toxicity in animals

PRO 140 has been administered intravenously or subcutaneously to more than 700 healthy and HIV-1 infected individuals in Phase III/IVa trials showing potent, long-term antiretroviral activity in vivo.

Designated FDA Fast Track drug candidate

For the PRO 140, CD42 study was designed to evaluate efficacy, safety, and tolerability of PRO 140 in combination with an existing failing antiretroviral therapy (ART) regimen for one week followed by Optimized Background Therapy (OBT) for 24 weeks.

The study population included treatment-experienced HIV-infected patients with CCR5-tropic virus and plasma HIV-1 RNA levels 400 copies/mL despite ongoing antiretroviral therapy with documented genotypic or phenotypic resistance to ART drugs within three drug classes (or within two drug classes with limited treatment options).

The primary efficacy endpoint for this study was proportion of patients with a 0.5 log10, or greater reduction in plasma HIV RNA viral load from baseline at the end of the 1-week double-blind treatment period.

PRO 140 was required to form a viable access to PRO 140 treatment when, in the opinion of the treating physician, PRO 140 was required to form a viable treatment strategy of PRO 140 SC as a single, long-acting, and potent anti-HIV-1 agent acting, single, and potent ART drugs with CCR5-tropic virus and demonstrated evidence of HIV-1 replication despite ongoing antiretroviral therapy with documented genotypic or phenotypic multi-drug resistance.

A roll-over study, PRO 140 CD02-Extension, extended access to PRO 140 treatment when, in the opinion of the treating physician, PRO 140 was required to form a viable suppressive regimen. Out of 52 patients, 32 patients enrolled into the extension study.

The PRO 140 CD03 study was designed to assess the clinical safety and treatment strategy of PRO 140 SC as a single, long-acting, and potent anti-HIV-1 agent acting, single, and potent ART drugs with CCR5-tropic virus and demonstrated evidence of HIV-1 replication despite ongoing antiretroviral therapy with documented genotypic or phenotypic multi-drug resistance.

Conclusions

- Significant plasma HIV-1 reduction for subjects treated with PRO 140, compared to placebo-treated subjects, was observed in all study treatments

- Subjects with ≥ 0.5 log10 copies/mL reduction:
  - 64% in the PRO 140 treated group
  - 23% in the placebo group

- PRO 140 SC offers several potential advantages over existing therapies in terms of infrequent weekly dosing and limited drug-drug or food interactions.

Path Forward

CytoDyn is anticipating a 2019 BLA submission for PRO 140 in treatment-experienced HIV-1 infected persons with CCR5-tropic virus and demonstrated evidence of HIV-1 replication despite ongoing antiretroviral therapy with documented genotypic or phenotypic multi-drug resistance.

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