Leronlimab (PRO 140)

HIV - Cancer

NASH - GvHD

LD Micro Invitational Conference (June-2019)

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

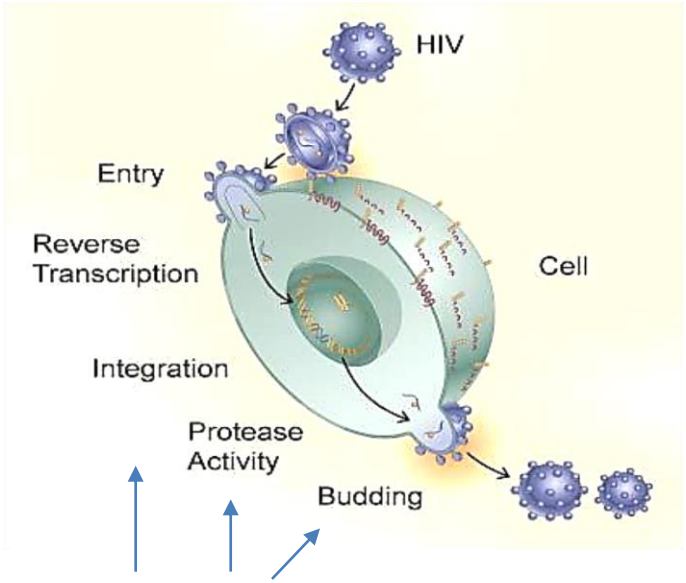
Forward-Looking Statements

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.

Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

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

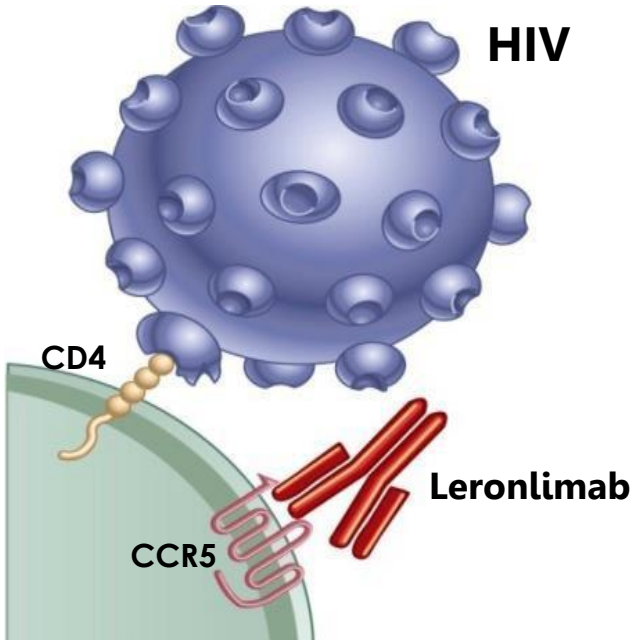
Humanized monoclonal antibody



HAART

Blocks HIV entry into white blood cells

Binds to CCR5 co-receptor on white blood cells



T-Cell

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

CytoDyn Overview

HIV

PHASE 3 - Completed

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

HIV

PHASE 3 - Monotherapy

110 patients reached about one year

GvHD

PHASE 2 – Initiated

Unmet Medical Need – ODD granted

TNBC

PHASE 1b/2 – Initiated

Unmet Medical Need - FTD

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 & NASH

8 Pre-clinical studies to be initiated

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

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 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**

Dose	Average duration post 10 weeks	Responder's rate post 10 weeks
350 mg	38 weeks	70%
525 mg	29 weeks	95%
700 mg	19 weeks	88%

- **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)

Year	HIV patients	Patients using HAART	1 resistance	2 resistance	3 resistance
2017	1,373,636	712,532	645,646	218,248	28,372
2018	1,400,406	745,167	671,257	232,291	27,875
2019	1,421,563	775,245	694,404	246,842	27,153
2020	1,432,683	799,418	712,153	261,677	26,168
2021	1,450,405	827,477	733,273	276,750	24,907
2022	1,468,530	856,284	754,947	291,950	23,356
2023	1,487,096	885,878	777,208	307,164	21,501
2024	1,506,237	916,377	800,152	338,545	20,313
2025	1,514,925	940,855	817,758	354,548	17,727

Source: GlobalData & https://doi.org/10.1086/597352

U.S. Market Potential for leronlimab (PRO 140) in HIV Alone

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**

* 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**

$1 billion worth of leronlimab ($120,000/year/patient) first part with deferred payment plan

~$10 billion before 2027

Partnering – Licensing Opportunities

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**

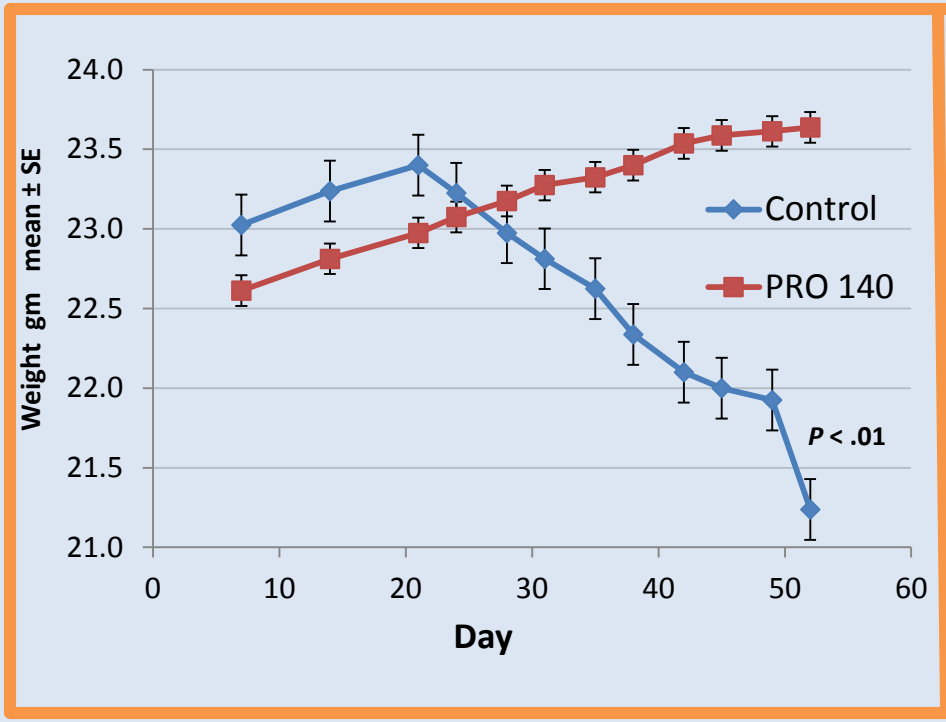
6) **Prevention study - Potential recent opportunity**

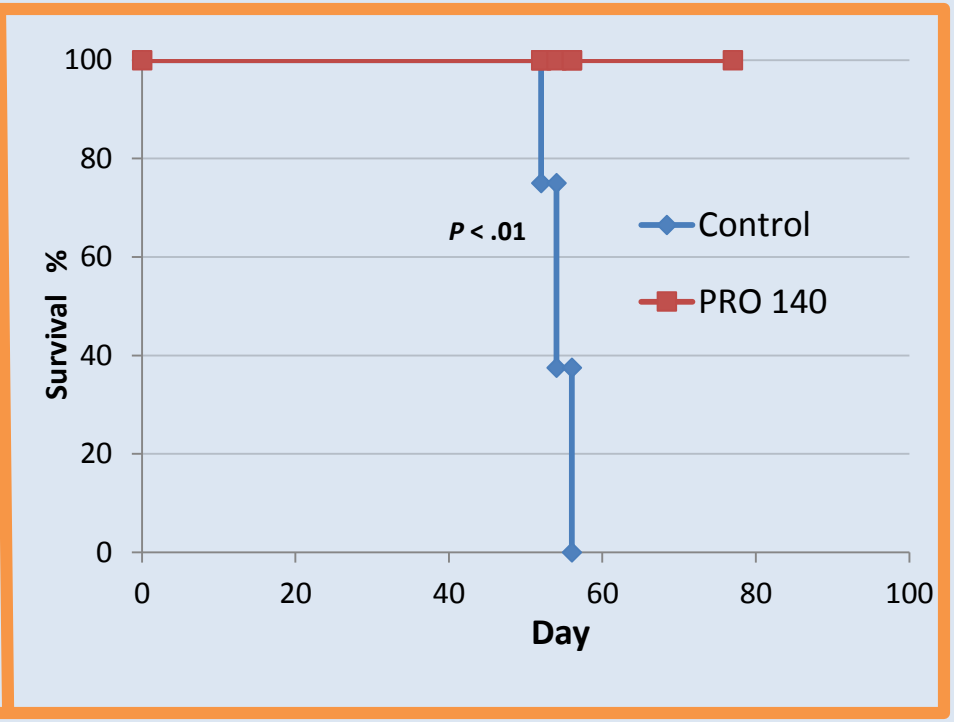
Effect of Leronlimab (PRO 140) on Xeno GvHD-Human

BM Transplanted Into Immuno-Deficient Mice

Results Published

TRIAL TO RE-INITIATE WITH MODIFIED DOSE/PROTOCOL IN MAY 2019





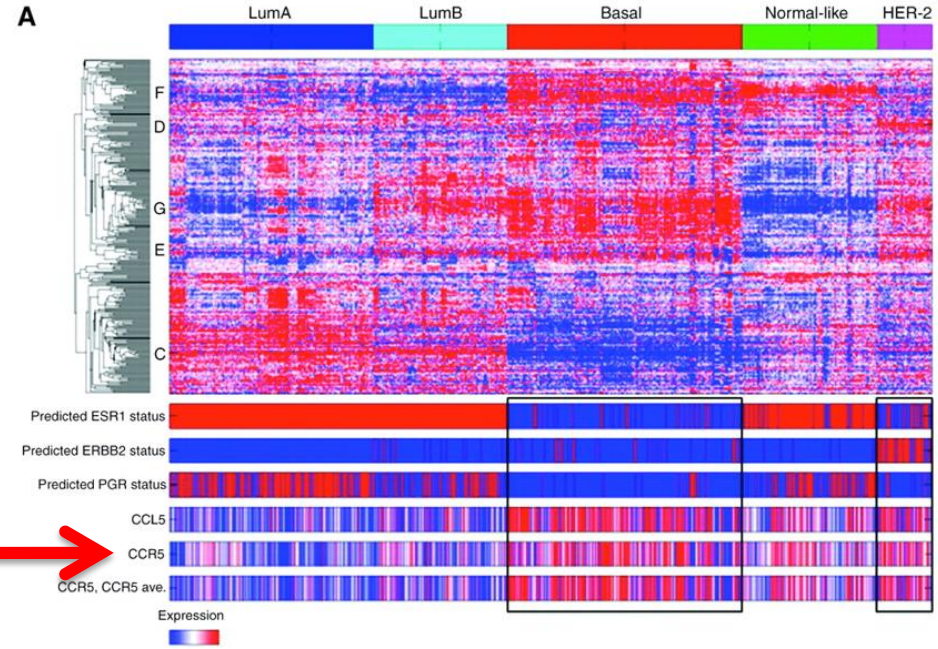
www.cytodyn.com

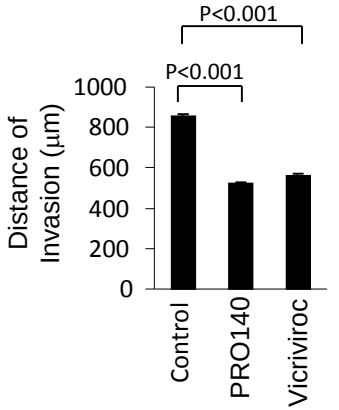
Expansion into Cancer Indications

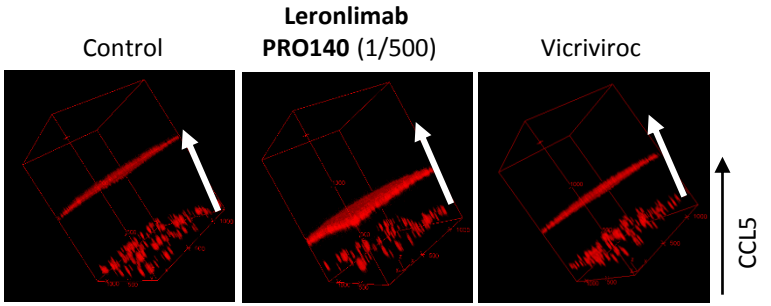
- Named world-renowned oncologist Dr. Richard Pestell as Chief Medical Officer and Vice Chairman (https://www.youtube.com/watch?v=98J1HgCm8wU)
  - Leads leronlimab (PRO 140) non-HIV development programs
  - Led 2 National Cancer Institute-designated cancer centers
    - Lombardi Comprehensive Cancer 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

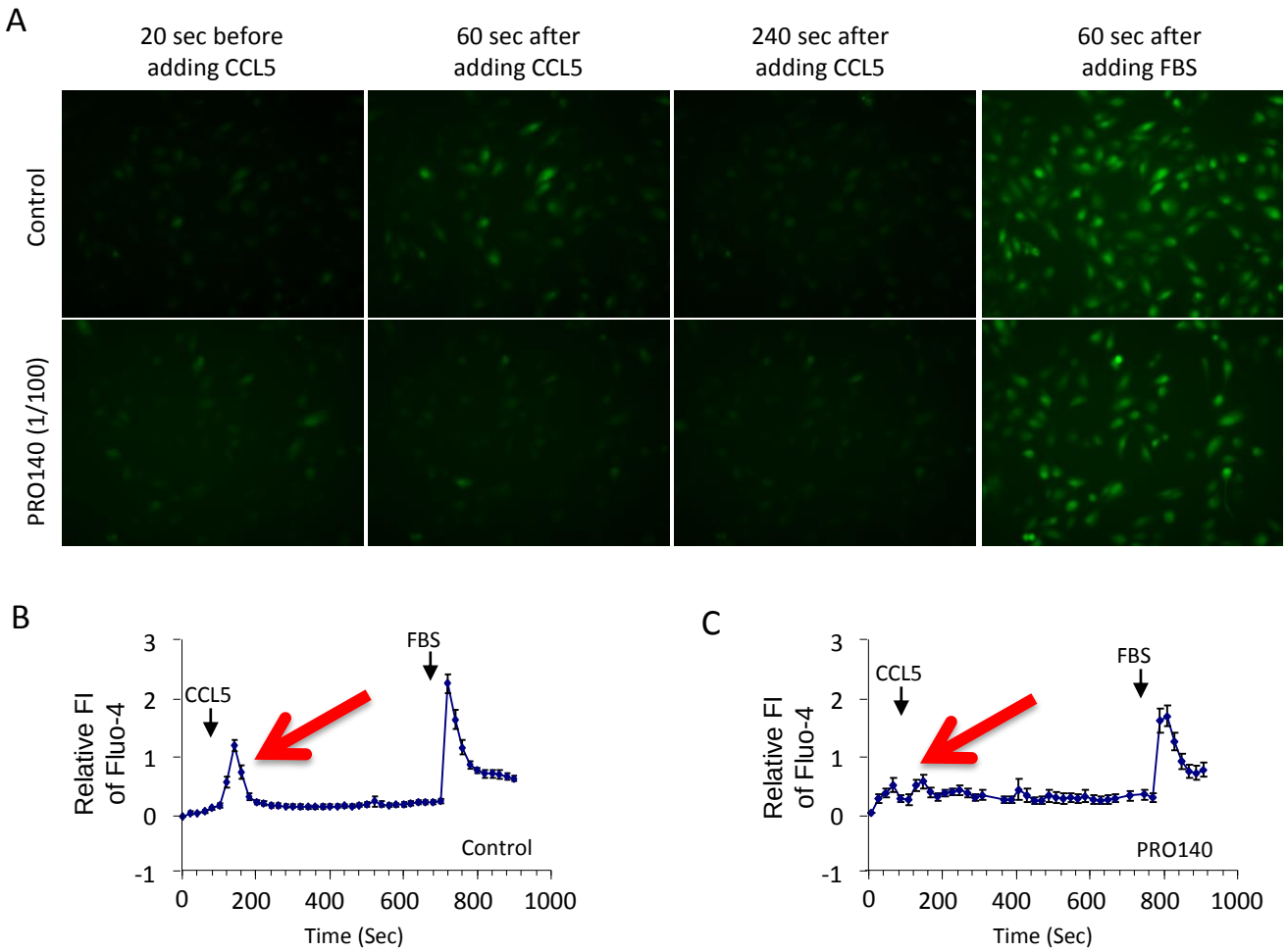






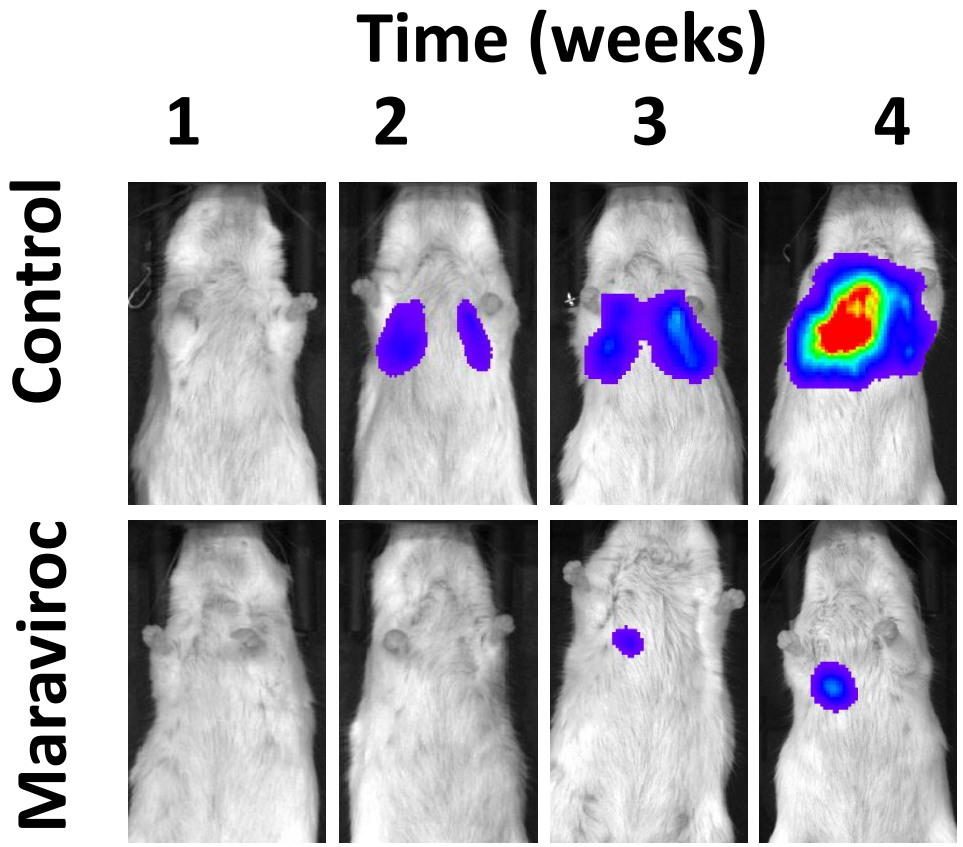
Professor Richard Pestell, PhD, MD

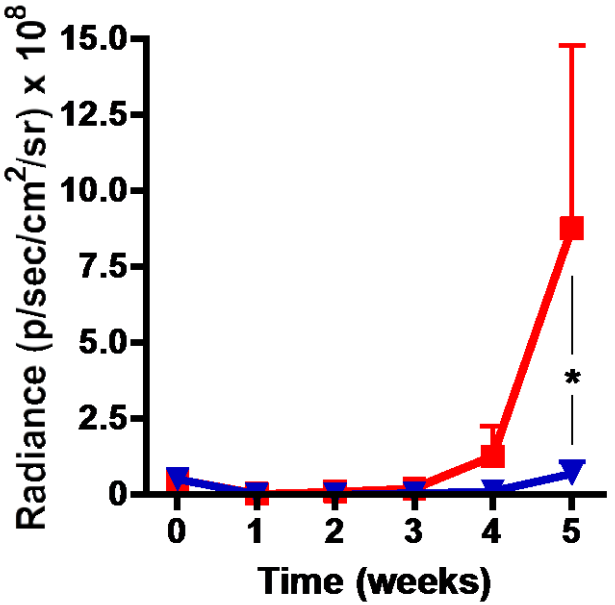
Leronlimab (PRO 140) Blocks Breast Cancer Ca^{+2} signaling



Professor Richard Pestell, PhD, MD

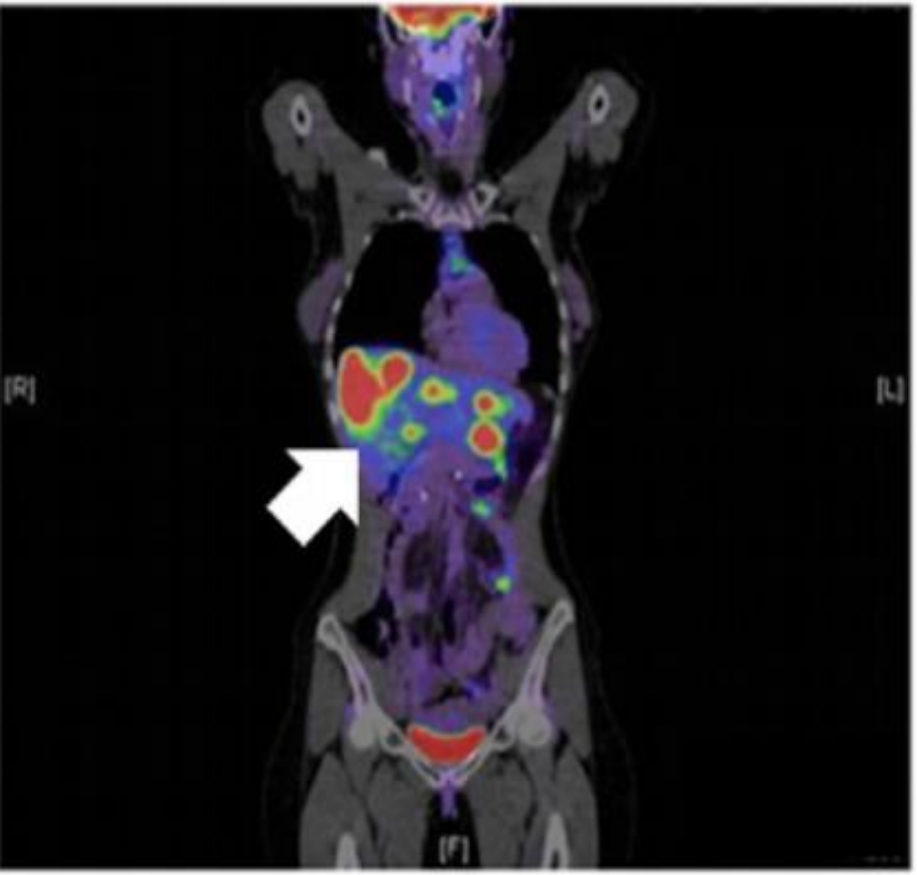
CCR5 Antagonists Block Breast Cancer Metastasis



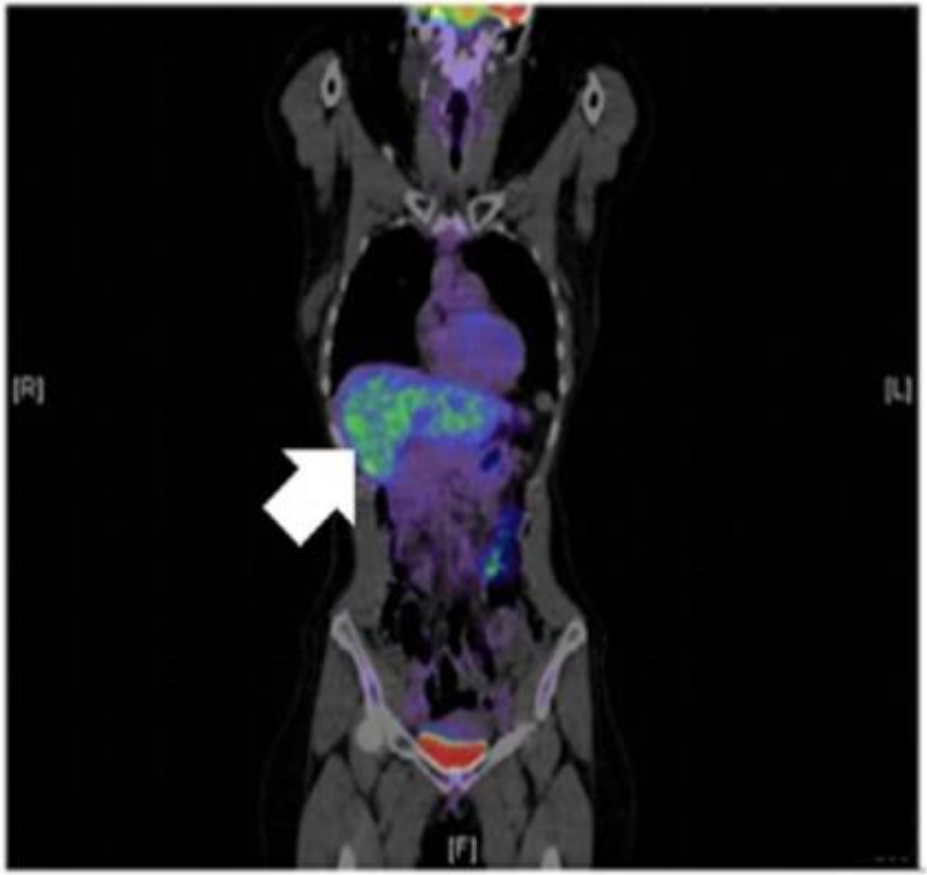


Professor Richard Pestell, PhD, MD

Objective Tumor Response, Phase 1 Trial

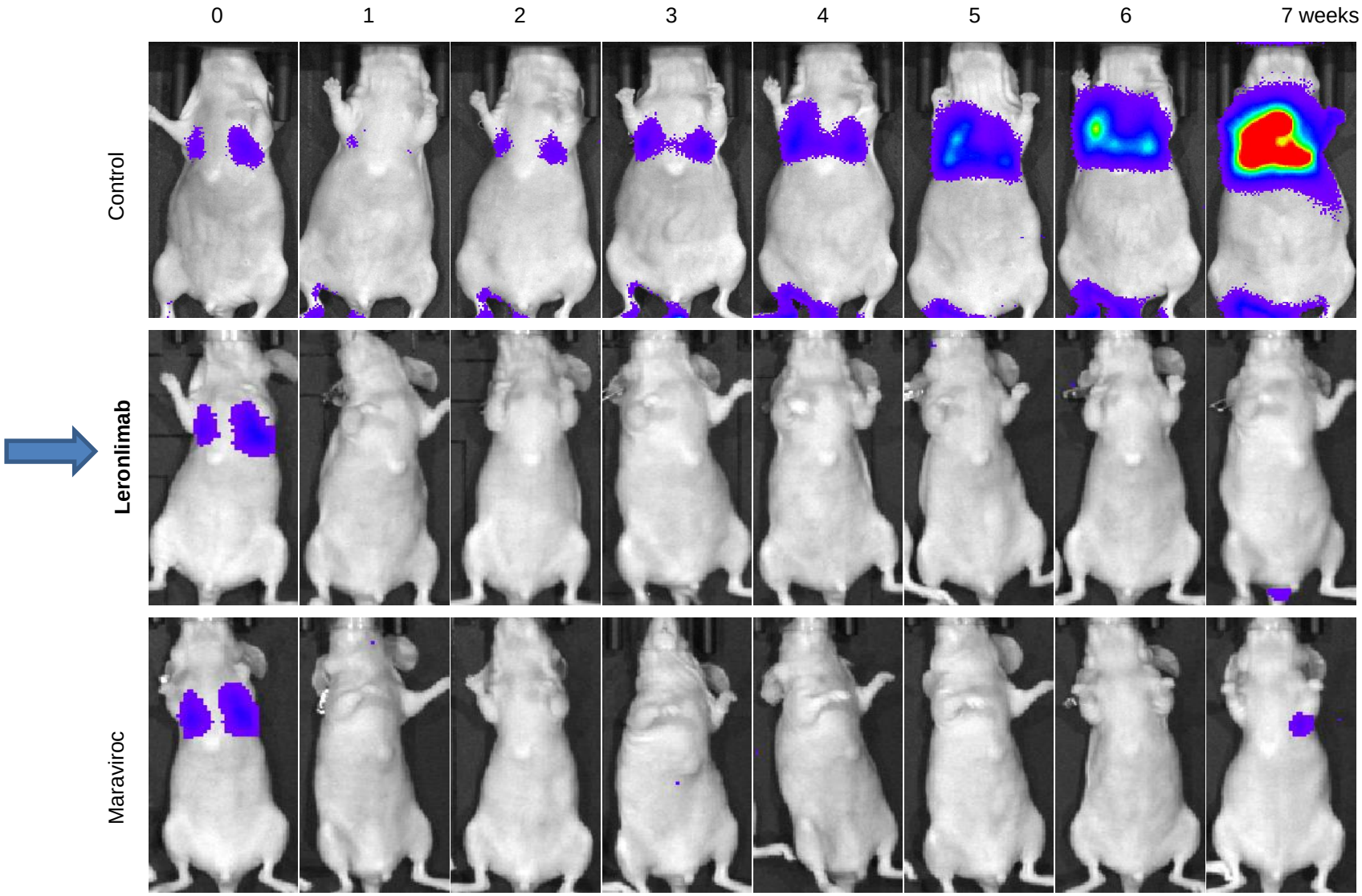


before CHT+CCR5 inh.

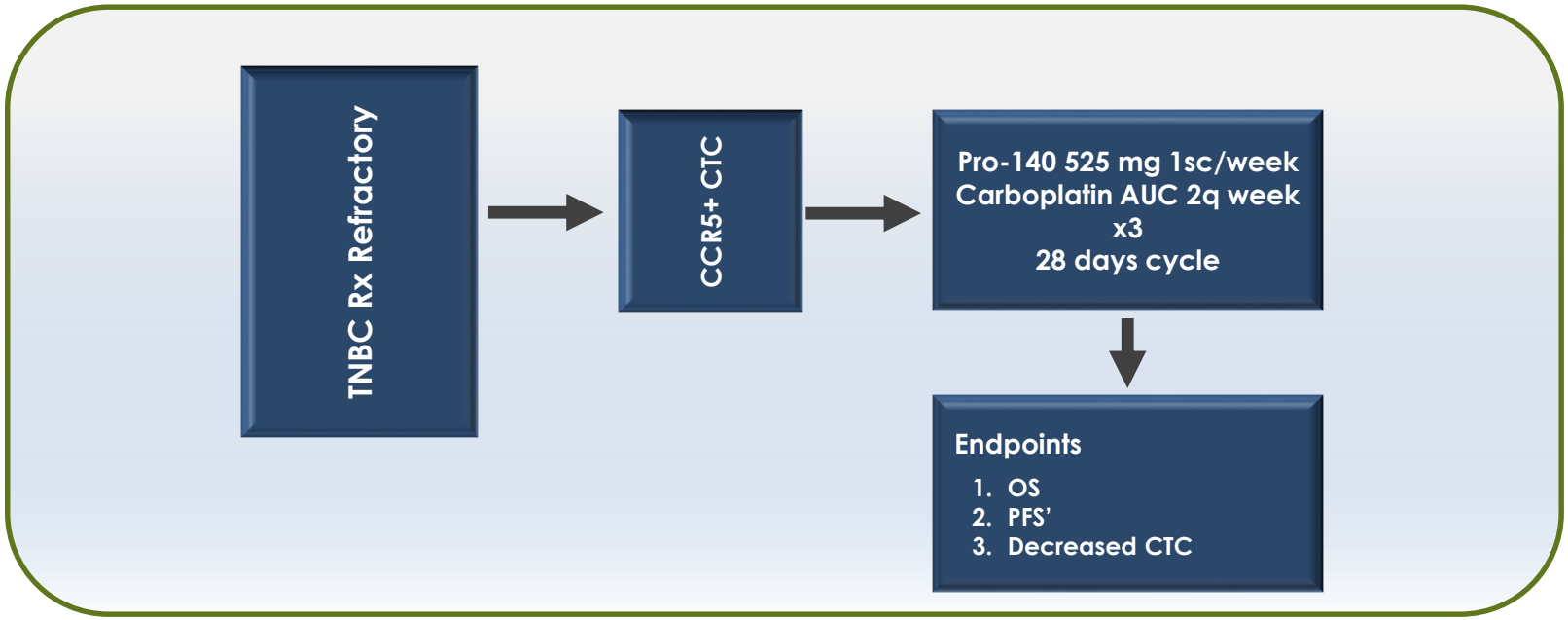


after CHT+CCR5 inh.

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)

PRO 140 Important Milestones for HIV and Cancer 2019

Milestones	Target Dates
BLA submission – HIV combination therapy – unmet medical need	2H2019
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	2019
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)

HIV - Cancer

NASH - GvHD

LD Micro Invitational Conference (June-2019)

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