HIV - Cancer

INVESTOR PRESENTATION
January 2019

Professor Richard G. Pestell
Vice Chairman and Chief Medical Officer

Nader Pourhassan
Ph.D., President & CEO
This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding leronlimab’s efficacy in certain cancer indications, the predictive value or benefit from the Company’s prostate cancer prognostic test, the Company’s clinical focus, and the Company’s current and proposed trials. 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 differ materially from those contained in or expressed by such statements. In evaluating all such statements, the Company urges investors to specifically consider the various risk factors identified in the Company’s Form 10-K for the fiscal year ended May 31, 2018 in the section titled “Risk Factors” in Part I, Item 1A, and in our Form 10-Q for the quarterly period ended August 31, 2018 in the section titled “Risk Factors” in Part II, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company’s forward-looking statements.

The Company’s forward-looking statements reflect its current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Investors should not place undue reliance on the Company’s forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company’s cash position and the Company’s ongoing ability to raise additional capital to fund its operations, (ii) the Company’s ability to complete its Phase 2b/3 pivotal combination therapy trial for leronlimab (CD02) and to meet the FDA’s requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) the Company’s ability to obtain FDA approval of PCaTest for use with prostate cancer patients; (iv) the Company’s ability to meet its debt obligations, if any, (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) design, implementation and conduct of 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 for infection with HIV 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. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by the Company’s forward-looking statements.

The Company intends that all forward-looking statements made in this presentation will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, the Company does not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this presentation. Additionally, the Company does not undertake any responsibility to update investors upon the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.
Recent Developments

- **CD02 Phase 3, Pivotal trial** - Combination Therapy
  - Achieved primary endpoint \( p=0.0032 \) – 81% response rate – BLA in 1Q2019

- **CD03 Phase 3** HIV investigative trial - 360+ enrolled (60 patients one year)
  - About 70% response rate at 525 mg - About 90% response rate at 700 mg

- **Phase 1b/2 in Triple Negative Breast Cancer**
  - IND and Protocol has been accepted by the FDA and trial initiated
  - Encouraging preclinical data

- **Phase 2 Graft-versus-Host Disease (GvHD)**
  - Received Orphan Drug Designation from FDA
  - Will have interim results in 1H 2019 (mouse model – GvHD eliminated)

- **Prognostic Test for Prostate Cancer**
  - More accurate than current standard of care
  - Licensing agreement could be completed in 1H 2019

- **Licensing and Partnering Discussions**
  - Rights to leronlimab (PRO 140) China – France – Japan – USA are being explored
Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

Blocking HIV entry receptor (CCR5)
Blocking CCR5/CCL5 interaction with leronlimab for use in CANCER

- Binds to CCR5 co-receptor on white blood cells
- Blocks HIV entry into white blood cells

Humanized monoclonal antibody

HAART

Blocks HIV entry into white blood cells
Leronlimab (PRO 140)

- No serious side effects and no serious adverse events (SAEs) in >670 patients in 8 clinical trials
- Negligible toxicity
- No drug resistance in patients on monotherapy for over 4 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 resistance
- Daily lifetime dosing with only 35% of patients with complete viral load suppression

BECAUSE

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

BECAUSE
• **52 patients** prescreened for R5 strain and failing current HAART regimen (3 class resistance or 2 class resistance with limited treatment options)

• **Primary efficacy endpoint:** reduction in viral load after 1 week following single PRO 140 dose
  - All patients continue current HAART; 50% receive PRO 140 / 50% receive placebo
  - PRO 140 patients achieved statistically significant reduction - \( p = 0.0032 \)

• **24-week open-label** with all patients on weekly PRO 140 with optimized HAART
  - **81%** of patients completing trial achieved HIV viral load suppression of <50 cp/mL
  - Recent approved drugs for this population range from **43%** after 24 weeks to **45%** after 48 weeks with viral load suppression of < 50 cp/mL

• **No reported SAEs** related to PRO 140 – (670 patients with zero drug related SAE)

• **40 patients** requested to continue PRO 140 in extension study

• **Regulatory path** – expected first FDA approval for PRO 140 in combination therapy
  - Submission of rolling BLA with full BLA submission expected in 1H2019
  - Safety data from 150 eligible patients from all CytoDyn HIV trials
### Timeline for submitting rolling BLA

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
<th>Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Clinical</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td>1Q19</td>
<td></td>
</tr>
<tr>
<td>CMC (Manufacturing)</td>
<td>1Q19</td>
<td></td>
</tr>
<tr>
<td><strong>Final Complete package:</strong></td>
<td><strong>1Q19</strong></td>
<td></td>
</tr>
</tbody>
</table>
CD03 leronlimab (PRO 140) Investigative Monotherapy Trial

- All patients prescreened for R5 strain with viral load suppression maintained with HAART
- **Ongoing open-label, 48-week trial** with all patients receiving PRO 140 weekly injections
- Investigative trial with focus on **increasing responder rate** and no harm to non-responders

**Increasing response rate**
- With **525 mg** - Responder rate of ~ **70%** so far (4 to 12 months)
- With **700 mg** - Responder rate of ~ **90%** so far (1 to ~4 months)

- **No reported SAEs** related to leronlimab in any trial to date (over 670 patients)
- **Regulatory path**
  - Conduct pivotal Phase 3 monotherapy trial
  - Submit leronlimab (PRO 140) for approval for label expansion as monotherapy, subject to approval as combination therapy
## U.S. Market Size for HIV Indication for leronlimab (PRO 140)

<table>
<thead>
<tr>
<th>Year</th>
<th>HIV patients</th>
<th>Patients using HAART</th>
<th>1 resistance</th>
<th>2 resistance</th>
<th>3 resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>1,373,636</td>
<td>712,532</td>
<td>645,646</td>
<td>218,248</td>
<td>28,372</td>
</tr>
<tr>
<td>2018</td>
<td>1,400,406</td>
<td>745,167</td>
<td>671,257</td>
<td>232,291</td>
<td>27,875</td>
</tr>
<tr>
<td>2019</td>
<td>1,421,563</td>
<td>775,245</td>
<td>694,404</td>
<td>246,842</td>
<td>27,153</td>
</tr>
<tr>
<td>2020</td>
<td>1,432,683</td>
<td>799,418</td>
<td>712,153</td>
<td>261,677</td>
<td>26,168</td>
</tr>
<tr>
<td>2021</td>
<td>1,450,405</td>
<td>827,477</td>
<td>733,273</td>
<td>276,750</td>
<td>24,907</td>
</tr>
<tr>
<td>2022</td>
<td>1,468,530</td>
<td>856,284</td>
<td>754,947</td>
<td>291,950</td>
<td>23,356</td>
</tr>
<tr>
<td>2023</td>
<td>1,487,096</td>
<td>885,878</td>
<td>777,208</td>
<td>307,164</td>
<td>21,501</td>
</tr>
<tr>
<td>2024</td>
<td>1,506,237</td>
<td>916,377</td>
<td>800,152</td>
<td>338,545</td>
<td>20,313</td>
</tr>
<tr>
<td>2025</td>
<td>1,514,925</td>
<td>940,855</td>
<td>817,758</td>
<td>354,548</td>
<td>17,727</td>
</tr>
</tbody>
</table>

Source: GlobalData & [https://doi.org/10.1086/597352](https://doi.org/10.1086/597352)
U.S. Market Potential for leronlimab (PRO 140) in HIV Alone

Initial approval **Combination Therapy**
- HAART failures: ~ 70,000* patients with 2 or more drug class resistances
- 70,000 patients x 70% (R5-HIV strain) = 49,000 HIV patient R5 eligible
- 49,000 patients x $24,000 (current market pricing) = ~ $1.2 billion
- 49,000 patients x $75,000 (current market pricing) = ~ $3.7 billion

Label Expansion **Switch to Monotherapy Maintenance**
- Target population (suppressed viral load) = 17.5% of 1.3 million HIV+ = 227,500**
- 227,500 patients x 70% (R5-HIV) = 159,250 patients
- 159,250 patients x $24,000 (current market pricing) = ~ $3.8 billion
- 159,250 patients x $75,000 (current market pricing) = ~ $12 billion

* Market size – BioVid Market Research: 2 class resistance ~ 5% to 20% ~ 70,000 to 280,000 patients
** Market size – BioVid Market Research: Monotherapy ~ 60% to 100% suppressed viral load among ~ 480,000 to 770,000
However, patients show a strong leronlimab (PRO 140) call to action

### Patient Reactions to PRO 140 (pre-video review)

<table>
<thead>
<tr>
<th></th>
<th>Monotherapy Patients</th>
<th>Combo Therapy Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRO 140 is a significant improvement vs. current options</td>
<td>55%</td>
<td>55%</td>
</tr>
<tr>
<td>Highly likely to start a conversation with my doctor</td>
<td>70%</td>
<td>60%</td>
</tr>
<tr>
<td>Highly likely to try to find more information about PRO 140</td>
<td>65%</td>
<td>60%</td>
</tr>
<tr>
<td>Would schedule an appointment within 3 months to discuss PRO 140</td>
<td>70%</td>
<td>65%</td>
</tr>
</tbody>
</table>

### Effort needed to make PRO 140 part of daily routine

<table>
<thead>
<tr>
<th>Effort Level</th>
<th>Monotherapy Patients</th>
<th>Combo Therapy Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very little/Moderate effort</td>
<td>85%</td>
<td>95%</td>
</tr>
<tr>
<td>A lot of effort</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Way too much effort to take on</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

#### Level of concern about taking PRO 140 as instructed

<table>
<thead>
<tr>
<th>Level of concern</th>
<th>Monotherapy Patients</th>
<th>Combo Therapy Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very concerned</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Somewhat concerned</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>A little bit concerned</td>
<td>40%</td>
<td>5%</td>
</tr>
<tr>
<td>Not concerned</td>
<td>15%</td>
<td>35%</td>
</tr>
</tbody>
</table>

#### Level of concern about taking PRO 140 long-term

<table>
<thead>
<tr>
<th>Level of concern</th>
<th>Monotherapy Patients</th>
<th>Combo Therapy Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very concerned</td>
<td>45%</td>
<td>25%</td>
</tr>
<tr>
<td>Somewhat concerned</td>
<td>35%</td>
<td>35%</td>
</tr>
<tr>
<td>A little bit concerned</td>
<td>35%</td>
<td>35%</td>
</tr>
<tr>
<td>Not concerned</td>
<td>25%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Base Size: Total Patients; Monotherapy Candidates (n=20); Combination Therapy Candidates (n=20)
Leronlimab (PRO 140) Immunologic Indications

Additional potential leronlimab (PRO 140) applications

- GvHD
- Cancer including tumor metastasis (Dr. Richard Pestell)
Effect of leronlimab (PRO 140) on Xeno-GvHD
Human BM Transplanted Into Immuno-Deficient Mice
Expansion into Cancer Indications

- Named world-renowned oncologist Dr. Richard Pestell Chief Medical Officer and Vice Chairman
  - Lead 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
- Founded ProstaGene to develop CCR5 technology in cancer
  - Important focus on metastasis of many types of cancer
  - Research showed nearly 50% of 2,200 patients with breast cancer had overexpressed CCR5
- Published preclinical studies provide support
  - CCR5 inhibitors effectively blocked breast and colon cancer spread; blocked prostate cancer metastasis to bones and brain
CCR5 is Expressed in >50% of Breast Cancer

- Metastatic cancer.
  - 50% of breast cancers CCR5+
  - Leronlimab(PRO 140) reduces breast cancer invasion
Leronlimab (PRO 140) Blocks Breast Cancer Ca\(^{2+}\) signaling

A

<table>
<thead>
<tr>
<th>Event</th>
<th>Image Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 sec before adding CCL5</td>
<td>Control image</td>
</tr>
<tr>
<td>60 sec after adding CCL5</td>
<td>Image showing increased fluorescence</td>
</tr>
<tr>
<td>240 sec after adding CCL5</td>
<td>Image showing decreased fluorescence</td>
</tr>
<tr>
<td>60 sec after adding FBS</td>
<td>Image showing increased fluorescence</td>
</tr>
</tbody>
</table>

B

- **CCL5** addition: Initial increase in Fluo-4 fluorescence, followed by a decrease.
- **FBS** addition: Immediate increase in Fluo-4 fluorescence.

C

- **CCL5** addition: Initial increase in Fluo-4 fluorescence, followed by a decrease.
- **FBS** addition: Immediate increase in Fluo-4 fluorescence.
CCR5 Antagonists Block Breast Cancer Metastasis

Time (weeks)

1 2 3 4

Control

Maraviroc

www.cytodyn.com

Radiance (p/sec/cm²/sr) x 10^8

0 2.5 5.0 7.5 10.0 12.5 15.0

Time (weeks)

0 1 2 3 4 5

Professor Richard Pestell, PhD, MD
CCR5 Antagonists Block Prostate Cancer Metastasis

Control

Maraviroc

Professor Richard G. Pestell, PhD, MD

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

Advanced-stage metastatic colorectal cancer who are refractory to standard chemotherapy, including regorafenib.


Objective Tumor Response, Phase 1 Trial

G

Change in SLD vs baseline (%)

<table>
<thead>
<tr>
<th>Patients (CHT+CCR5 inhib.)</th>
<th>Pt 1</th>
<th>Pt 2</th>
<th>Pt 3</th>
<th>Pt 4</th>
<th>Pt 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in SLD vs baseline (%)</td>
<td>NE**</td>
<td>-20</td>
<td>-10</td>
<td>-30</td>
<td>-40</td>
</tr>
</tbody>
</table>

Partial Response (RECIST)
**Leronlimab (PRO 140) Breast Cancer Study**

November 2018-March 2019
Phase II

April 2019-July 2021 (Phase III)

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

Endpoints
1. OS
2. PFS'
3. Decreased CTC
Trastuzumab for breast cancer with HER-2+ patients
Annual sales = $15 billion

HER-2+ is about 12% of breast cancer population
CCR5 + is about 50% breast cancer population

Market potential ~ 4 x $15 billion = $60 billion
Other Potential Non-Dilutive Capital Raise

- **Prognostic Test**
  Potential licensing in 2019

- **Potential use of leronlimab**
  - Already sent product to interested EU collaborators
  - Already testing for CCR5 staining purposes

- **Several abstracts**
  - At least 5 abstract are ready or will be submitted for publishing in 2019
  - Presenting in many Prostate and other oncology conferences in 2019
## PRO 140 Important Milestones for HIV and Cancer 2019

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Target Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLA submission</td>
<td>1H2019</td>
</tr>
<tr>
<td>Revenue potential of about $480 million</td>
<td>2020</td>
</tr>
<tr>
<td>Large Pharma discussion for potential licensing or partnering</td>
<td>1H2019</td>
</tr>
<tr>
<td>Triple Negative Breast Cancer study first patient injected</td>
<td>1Q2019</td>
</tr>
<tr>
<td>Triple Negative Breast Cancer study Interim results</td>
<td>1H2019</td>
</tr>
<tr>
<td>Late Breaker at CROI – Combination therapy – Monotherapy</td>
<td>Will apply</td>
</tr>
<tr>
<td>Prognostic test licensed</td>
<td>2019</td>
</tr>
<tr>
<td>IND-Protocol for colon cancer Phase 2</td>
<td>1H2019</td>
</tr>
</tbody>
</table>