Weekly injections of PRO 140 in combination with optimized ART shows HIV-1 viral suppression

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Results from a pivotal trial of PRO 140, a new HIV therapy, show that PRO 140 is an effective, long-acting therapeutic in combination with antiretroviral treatment (ART) for previously treated HIV-1 infected patients. This is an ongoing randomized, double-blind, placebo-controlled trial. The research is presented at ASM Microbe, the annual meeting of the American Society for Microbiology, held from June 7th to June 11th in Atlanta, GA.

PRO 140 is a novel humanized CCR5 monoclonal antibody under development by CytoDyn Inc. (OTC.QB: CYDY). At one week following a single subcutaneous injection of PRO 140 together with existing ART, patients achieved a mean viral load reduction of approximately 97% from a mean baseline viral load. The trial met its primary efficacy endpoint: the proportion of patients with 0.5 log10 reduction in HIV-1 RNA viral load from baseline at the end of the one-week treatment period.

"While ART has greatly advanced over the years, new agents are needed to improve the potency and pharmacokinetic profiles, decrease toxicity, combat drug resistance, and improve convenience to facilitate patient compliance," said Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer. "These trial results support the continued development of PRO 140 as a simple-to-administer, long-acting HIV-1 therapy that, together with optimized background ART, can provide a

valuable new therapeutic option for patients who have become resistant to multi-antiretroviral agents."

Fifty patients with demonstrated evidence of HIV-1 replication on existing ART and documented resistance to two or more antiretroviral drug classes participated in the ongoing two-part pivotal trial. In the first one-week portion of the trial, patients were randomized into two arms with both arms continuing on existing ART. The researchers administered a single PRO 140 350 mg subcutaneous injection to one arm of the trial, and the second arm received a placebo.

The trial met the primary efficacy endpoint: the proportion of patients with ?0.5 log10 reduction in HIV-1 RNA viral load from baseline at the end of the one-week treatment period (p ~ 0.0032). In part two of the trial, all patients received 24-weeks of PRO 140 subcutaneous with optimized background ART in an open-label setting. Continuing access to PRO 140 is provided to patients completing 25 weeks in the trial.

"With the highly favorable efficacy results for this combination therapy trial, and data from our previous trials and our ongoing monotherapy trial, we are now working toward the filing of a Biological License Application, or BLA, with the FDA for PRO 140 in the combination therapy indication," added Dr. Pourhassan.

Primary efficacy results of the trial are being presented on June 9 from 11:00 am-1:00 pm ET in a Late-Breaker Abstract session at ASM Microbe 2018 in the Exhibit and Poster Hall, Building B, Halls B2-B5, Georgia World Congress Center in Atlanta. The CytoDyn-sponsored trial is being presented by Kush Dhody of Amarex Clinical Research, LLC. Additional authors include Kazem Kazempour, Ph.D. of Amarex Clinical Research, LLC, Nader Pourhassan of CytoDyn Inc., and Paul Maddon, M.D., Ph.D., PRO 140 discoverer.