UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 2, 2019

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-49908**	**83-1887078**
(State or other jurisdiction of incorporation)	**(SEC File Number)**	**(I.R.S. Employer Identification No.)**

1111 Main Street, Suite 660 **Vancouver, Washington**	**98660**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (360) 980-8524

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**

Item 8.01. Other Events.

On May 2, 2019, the Company posted an updated version of the investor presentation deck titled “Leronlimab (PRO 140) HIV - Cancer” to its website at www.cytodyn.com. A copy of the investor presentation is filed as Exhibit 99.1 to this Form 8-K.

The Company does not intend to incorporate any contents from its website into thisForm 8-K.

Item 9.01. Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	99.1	Investor Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CytoDyn Inc.

May 2, 2019

By: */s/ Michael D. Mulholland*
Name: Michael D. Mulholland
Title: Chief Financial Officer

Exhibit 99.1

Leronlimab (PRO 140)

CytoDyn

Trading Symbol
CYDY

HIV - Cancer

CytoDyn

Trading Symbol
CYDY

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.
Vice Chairman and Chief Medical Officer

Nader Pourhassan, Ph.D.
Director, President & CEO

Forward-Looking Statements

This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. 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 vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to enter into partnership or licensing arrangements with third parties, (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) the design, implementation and conduct of the Company's 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 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. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this presentation.

CytoDyn Overview

HIV

PHASE 3 - Completed

World's first self-injectable for Unmet Medical Need Population

HIV

PHASE 3 - Monotherapy

Several patients on monotherapy for > 4.5 years

GvHD

PHASE 2 – Initiated

Unmet Medical Need

TNBC

PHASE 1b/2 – Initiated

Unmet Medical Need

Colon Cancer

PHASE 2

IND to be filed

File for Orphan Drug Designation

Prognostic

510(k) for medical device

File with FDA for prostate cancer prognostic test

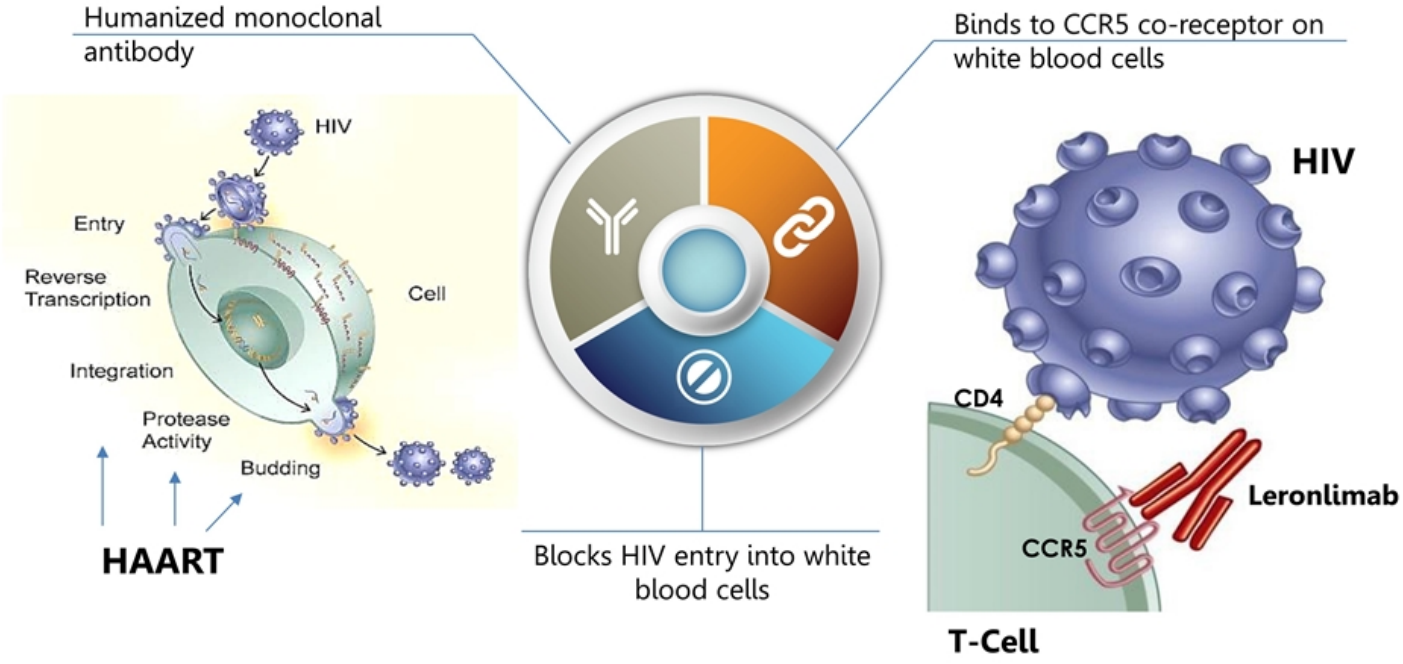
8 Cancer indications

8 Pre-clinical studies to be initiated

Melanoma, Pancreatic, Breast, Prostate, Colon, Lung, Liver and Stomach Cancer

Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

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



FDA: "fast track designation" – "accelerated approval possible"
NIH: $28 million grants

Leronlimab (PRO 140)		HAART
No serious side effects and no drug related serious adverse events (SAEs) in >740 patients in 8 clinical trials	Side Effects	Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)
Negligible toxicity in 740 patients	Toxicity	Problems with short- and long-term toxicity
No drug resistance in patients on monotherapy for over 4.5 years	Resistance	76% of HIV patients have at least one drug resistance
Weekly, easy, subcutaneous self administration	Compliance	Daily lifetime dosing with only 35% of patients with complete viral load suppression

CD02 Pivotal Combination Trial with Leronlimab (PRO 140)

Pivotal Phase 3 Completed
Primary Efficacy End Point Hit - ***p*=0.0032**
Safety of 24 weeks completed - With **81% of patients** with suppressed viral load as compared to **43%** last approved drug for this population
No reported SAEs related to leronlimab
BLA – submission green light from FDA
Rolling Review Submission Granted by FDA
1/3 of BLA already submitted in March 2019

Potential label:

One drug resistance in three classes

or

One drug resistance in two classes with limited treatment option to another class

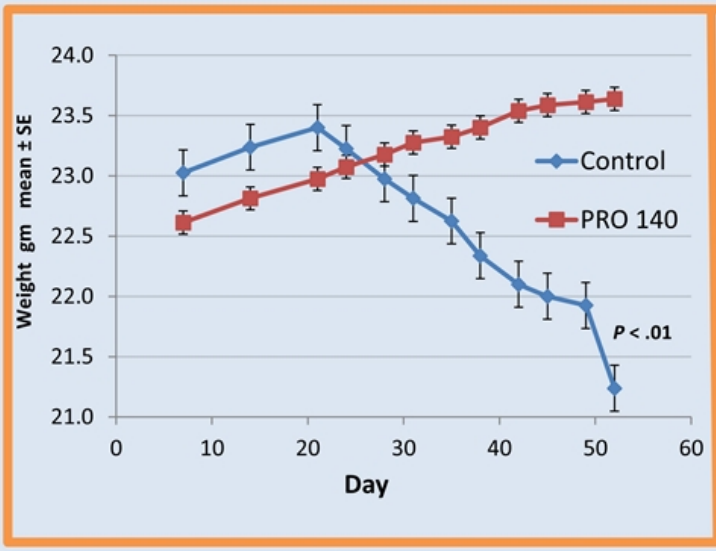
CD03 Leronlimab (PRO 140) Investigative Monotherapy Trial

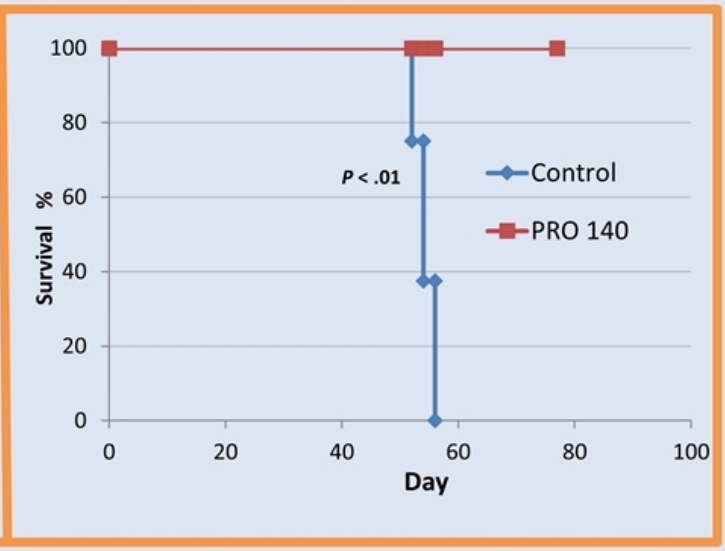
- R5 patients w/suppressed viral load replacing HAART for leronlimab monotherapy
- **Leronlimab monotherapy – One dose (2 consecutive injections), once a week**
- High responder's rate – non-responders return to their original regimen without any resistance or harm – No ADA (Anti-Drug Antibody) presence – No X4 grow out during the monotherapy
- **Increasing response rate** **(Suppressed viral load without pills)**

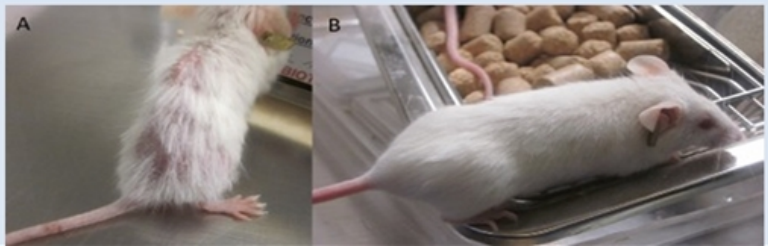
Dose	Average duration post 10 weeks	Responder's rate post 10 weeks
525 mg	26 weeks	95%
700 mg	9 weeks	91%

- **Regulatory path**
  - **Submit pivotal trial to the FDA 2Q2019**

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





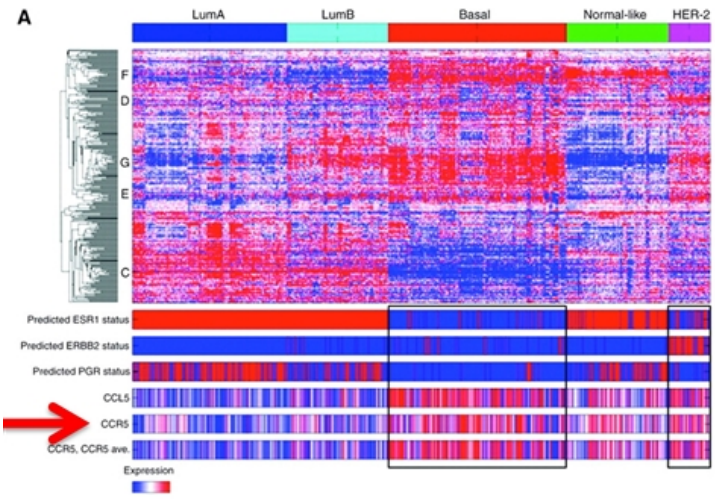


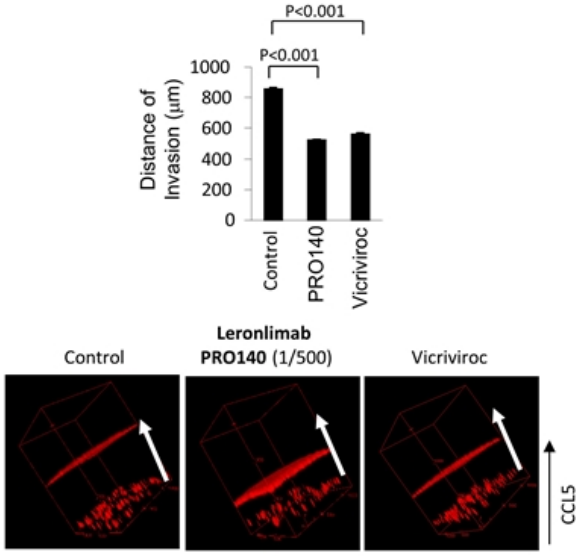
Expansion into Cancer Indications

- Named world-renowned oncologist Dr. Richard Pestell 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

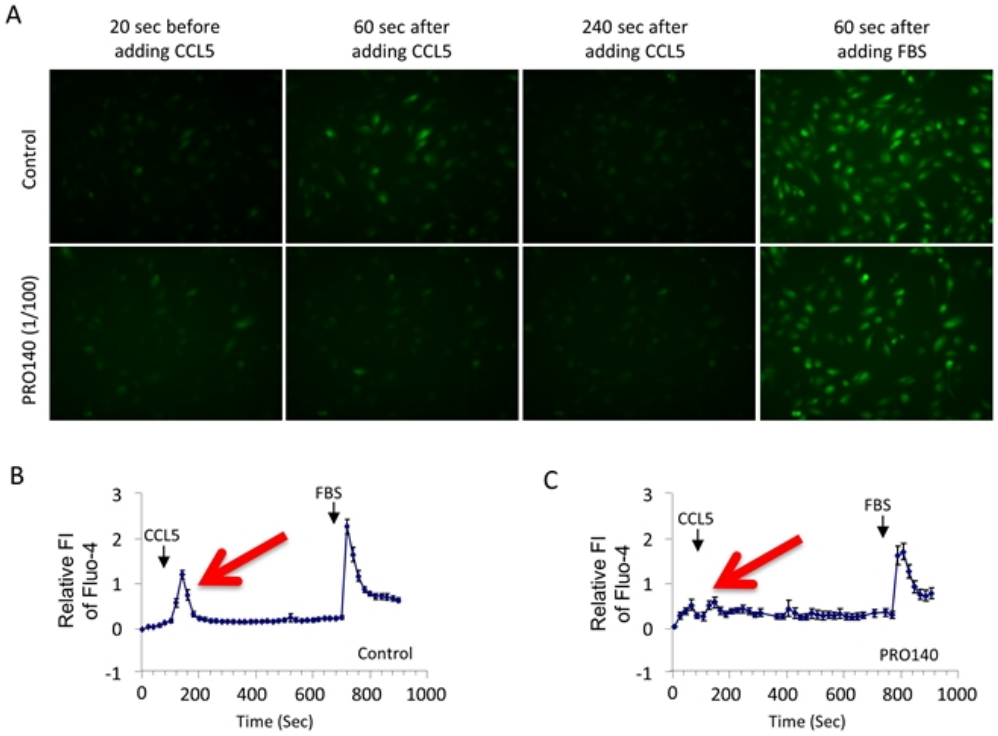
CCR5 is Expressed in >50% of Breast Cancer

- **Metastatic cancer.**
  - 50% of breast cancers CCR5+
  - Leronlimab (PRO 140) reduces breast cancer invasion in pre-clinical studies



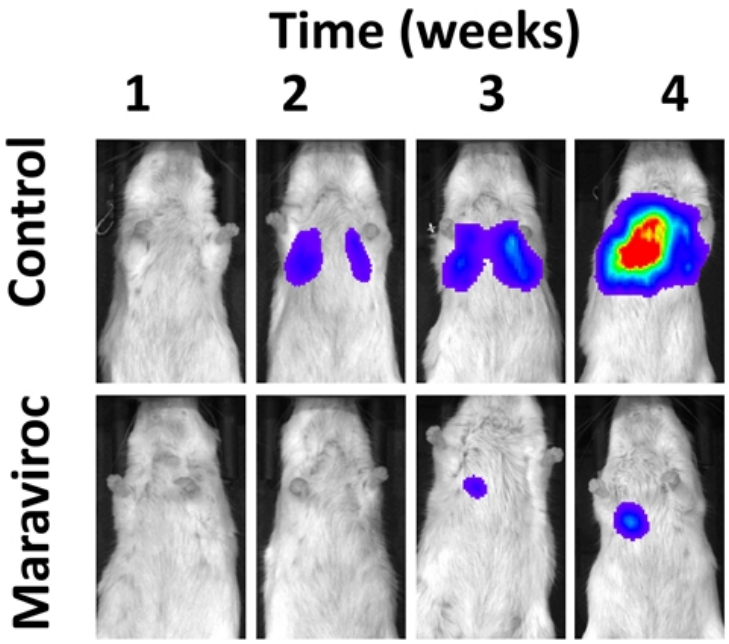


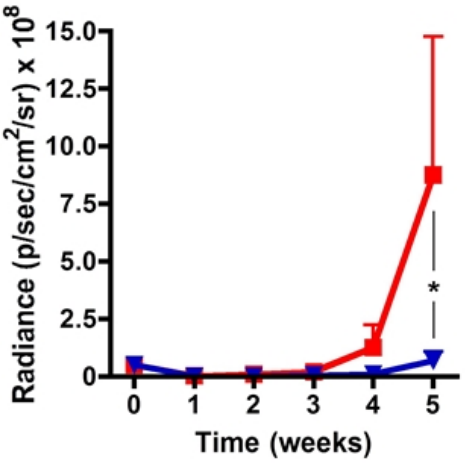
Leronlimab (PRO 140) Blocks Breast Cancer Ca^{+2} signaling



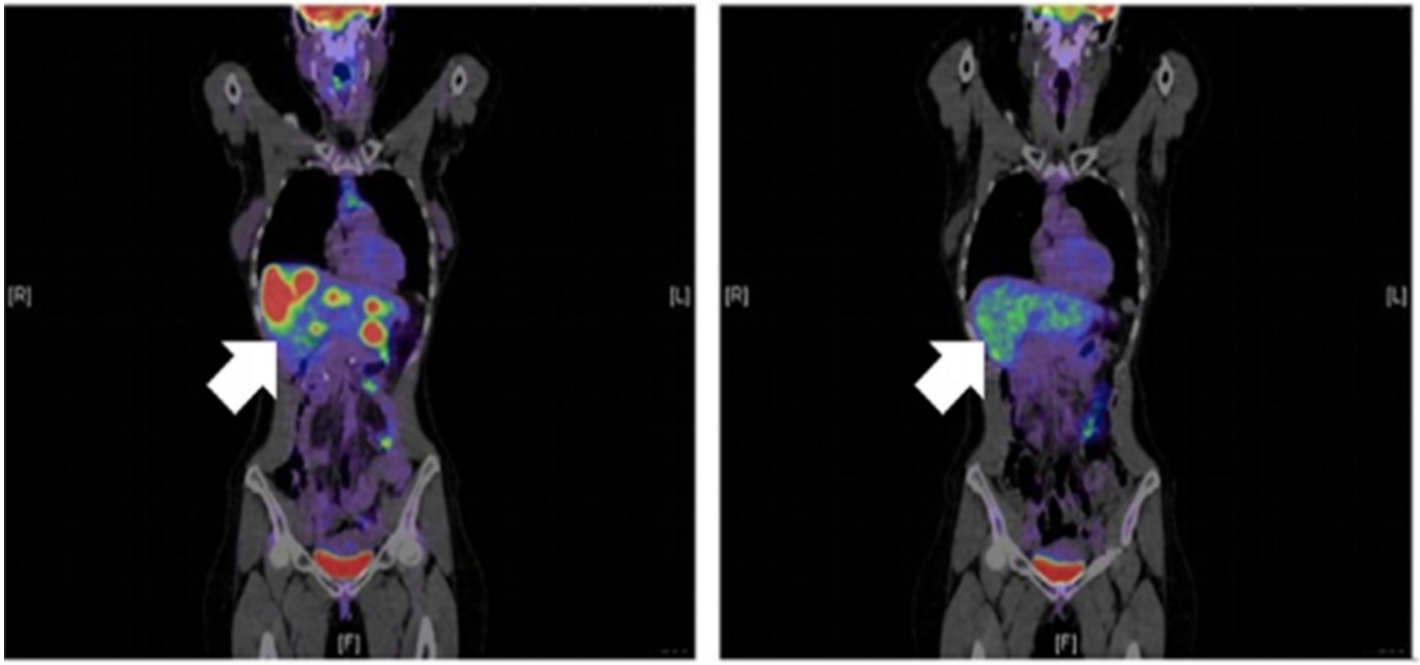
Professor Richard Pestell, PhD, MD

CCR5 Antagonists Block Breast Cancer Metastasis



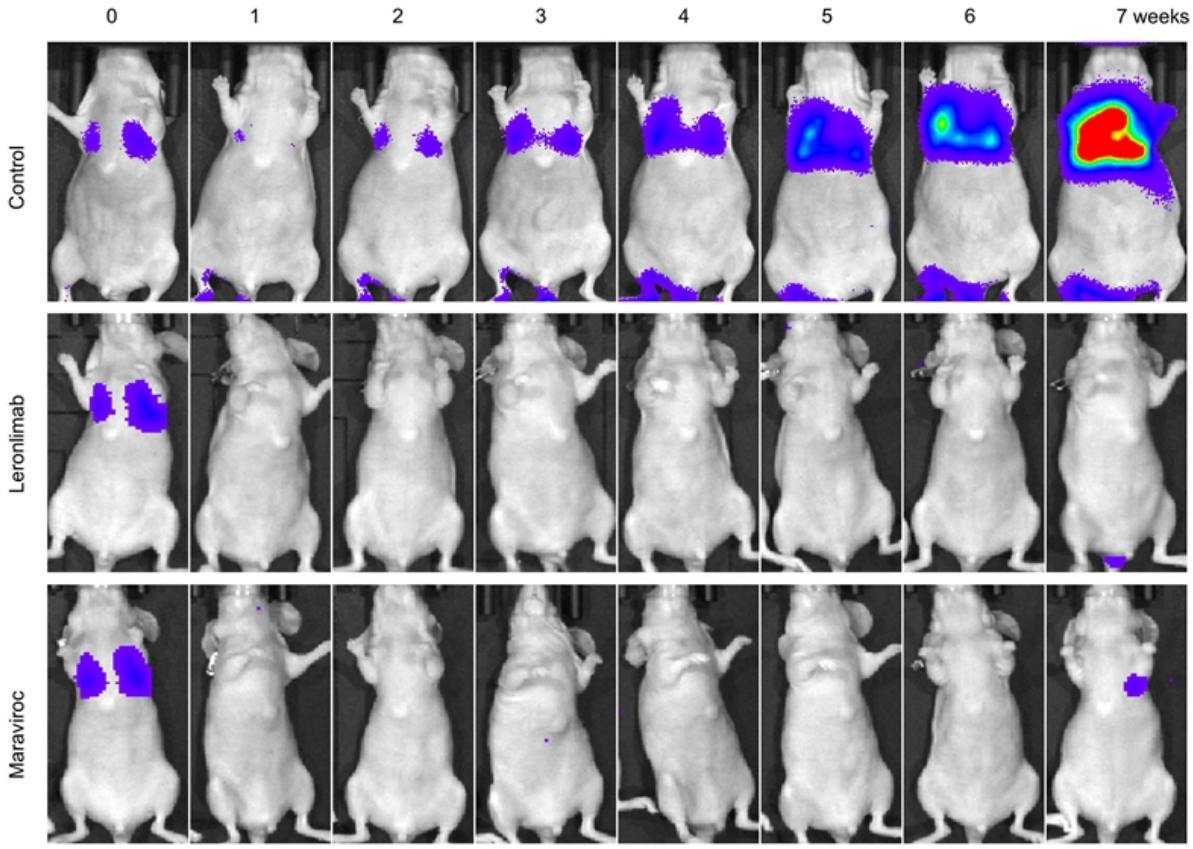


Objective Tumor Response, Phase 1 Trial

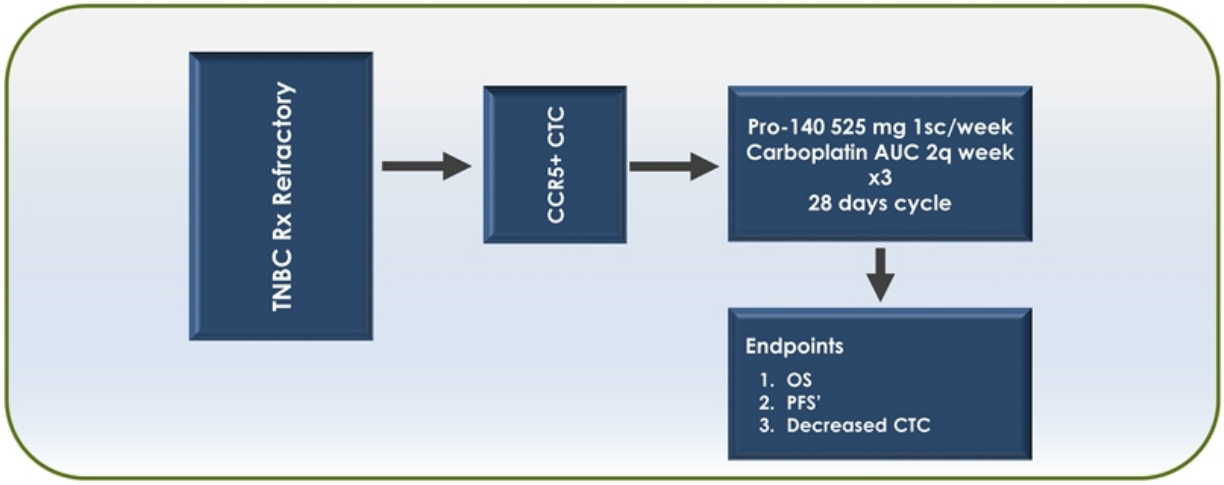


before CHT+CCR5 inh. after CHT+CCR5 inh.

CCR5 Antagonists Block Metastasis



Leronlimab (PRO 140) Breast Cancer Trial



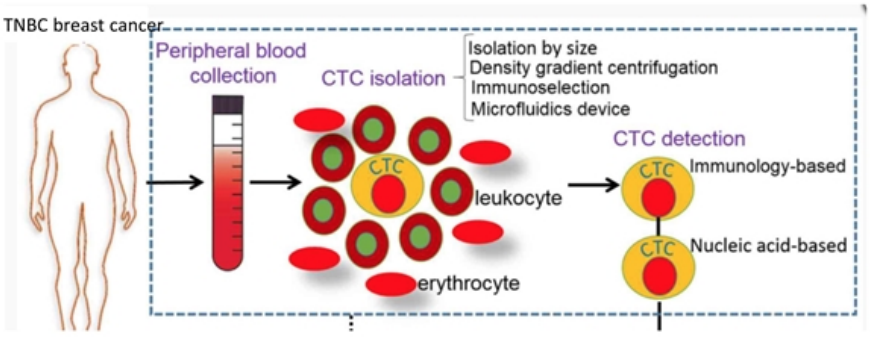
November 2018-December 2019
Phase II

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

Clinical studies updates

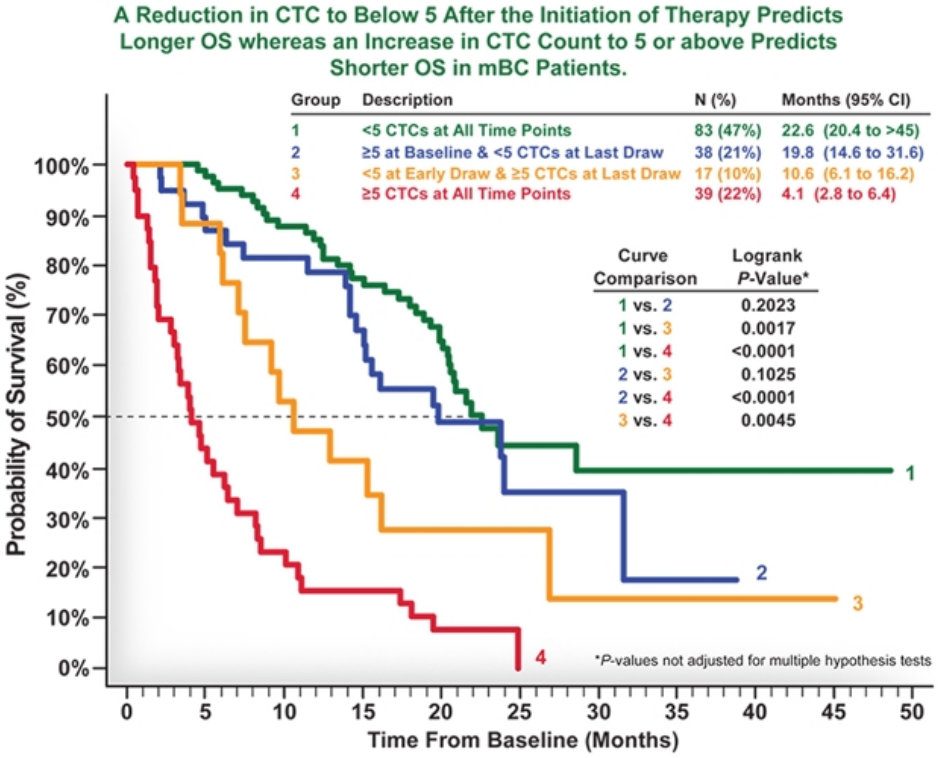
1. AACR presentation April 1 Atlanta Georgia.

CCR5 associated with HER2 in circulating tumor cells (CTCs) is a novel biomarker for patients with metastatic breast cancer (MBC) . CTCs were found positive (≥5) in all seven MBC patients with a range of numbers between 124 and 442



Trial open to accrual measuring CTC

CytoDyn



Trial open to accrual

1. Pacific Hematology Oncology Associates
Dr. Milana Dolezal mdolezal@phoamd.com
2100 Webster street suite 220, San Francisco, ca 9411
david@PHOAMD.COM
415-923-3012

Other sites to open:
1. Northwestern University Medical School,
2. Methodist Houston,
3. Vanderbilt University,
4. Sidney Kimmel Cancer Center.

PRO 140 Important Milestones for HIV and Cancer 2019

Milestones	Target Dates
BLA submission – HIV combination therapy – unmet medical need	3Q2019
Revenue potential of about $480 million	2020
Initiate first ever monotherapy Phase 3 pivotal trial	1H2019
Triple-Negative Breast Cancer study first patient injected	2Q2019
Triple-Negative Breast Cancer study interim results	2019
GvHD interim results	2H2019
Prognostic test licensed – 510(k) filing with the FDA	1H2019
IND-Protocol for colon cancer Phase 2	1H2019
Large Pharma discussion for potential licensing or partnering	1H2019
8 preclinical studies with leronlimab - Filing 8 INDs for 8 Phase 2 trials (if results of preclinical studies are positive)	2019

Leronlimab (PRO 140)

CytoDyn

Trading Symbol
CYDY

HIV - Cancer

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Vice Chairman and Chief Medical Officer

Nader Pourhassan, Ph.D.
Director, President & CEO