**Leronlimab (PRO 140): First self-administered therapy for HIV in late-stage clinical development**

In early-stage development to stop cancer metastasis and other immunological disorders

**CytoDyn** is focused on the clinical development and commercialization of leronlimab (PRO 140), a fully humanized monoclonal antibody. Leronlimab blocks the predominant HIV (R5) subtype entry into T-cells by masking this required co-receptor, CCR5. Importantly, leronlimab does not appear to interfere with the normal function of CCR5 in mediating immune responses. CytoDyn has achieved its primary endpoint in a pivotal trial with leronlimab as a combination therapy for treatment-experienced HIV-infected patients and is conducting a Phase 3 investigative trial with leronlimab in HIV as a monotherapy (first single agent HIV therapy ever). In September 2018, CytoDyn announced plans to develop leronlimab as a therapy for triple-negative breast cancer (TNBC) that has metastasized. Previously announced findings from preclinical studies showed the ability of leronlimab to block human breast cancer cellular invasion in a surrogate assay for metastatic breast cancer (TNBC). CytoDyn has just received a green light from the FDA to initiate it’s TNBC clinical trial a phase (1b/2). If successful, the interim results could be announced in first quarter of 2019 and breakthrough therapy designation (BTD) application will be filed.

**Recent Developments in Leronlimab (PRO 140) Clinical Programs**

**Completed - CD02 Phase 3, pivotal trial in combination therapy for HIV**
- Achieved primary endpoint ($p=0.0032$)
- **81%** of patients achieved suppressed viral load (VL) with plasma HIV-1 RNA <50 copies/mL
- No serious adverse events (SAEs) related to PRO 140 (over 650 patients exposed to PRO 140)
- Rolling BLA submission expected to be complete in 1H19

**Underway - CD03 Phase 3 HIV investigative monotherapy trial**
- 366 patients enrolled, enrollment continuing
- ~70% response rate at 525 mg
- ~90% response rate at 700 mg

**Leronlimab (PRO 140) for HIV: Clinical Trial Overview**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Study</th>
<th># patients</th>
<th>Design/Findings</th>
<th>Status</th>
<th>P&lt;0.05</th>
<th>Ph1</th>
<th>Ph2</th>
<th>Ph3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Phase 1 study</td>
<td>54</td>
<td>Healthy patients, no safety concerns</td>
<td>Complete</td>
<td></td>
<td></td>
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<tr>
<td>1300 N Phase 1 study</td>
<td>39</td>
<td>Intravenous, single-dose VL, reduction for 3 weeks</td>
<td>Complete</td>
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<td></td>
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<tr>
<td>2300 N Phase 2 studies</td>
<td>31</td>
<td>Intravenous, single-dose VL; reduction for 3 weeks</td>
<td>Complete</td>
<td></td>
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<tr>
<td>2101 SC Phase 2 studies</td>
<td>44</td>
<td>Subcutaneous, long-acting, self-administered, proof-of-concept shown</td>
<td>Complete</td>
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<tr>
<td>CD01 Phase 2b</td>
<td>43</td>
<td>12-week drug substitution: monotherapy</td>
<td>Complete</td>
<td>Jan. 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD02 Phase 2b/3 Pivotal path to approval</td>
<td>52</td>
<td>Combination therapy in HAART failures, 1 week efficacy + 24 weeks durability</td>
<td>Complete</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CD03 Phase 2b/3 Investigative Trial - Largest market size</td>
<td>303</td>
<td>Long-term monotherapy</td>
<td>300 patients completed</td>
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</tbody>
</table>

**PRO 140 Advantages over Highly Active Antiretroviral Therapy (HAART) for HIV**

- **No serious side effects and no serious adverse events (SAEs) in >400 patients in 8 clinical trials**
- Negligible toxicity
- No drug resistance in patients on monotherapy for over 3 years
- Weekly, easy, subcutaneous self administration
- Daily lifetime dosing with only 35% of patients with complete viral load suppression

**PRO 140**

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

**Completed - CD02 Pivotal HIV Combination Trial with PRO 140 (Leronlimab)**

- **52 patients** prescreened for R5 strain and failing current HAART regimen (multi-class resistance patient)
- **Achieved primary efficacy endpoint**: reduction in viral load after 1 week following single PRO 140 dose
- Leronlimab (PRO 140) patients versus placebo achieved statistically significant reduction - **$p = 0.0032$**
- **24-week open-label** with all patients on weekly PRO 140 with optimized HAART. Of patients completing the trial:
- **81%** had HIV viral load suppression of <50 cp/mL
- **92%** had viral load suppression of <400 cp/mL
- Recent approved drug for this population was 43%
- No reported SAEs related to PRO 140
- **40 patients** requested to continue PRO 140 in extension study
- **Regulatory path** – expected first FDA approval for PRO 140 in combination therapy
- Filing rolling BLA; full BLA filing expected 1H19 (fast-track)
- Safety data from 150 eligible patients from all CytoDyn HIV trials
Ongoing - CD03 HIV Investigative Monotherapy Trial with PRO 140 (Leronlimab)

- All patients prescreened for R5 strain with viral load suppression maintained with HAART
- **Ongoing open-label, 48-week trial** with all patients receiving leronlimab (PRO 140) weekly injections
- **Investigative trial** with focus on increasing responder rate and no harm to non-responders
- **Increasing response rate**
  - 525 mg dose produced responder rate of ~70%
  - 700 mg dose produced responder rate of ~90%

**Options for non-responders**
- 100% of non-responders re-suppressed viral load with prior HAART regimen
- **No reported SAEs** drug related in any trial (>670 patients)
- **Regulatory path**
  - Conduct pivotal Phase 3 monotherapy trial
  - Submit PRO 140 for approval for label expansion as monotherapy, subject to approval as combination therapy

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**U.S. Market for HIV Indication for leronlimab (PRO 140)**

**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

**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

**Expansion into Cancer Indications**

- Named world-renowned oncologist as Chief Medical Officer and CytoDyn board member: **Professor Richard G. Pestell** M.D., Ph.D., MB., B.S., F.A.C.P., F.R.A.C.P., F.A.A.A.S., M.B.A.
  - 700 publications with over 500 in peer review
  - Lead leronlimab (PRO 140) non-HIV development programs
  - Led 2 National Cancer Institute-designated cancer centers: Lombardi Comprehensive Cancer Center at Georgetown University and 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
  - **CCRS inhibitors effectively blocked breast and colon cancer spread; blocked prostate cancer metastasis to bones and brain**

**Milestones**

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