



OTCQB: CYDY www.cytodyn.com

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

**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 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**

**Underway - Phase 2 graft-versus-host disease (GvHD)**

- Modified protocol to improve enrollment and reflect positive preclinical findings
- Orphan drug designation granted by FDA; if interim results are positive, BTD will be filed for expedited approval

**New, Underway - Phase 1b/2 triple negative breast cancer**

- Interim data review following treatment of first 10 patients in the new protocol; TNBC is unmet medical need
- Interim results could be announced in 1<sup>st</sup> Q of 2019
- CTC (Circulating Tumor Cell) test will be conducted with all patients and the test is conducted every 21 days

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

Study	# patients	Design/Findings	Status	Stage			
				P-Cl.	Ph1	Ph2	Ph3
2 Phase 1 study	54	Healthy patients, no safety concerns	Complete	█			
1302 IV Phase 1 study	39	Intravenous, single-dose VL reduction for 3 weeks	Complete	█			
2301 IV Phase 2 studies	31	Intravenous, single-dose VL reduction for 3 weeks	Complete	█			
2101 SC Phase 2 studies	44	Subcutaneous, long-acting, self-administered, proof-of-concept shown	Complete	█			
CD01 Phase 2b	43	12-week drug-substitution <b>monotherapy</b> Long-term <b>monotherapy</b> extension: 14 patients with VL suppression at 12 weeks	Complete Jan. 2015	█			
CD02 Phase 2b/3 Pivotal-Fastest path to approval	52	Combination therapy in HAART failures, 1 week efficacy + 24 weeks durability	Complete	█			
CD03 Phase 2b/3 Investigative Trial - Largest market size	303	Long-term <b>monotherapy</b>	300 patients original trial Enrollment completed	█			

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

PRO 140	VS	HAART
<b>No serious side effects and no serious adverse events (SAEs) in &gt;400 patients in 8 clinical trials</b>	Side Effects	Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)
<b>Negligible toxicity</b>	Toxicity	Problems with short- and long-term toxicity
<b>No drug resistance in patients on monotherapy for over 3 years</b>	Resistance	76% of HIV patients have at least one resistance
<b>Weekly, easy, subcutaneous self administration</b>	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

## 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**

\* 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

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