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PRO140

First self-administered antibody therapy for HIV
in late-stage clinical trials

CytoDyn Annual Meeting of Stockholders

August 24, 2017

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Accomplishments over the Past Year

- Continuing enrollment on Phase 2b/3 Combination Therapy trial
- Initiated enrollment in Phase 2b/3 Monotherapy trial and is well underway
- Initiated patient treatment in Phase 2 GvHD trial
- Initiated rollover trial to accommodate patients who successfully complete Combination Therapy trial
- Continued to support patients in Phase 2b monotherapy trial
  - Now experiencing 3 years of successfully suppressed viral load and continuing

Accomplishments over the Past Year

- Further advanced preparations for manufacturing cGMP PRO 140 and engaged a new CMO
- Presented PRO 140 clinical trial results at two scientific conferences
  - CROI – February
  - ASM – June
- Initiated several animal studies to explore non-HIV indications for PRO 140
- Raised approximately $20 million of new capital

PRO 140 in Four Clinical Trials

Trial		
Study	**Design / Findings**	**Status**
CD02 Pivotal Phase 2b/3 HIV Trial **First path to approval**	**Combination** therapy in HAART failures, 1 week efficacy + 24 weeks safety and durability	Primary endpoint results in 2017
CD03 Phase 2b/3 Investigative HIV Trial **Large market size**	Long-term **monotherapy**	Data in 2018
CD01 Phase 2b HIV extension study	Long-term **monotherapy** extension: 9 patients with viral load suppression nearing 3 years	Ongoing
CD04 Phase 2 Trial in acute Graft versus Host Disease (GvHD)	60 patient, 100-day trial period	Ongoing

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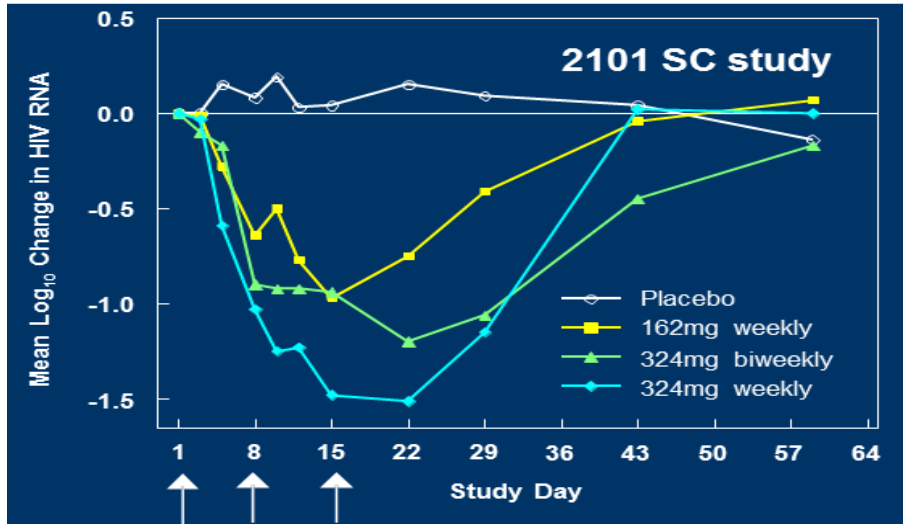
CD02 Pivotal Phase 2b/3 Combination Trial
Treatment-Experienced HIV-infected Patients

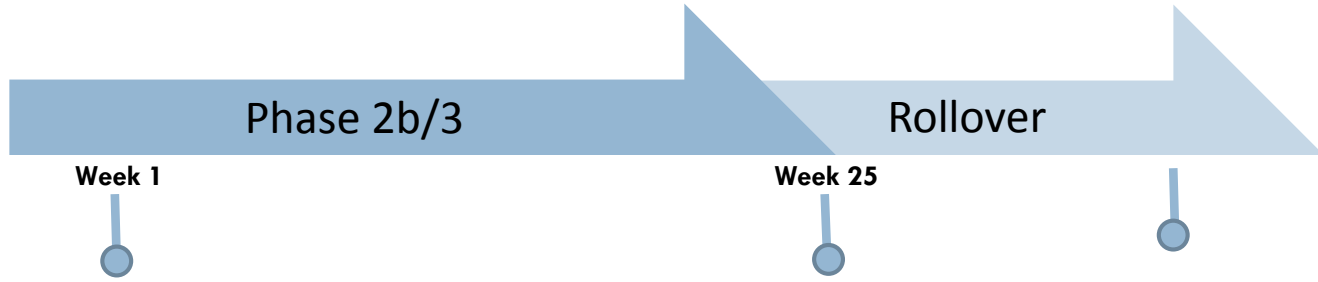
Prior Study Shows Viral Load Reduction

First proof-of-concept for a long-acting, self-administrable HIV drug administered weekly or bi-monthly



Pivotal Phase 2b/3 Combination Trial

- PRO 140 + HAART
- Anticipated path to 1st FDA Approval of PRO 140
- Potential for FDA with Breakthrough Therapy Designation



Primary Efficacy Endpoint:
33 patients to date

Full Protocol:
11 Patients to date with undetectable viral loads

10 Patients currently in rollover

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CD02 Pivotal Phase 2b/3 Combination Trial
Enrollment of Treatment-Experienced HIV-infected Patients

Therapy Class:	EI	NRTI	NNRTI	INTI	PI
Therapy Target:	Step 1: Binding	Step 2: Reverse Transcription	Step 2: Reverse Transcription	Step 3: Integration	Step 6: Viral Assembly
Therapy Name:	MVR PRO 140	AZT ddI ddC d4T 3TC ABC TDF FTC	NVP DLV EFV ETV	RTG RVG DTG	SQV RTV IDV NFV APV LPV/r FPV ATV TPV DRV

Enrollment Criteria:
Resistance to **ONE drug from TWO different classes**
+ Limited Treatment Options

CD03 Phase 2b/3 Investigative Monotherapy Trial

Phase 2b/3 Investigate Monotherapy Trial:

- Supported by long-term viral efficacy from Phase 2b extension study
- HIV viral load managed with HAART
- Potential for enrollment completion in 2017

48 Weeks | N = 300

Primary Endpoint:
Proportion of patients who remain on PRO 140 without experiencing virologic failure

Secondary Endpoint:
Efficacy, safety and tolerability data

Safety results to support BLA submission for PRO 140 in combination with HAART

Primary Objective:
Identify PRO 140 responders and increase responder rate **above 70%**

	<1cp/mL	<40cp/mL
Distribution of HIV patients	70%	30%
Patients with initial viral load breakout exhibited a decrease in viral load with PRO 140 administered more frequently		
Patients on PRO 140 monotherapy for approximately 3 years did not develop anti-drug antibodies.		

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CD01 Phase 2b Monotherapy Extension Study

- 9 patients in ongoing extension study
- 8 patients nearly three years of viral load suppression with once weekly PRO 140 injection

Patients cite lower toxicity and fewer side effect with PRO 140 versus HAART with completely suppressed viral load

Phase 2 Trial in Graft versus Host Disease (GvHD)

GvHD Prophylaxsis Trial:

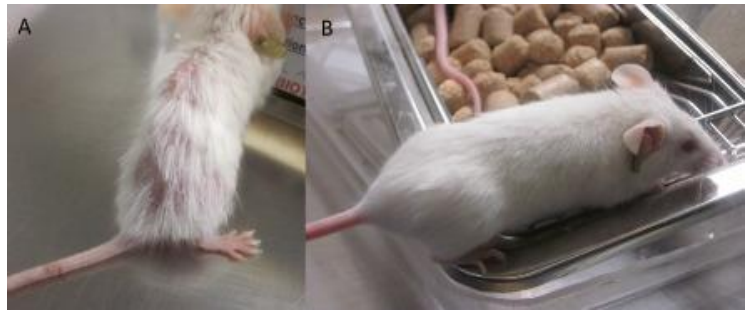
Randomized, double blind, placebo controlled, 60 patients, multicenter trial

100 days | N = 60

Primary Endpoint: Incidence & severity of GvHD

Secondary Endpoint: Durability & safety

- GvHD is potentially life-threatening complication following bone marrow transplant
- Immune systems depleted during aggressive cancer therapy for leukemia patients (AML/MDS)
- GvHD as the leading causes of death in these patients
- Plan to file for Breakthrough Designation subject to results from Phase 2 study
- Supported by remarkable animal data



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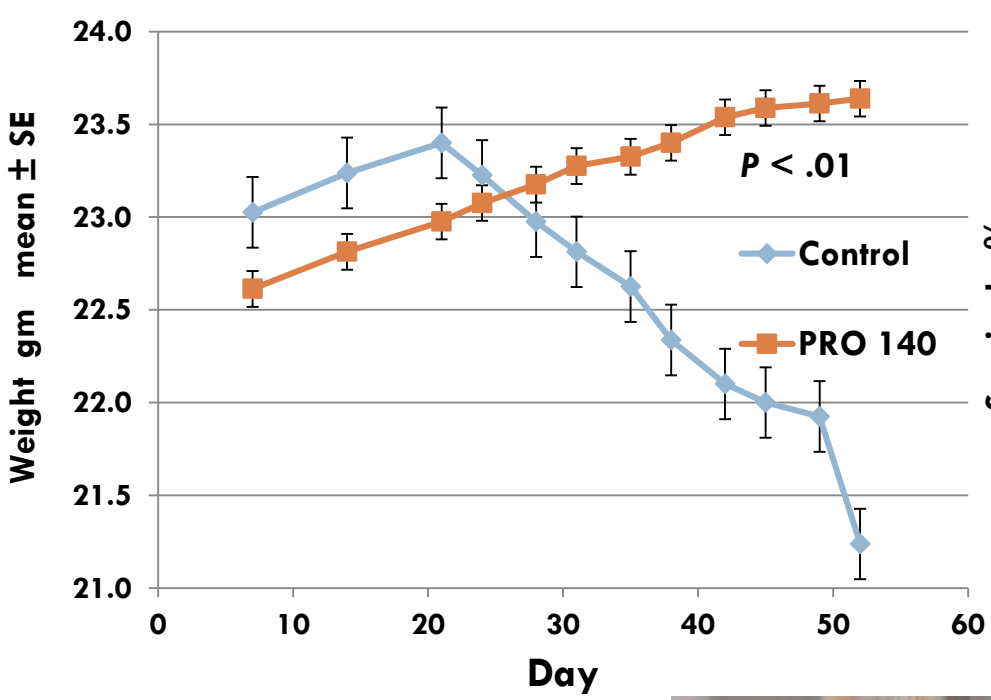
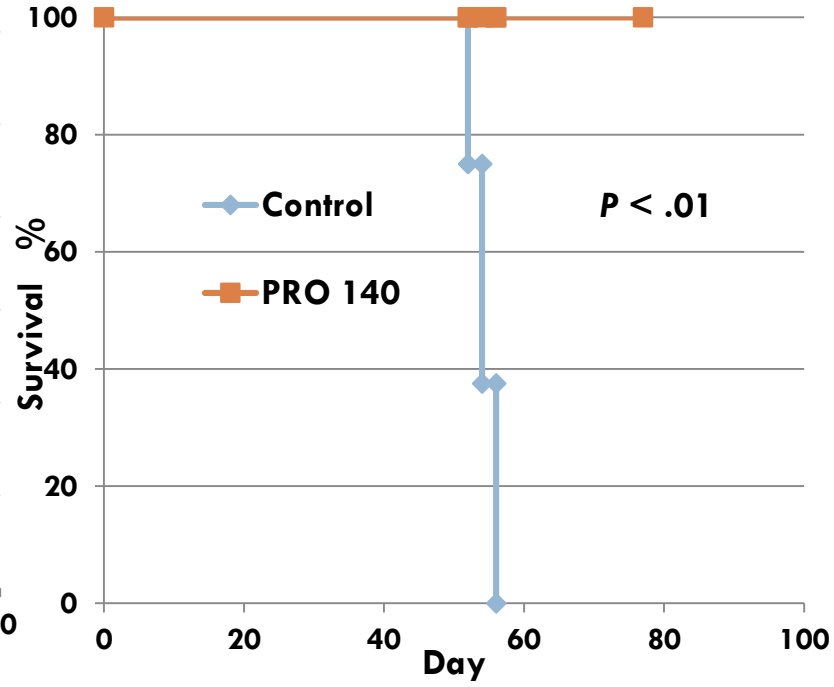
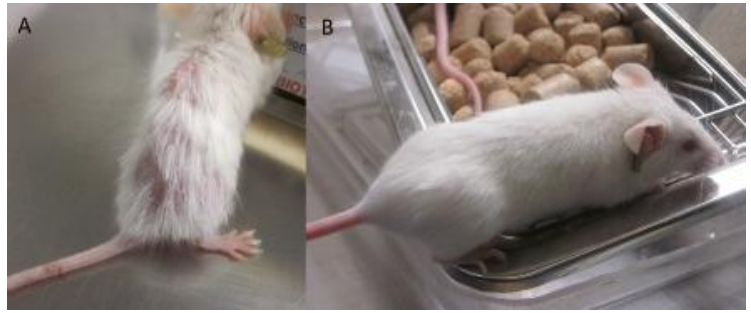
Effect of PRO 140 on xeno-GVHD in NSG mice







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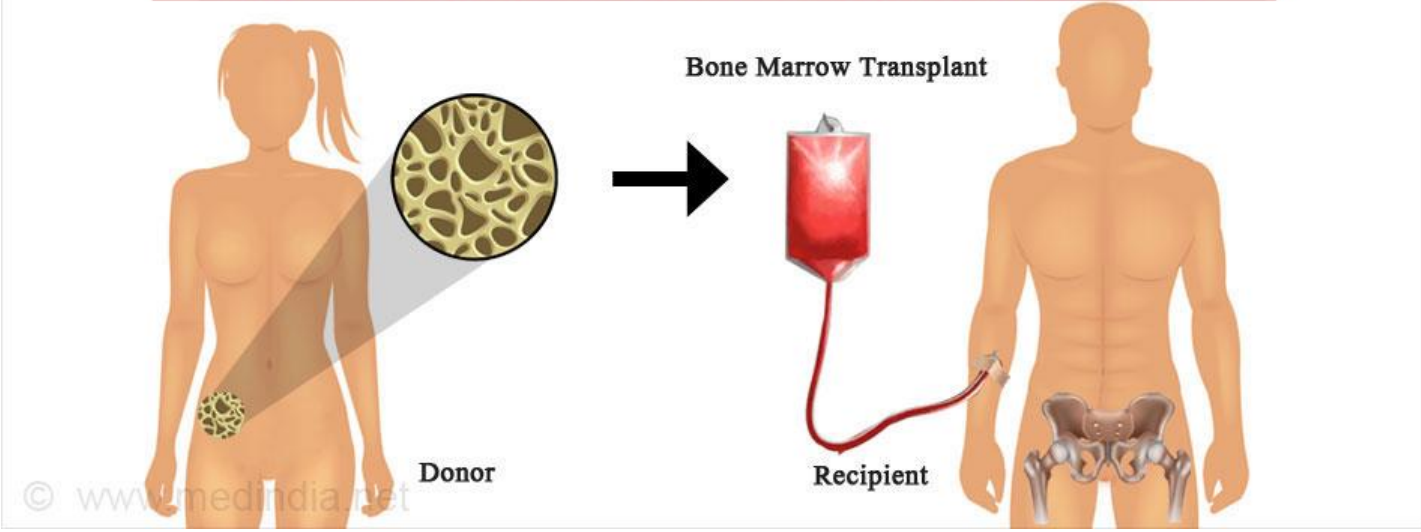
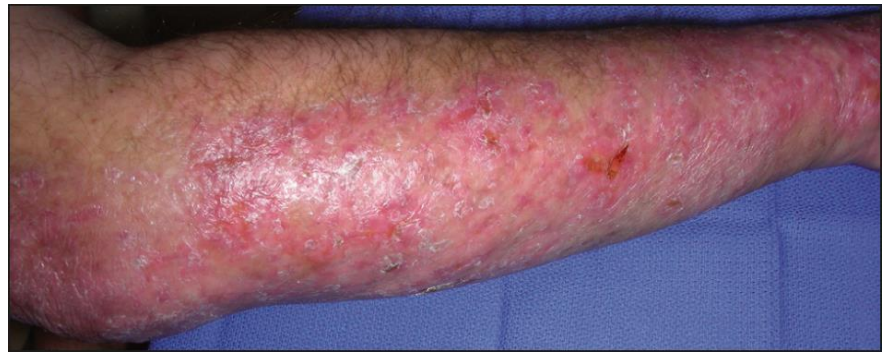
BONE MARROW TRANSPLANT IS A MAJOR CAUSE OF GvHD.





PRO 140 Important Milestones 2017/2018

Milestones	Target Dates
HIV Fast Track Designation	Granted
HIV Breakthrough Therapy Designation (application submitted)	2017
Pivotal Phase 2b/3 HIV Combo Trial Primary Endpoint	2017
Pivotal Phase 2b/3 HIV Combo BLA (Biologic License Application) Submission	2018
Pivotal Phase 2b/3 HIV Combo BLA (Biologic License Application) Approval	2018 w/BTD
Published studies – 2 in HIV; 2 in Inflammatory Diseases	2017
Conference Presentations at CROI and ASM Microbe	Completed & Ongoing
Monotherapy Phase 2b/3 Investigative Trial Readout	2018