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 its 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>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</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>
<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>
<td></td>
<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>
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<tr>
<td>2100 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 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>
<td></td>
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<tr>
<td>CD03 Phase 2b/3 Investigative Trial - Largest market size</td>
<td>303</td>
<td>Long-term monotherapy</td>
<td>Complete</td>
<td></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

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

Recent Stock Price (12/03/18) $0.60
52-Week Range $0.40-$0.84
Market Capitalization $174.5M
Shares Outstanding 290.8M
Fiscal Year-End May 31

CytoDyn has just achieved a statistically significant reduction in viral load for patients in the new protocol following treatment of first 10 patients. This is expected first FDA approval for PRO 140 in combination therapy. Leronlimab has achieved 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 its 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.
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

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
  - CCR5 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>
</table>

* 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