Leronlimab (PRO 140)

HIV - Cancer

Professor Richard G. Pestell
Vice Chairman and Chief Medical Officer

Nader Pourhassan, Ph.D.
Director, President & CEO
Forward-Looking Statements

This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,” “intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. The Company’s forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the sufficiency of the Company’s cash position, (ii) the Company’s ability to raise additional capital to fund its operations, (iii) the Company’s ability to meet its debt obligations, if any, (iv) the Company’s ability to enter into partnership or licensing arrangements with third parties, (v) the Company’s ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Company’s ability to achieve approval of a marketable product, (vii) the design, implementation and conduct of the Company’s clinical trials, (viii) the results of the Company’s clinical trials, including the possibility of unfavorable clinical trial results, (ix) the market for, and marketability of, any product that is approved, (x) the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) various other matters, many of which are beyond the Company’s control. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this presentation.
CytoDyn Overview

**PHASE 3 - Completed**
World’s first self-injectable for Unmet Medical Need Population

**PHASE 3 - Monotherapy**
Several patients on monotherapy for > 4.5 years

**PHASE 2 - Initiated**
Unmet Medical Need

**PHASE 1b/2 – Initiated**
Unmet Medical Need

**HIV**

**GvHD**

**Colon Cancer**

**TNBC**

**Prognostic**

8 Cancer indications

8 Pre-clinical studies to be initiated
Melanoma, Pancreatic, Breast, Prostate, Colon, Lung, Liver and Stomach Cancer

**510(k) for medical device**
File with FDA for prostate cancer prognostic test

**IND to be filed**
File for Orphan Drug Designation
Blocking **HIV** entry receptor (CCR5)
Blocking CCR5/CCL5 interaction with leronlimab for use in **CANCER**

- **Humanized monoclonal antibody**
- **Binds to CCR5 co-receptor on white blood cells**

**HAART**

**Blocks HIV entry into white blood cells**

**HIV**

**CD4**

**CCR5**

**T-Cell**

**Leronlimab**
FDA: “fast track designation” – “accelerated approval possible”
NIH: $28 million grants

**Leronlimab**  
(PRO 140)

- No serious side effects and no drug related serious adverse events (SAEs) in >740 patients in 8 clinical trials
- Negligible toxicity in 740 patients
- No drug resistance in patients on monotherapy for over 4.5 years
- Weekly, easy, subcutaneous self administration

**HAART**

- Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)
- Problems with short- and long-term toxicity
- 76% of HIV patients have at least one drug resistance
- Daily lifetime dosing with only 35% of patients with complete viral load suppression

Trading Symbol: CYDY
<table>
<thead>
<tr>
<th><strong>Pivotal Phase 3 Completed</strong></th>
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<tbody>
<tr>
<td><strong>Primary Efficacy End Point Hit</strong> - $p=0.0032$</td>
</tr>
<tr>
<td>Safety of 24 weeks completed - With <strong>81% of patients</strong> with suppressed viral load as compared to <strong>43%</strong> last approved drug for this population</td>
</tr>
<tr>
<td><strong>No reported SAEs related to leronlimab</strong></td>
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<tr>
<td><strong>BLA – submission green light from FDA</strong></td>
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<tr>
<td><strong>Rolling Review Submission Granted by FDA</strong></td>
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<tr>
<td><strong>1/3 of BLA already submitted in March 2019</strong></td>
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**Potential label:**
One drug resistance in three classes
or
One drug resistance in two classes with limited treatment option to another class
CD03 Leronlimab (PRO 140) Investigative Monotherapy Trial

- R5 patients w/suppressed viral load replacing HAART for leronlimab monotherapy
- **Leronlimab monotherapy** – One dose (2 consecutive injections), once a week
- High responder’s rate – non-responders return to their original regimen without any resistance or harm – No ADA (Anti-Drug Antibody) presence – No X4 grow out during the monotherapy

**Increasing response rate** *(Suppressed viral load without pills)*

<table>
<thead>
<tr>
<th>Dose</th>
<th>Average duration post 10 weeks</th>
<th>Responder’s rate post 10 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>525 mg</td>
<td>26 weeks</td>
<td>95%</td>
</tr>
<tr>
<td>700 mg</td>
<td>9 weeks</td>
<td>91%</td>
</tr>
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</table>

**Regulatory path**
- Submit pivotal trial to the FDA 2Q2019

Trading Symbol: CYDY

www.cytodyn.com
Effect of Leronlimab (PRO 140) on Xeno GvHD-Human BM Transplanted Into Immuno-Deficient Mice

Results Published

TRIAL TO RE-INITIATE WITH MODIFIED DOSE/PROTOCOL IN MAY 2019
Expansion into Cancer Indications

- Named world-renowned oncologist Dr. Richard Pestell Chief Medical Officer and Vice Chairman (https://www.youtube.com/watch?v=98J1HgCm8wU)
  - Leads leronlimab (PRO 140) non-HIV development programs
  - Led 2 National Cancer Institute-designated cancer centers
    - Lombardi Comprehensive Cancer Center at Georgetown University
    - Sidney Kimmel Cancer Center at Thomas Jefferson University
  - Executive Vice President Thomas Jefferson University (25,000 employees, $5.6B)
- Founded ProstaGene to develop CCR5 technology in cancer
  - Issued patents for technology on metastasis (many types of cancer)
  - Showed > 50% of 2,200 patients -increased CCR5 in breast cancer
  - CCR5 inhibitors blocked breast, prostate and colon cancer metastasis in pre-clinical studies

Trading Symbol: CYDY
CCR5 is Expressed in >50% of Breast Cancer

- Metastatic cancer.
  - 50% of breast cancers CCR5+
  - Leronlimab (PRO 140) reduces breast cancer invasion in pre-clinical studies

Professor Richard Pestell, PhD, MD

Trading Symbol: CYDY

www.cytodyn.com
Leronlimab (PRO 140) Blocks Breast Cancer Ca\(^{2+}\) signaling

A

20 sec before adding CCL5
60 sec after adding CCL5
240 sec after adding CCL5
60 sec after adding FBS

Control

PRO140 (1/100)

B

C

Relative Fl of Fluo-4

Time (Sec)

0 200 400 600 800 1000

CCL5
FBS

Relative Fl of Fluo-4

Time (Sec)

0 200 400 600 800 1000

CCL5
FBS

Professor Richard Pestell, PhD, MD

Trading Symbol: CYDY

www.cytodyn.com
CCR5 Antagonists Block Breast Cancer Metastasis

Time (weeks)

1  2  3  4

Control

Maraviroc

Radiance (p/sec/cm²/sr) x 10⁸

Professor Richard Pestell, PhD, MD

Trading Symbol: CYDY

www.cytodyn.com
Objective Tumor Response, Phase 1 Trial

before CHT+CCR5 inh.  after CHT+CCR5 inh.
CCR5 Antagonists Block Metastasis

- **Control**
- **Leronlimab**
- **Maraviroc**

*Images showing the progression of metastasis over 7 weeks for different treatments.*
Leronlimab (PRO 140) Breast Cancer Trial

TNBC Rx Refractory → CCR5+ CTC

Pro-140 525 mg 1sc/week
Carboplatin AUC 2q week
x3
28 days cycle

Endpoints
1. OS
2. PFS'
3. Decreased CTC

November 2018-December 2019
Phase II

Breakthrough (unmet need)
April 2019-July 2021 (Phase III)
1. AACR presentation April 1 Atlanta Georgia.

**CCR5 associated with HER2 in circulating tumor cells (CTCs) is a novel biomarker for patients with metastatic breast cancer (MBC).** CTCs were found positive (≥5) in all seven MBC patients with a range of numbers between 124 and 442.
A Reduction in CTC to Below 5 After the Initiation of Therapy Predicts Longer OS whereas an Increase in CTC Count to 5 or above Predicts Shorter OS in mBC Patients.

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
<th>N (%)</th>
<th>Months (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt;5 CTCs at All Time Points</td>
<td>83 (47%)</td>
<td>22.6 (20.4 to &gt;45)</td>
</tr>
<tr>
<td>2</td>
<td>≥5 at Baseline &amp; &lt;5 CTCs at Last Draw</td>
<td>38 (21%)</td>
<td>19.8 (14.6 to 31.6)</td>
</tr>
<tr>
<td>3</td>
<td>&lt;5 at Early Draw &amp; ≥5 CTCs at Last Draw</td>
<td>17 (10%)</td>
<td>10.6 (6.1 to 16.2)</td>
</tr>
<tr>
<td>4</td>
<td>≥5 CTCs at All Time Points</td>
<td>39 (22%)</td>
<td>4.1 (2.8 to 6.4)</td>
</tr>
</tbody>
</table>

*P-values not adjusted for multiple hypothesis tests
1. Pacific Hematology Oncology Associates  
Dr. Milana Dolezal  mdolezal@phoamd.com  
2100 Webster street suite 220, San Francisco, ca 9411  
david@PHOAMD.COM  
415-923-3012

Other sites to open:  
1. Northwestern University Medical School,  
2. Methodist Houston,  
3. Vanderbilt University,  
4. Sidney Kimmel Cancer Center.
**PRO 140 Important Milestones for HIV and Cancer 2019**

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Target Dates</th>
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<tbody>
<tr>
<td>BLA submission – HIV combination therapy – unmet medical need</td>
<td>3Q2019</td>
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<tr>
<td>Revenue potential of about $480 million</td>
<td>2020</td>
</tr>
<tr>
<td>Initiate first ever monotherapy Phase 3 pivotal trial</td>
<td>1H2019</td>
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<tr>
<td>Triple-Negative Breast Cancer study first patient injected</td>
<td>2Q2019</td>
</tr>
<tr>
<td>Triple-Negative Breast Cancer study interim results</td>
<td>2019</td>
</tr>
<tr>
<td>GvHD interim results</td>
<td>2H2019</td>
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<tr>
<td>Prognostic test licensed – 510(k) filing with the FDA</td>
<td>1H2019</td>
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<tr>
<td>IND-Protocol for colon cancer Phase 2</td>
<td>1H2019</td>
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<tr>
<td>Large Pharma discussion for potential licensing or partnering</td>
<td>1H2019</td>
</tr>
<tr>
<td>8 preclinical studies with leronlimab - Filing 8 INDs for 8 Phase 2 trials</td>
<td>2019</td>
</tr>
<tr>
<td>(if results of preclinical studies are positive)</td>
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