Leronlimab (PRO 140)

HIV - Cancer
NASH - GvHD

LD Micro Invitational Conference (June-2019)

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&

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Vice Chairman and Chief Medical Officer
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**Leronlimab (PRO 140) – A Humanized Monoclonal Antibody**

Blocking **HIV** entry receptor (CCR5)

Blocking CCR5/CCL5 interaction with leronlimab for potential use in **CANCER**

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

[Diagram showing the interaction between HIV, T-Cell, CD4, CCR5, and leronlimab.]
Leronlimab (PRO 140)

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>HAART</th>
</tr>
</thead>
<tbody>
<tr>
<td>No serious side effects and no drug related serious adverse events (SAEs) in &gt;740 patients in 8 clinical trials</td>
<td>Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)</td>
</tr>
<tr>
<td>Negligible toxicity in 740 patients</td>
<td>Toxicity</td>
</tr>
<tr>
<td>No drug resistance in patients on monotherapy for over 4.5 years</td>
<td>Problems with short- and long-term toxicity</td>
</tr>
<tr>
<td>Weekly, easy, subcutaneous self administration</td>
<td>Resistance</td>
</tr>
<tr>
<td></td>
<td>76% of HIV patients have at least one drug resistance</td>
</tr>
<tr>
<td></td>
<td>Compliance</td>
</tr>
<tr>
<td></td>
<td>Daily lifetime dosing with only 35% of patients with complete viral load suppression</td>
</tr>
</tbody>
</table>

FDA: “Fast Track designation” – “accelerated approval possible”
NIH: $28 million grants
<table>
<thead>
<tr>
<th>Disease</th>
<th>Phase</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>PHASE 3</td>
<td>Completed. World’s first self-injectable for Unmet Medical Need Population</td>
</tr>
<tr>
<td>HIV</td>
<td>PHASE 3</td>
<td>Monotherapy. 110 patients reached about one year</td>
</tr>
<tr>
<td>GvHD</td>
<td>PHASE 2</td>
<td>Initiated. Unmet Medical Need – ODD granted</td>
</tr>
<tr>
<td>TNBC</td>
<td>PHASE 1b/2</td>
<td>Initiated. Unmet Medical Need - FTD</td>
</tr>
<tr>
<td>Colon Cancer</td>
<td>PHASE 2</td>
<td>IND to be filed. File for Orphan Drug Designation</td>
</tr>
<tr>
<td>Prognostic</td>
<td></td>
<td>510(k) for medical device. File with FDA for prostate cancer prognostic test</td>
</tr>
</tbody>
</table>

**8 Cancer Indications & NASH**

8 Pre-clinical studies to be initiated

Melanoma, Pancreatic, Breast, Prostate, Colon, Lung, Liver and Stomach Cancer
<table>
<thead>
<tr>
<th>Pivotal Phase 3 Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Efficacy End Point Hit -  $p=0.0032$</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>No reported SAEs related to leronlimab</td>
</tr>
<tr>
<td>BLA – submission green light from FDA</td>
</tr>
<tr>
<td>Rolling Review Submission Granted by FDA</td>
</tr>
<tr>
<td>1/3 of BLA already submitted in March 2019</td>
</tr>
</tbody>
</table>

**Potential label:**
- One drug resistance in three classes
- or
- One drug resistance in two classes with limited treatment options to another class
**CD03 Leronlimab (PRO 140) Investigative Monotherapy Trial**

- R5 patients w/suppressed viral load replacing HAART with leronlimab monotherapy
  1) One dose (2 consecutive injections), once a week, self administered at home
  2) 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

- Regulatory path
  - Submit pivotal trial to the FDA 2Q2019 – Currently in discussion with the FDA

<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>350 mg</td>
<td>38 weeks</td>
<td>70%</td>
</tr>
<tr>
<td>525 mg</td>
<td>29 weeks</td>
<td>95%</td>
</tr>
<tr>
<td>700 mg</td>
<td>19 weeks</td>
<td>88%</td>
</tr>
</tbody>
</table>

- **VF criteria** – Induction period: 2 consecutive VL> 50 cp/mL or 1 VL>200 cp/mL also the VL<50 cp/mL at the end of induction period is a must
- **VF criteria** – Maintenance period: 3 increase VL> 50 cp/mL

- 110 patients have completed almost one year of monotherapy with five patients reaching almost **FIVE YEARS** of MONOTHERAPY
# 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)
Initial approval **Combination Therapy**

- HAART failures: ~ 70,000* patients with 2 or more drug class resistances
- 70,000 – 150,000 patients x 70% (R5-HIV strain) = 49,000 -HIV patient R5 eligible
- 50,000 -100,000 patients x $35,000 = ~ $1.7 to $3.4 billion

Label Expansion **Switch to Monotherapy Maintenance**

- 227,500 patients x 70% (R5-HIV) = 159,250 patients
- 160,000 – 300,000 patients x $35,000 = ~ $6 to $11 billion

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* 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** patients
U.S. Market Potential for leeronlimab (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
• 25,000 patients x $120,000 (current market pricing) = ~$3 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
• 90,000 patients x $120,000 (current market pricing) = ~$11 billion

$1 billion worth of leeronlimab ($120,000/year/patient) first part with deferred payment plan
~$10 billion before 2027
Number of opportunities:

1) Chinese investment w/potential significant upfront payment
2) Potential deal with large pharma
3) Potential licensing/partnering deal for TNBC, GvHD, NASH
4) Potential licensing the commercialization rights for HIV
5) Potential licensing agreement for Dr. Pestell’s Prognostic test for prostate cancer

6) Prevention study - Potential recent opportunity
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

www.cytodyn.com
Expansion into Cancer Indications

- Named world-renowned oncologist Dr. Richard Pestell as 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
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
Leronlimab (PRO 140) Blocks Breast Cancer Ca\textsuperscript{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)

Relative Fl of Fluo-4

Time (Sec)

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
Advanced-stage metastatic colorectal cancer who are refractory to standard chemotherapy, including regorafenib.
CCR5 Antagonists Block Metastasis

Control

Leronlimab

Maraviroc

0 1 2 3 4 5 6 7 weeks
Leronlimab (PRO 140) Breast Cancer Trial

November 2018-December 2019
Phase II

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

Breakthrough (unmet need)
April 2019-July 2021 (Phase III)

Endpoints
1. OS
2. PFS'
3. Decreased CTC
### 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 – HIV combination therapy – unmet medical need</td>
<td>2H2019</td>
</tr>
<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>
</tr>
<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>2019</td>
</tr>
<tr>
<td>Prognostic test licensed – 510(k) filing with the FDA</td>
<td>1H2019</td>
</tr>
<tr>
<td>IND-Protocol for colon cancer Phase 2</td>
<td>1H2019</td>
</tr>
<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 (if results of preclinical studies are positive)</td>
<td>2019</td>
</tr>
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