Leronlimab (PRO 140)

HIV - Cancer

Investor Presentation
December 2018

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Forward-Looking Statements

This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding leronlimab's efficacy in certain cancer indications, the predictive value or benefit from the Company's prostate cancer prognostic test, the Company's clinical focus, and the Company's current and proposed trials. 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 differ materially from those contained in or expressed by such statements. In evaluating all such statements, the Company urges investors to specifically consider the various risk factors identified in the Company's Form 10-K for the fiscal year ended May 31, 2018 in the section titled "Risk Factors" in Part I, Item 1A, and in our Form 10-Q for the quarterly period ended August 31, 2018 in the section titled "Risk Factors" in Part II, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company's forward-looking statements.

The Company's forward-looking statements reflect its current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Investors should not place undue reliance on the Company's forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company's cash position and the Company's ongoing ability to raise additional capital to fund its operations, (ii) the Company's ability to complete its Phase 2b/3 pivotal combination therapy trial for leronlimab (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) the Company's ability to obtain FDA approval of PCaTest for use with prostate cancer patients; (iv)the Company's ability to meet its debt obligations, if any, (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) design, implementation and conduct of 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 for infection with HIV 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. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by the Company's forward-looking statements.

The Company intends that all forward-looking statements made in this presentation will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, the Company does not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this presentation. Additionally, the Company does not undertake any responsibility to update investors upon the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

Recent Developments

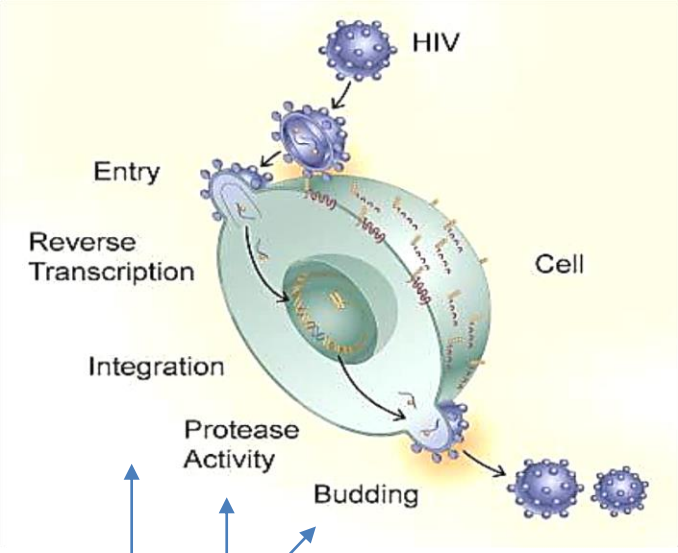
- **CD02 Phase 3, Pivotal trial** - Combination Therapy
  - Achieved primary endpoint (***p*=0.0032**) – **81%** response rate – BLA in 1Q2019
- **CD03 Phase 3** HIV investigative trial - **360+** enrolled (**60** patients **one year**)
  - About **70%** response rate at 525 mg - About **90%** response rate at 700 mg
- **Phase 1b/2 in Triple Negative Breast Cancer**
  - IND and Protocol has been accepted by the FDA and trial initiated
  - Encouraging preclinical data
- **Prognostic Test for Prostate Cancer**
  - More accurate than current standard of care
- **Phase 2 Graph-versus-Host Disease (GvHD)**
  - Reduced Intensity Conditioning patients – Received **Orphan Drug Designation** from FDA

Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

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

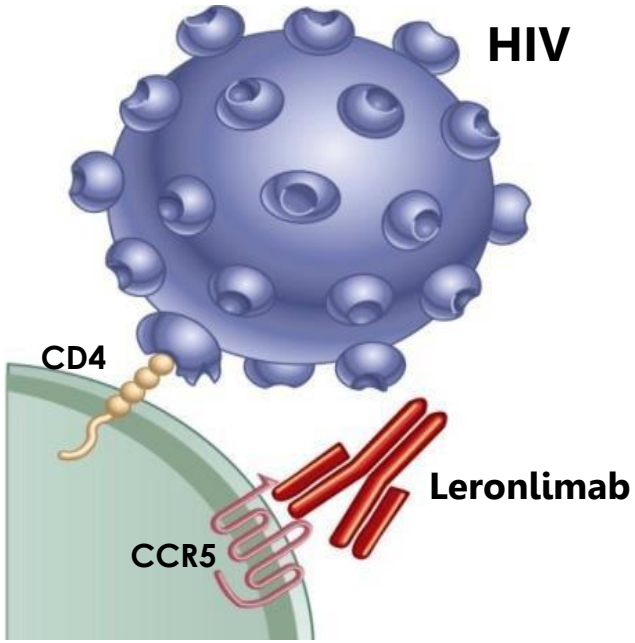
Humanized monoclonal antibody

Binds to CCR5 co-receptor on white blood cells



HAART

Blocks HIV entry into white blood cells



T-Cell

Leronlimab (PRO 140) Advantages over HAART

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

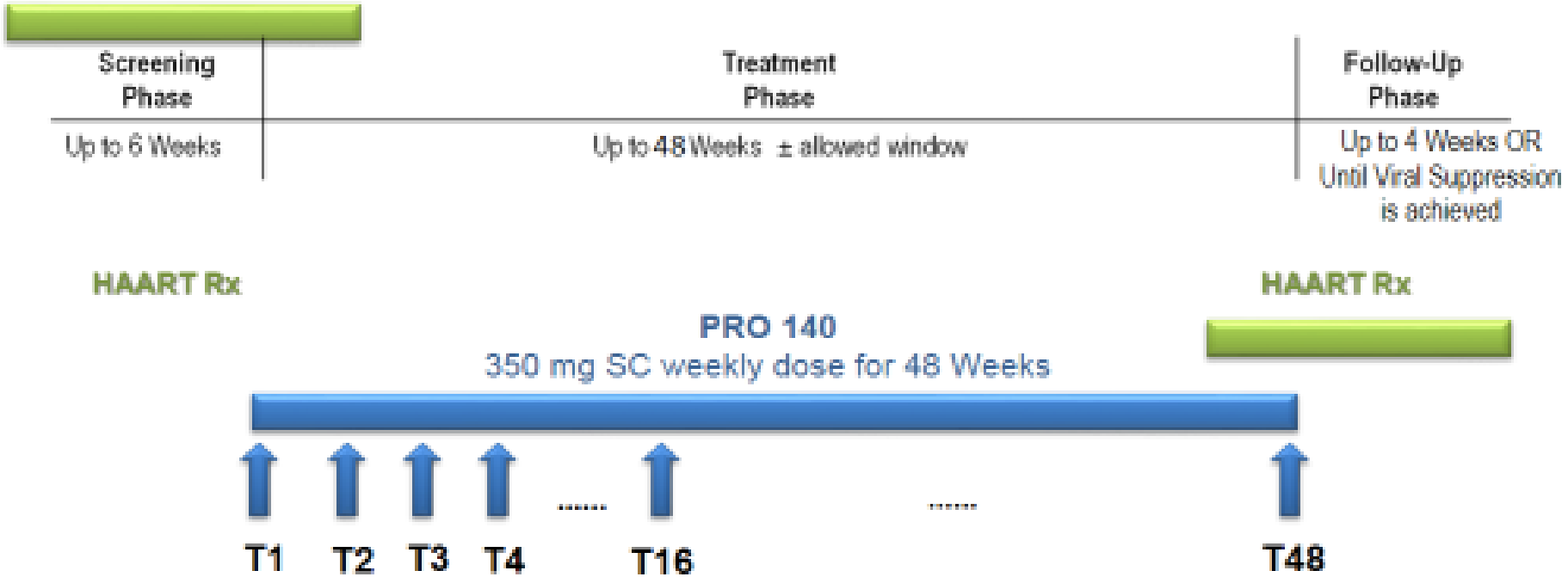
- **52 patients** prescreened for R5 strain and failing current HAART regimen (3 class resistance or 2 class resistance with limited treatment options)
- **Primary efficacy endpoint**: reduction in viral load after 1 week following single PRO 140 dose
  - All patients continue current HAART; 50% receive PRO 140 / 50% receive placebo
  - PRO 140 patients achieved statistically significant reduction - ***p* =0.0032**
- **24-week open-label** with all patients on weekly PRO 140 with optimized HAART
  - **81%** of patients completing trial achieved HIV viral load suppression of <50 cp/mL Recent approved drugs for this population range from **43%** after 24 weeks to **45%** after 48 weeks with vial load suppression of < 50 cp/mL
- **No reported SAEs** related to PRO 140 – (**670 patients** with zero drug related SAE)
- **40 patients** requested to continue PRO 140 in extension study
- **Regulatory path** – expected first FDA approval for PRO 140 in combination therapy
  - Submission of rolling BLA with full BLA submission expected in 1Q2019
  - Safety data from 150 eligible patients from all CytoDyn HIV trials

Potential Approval for leronlimab (PRO 140) in HIV in 2019

- **Timeline for submitting rolling BLA**
  - Non-Clinical - 4Q18
  - Clinical - 1Q19
  - CMC (Manufacturing) - 1Q19

- **Final Complete package: 1Q19**

Leronlimab (PRO 140) – HIV Indication Phase 3 Monotherapy



CD03 leronlimab (PRO 140) Investigative Monotherapy Trial

- All patients prescreened for R5 strain with viral load suppression maintained with HAART
- **Ongoing open-label, 48-week trial** with all patients receiving PRO 140 weekly injections
- Investigative trial with focus on **increasing responder rate** and no harm to non-responders

- **Increasing response rate**
  - With **350 mg** - Responder rate of **~ 40%**
  - With **525 mg** - Responder rate of **~ 70%** so far (4 to 12 months)
  - With **700 mg** - Responder rate of **~ 90%** so far (1 to ~4 months)

- **No reported SAEs** related to leronlimab in any trial to date (over 670 patients)
- **Regulatory path**
  - Conduct pivotal Phase 3 monotherapy trial
  - Submit leronlimab (PRO 140) for approval for label expansion as monotherapy, subject to approval as combination therapy

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 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**

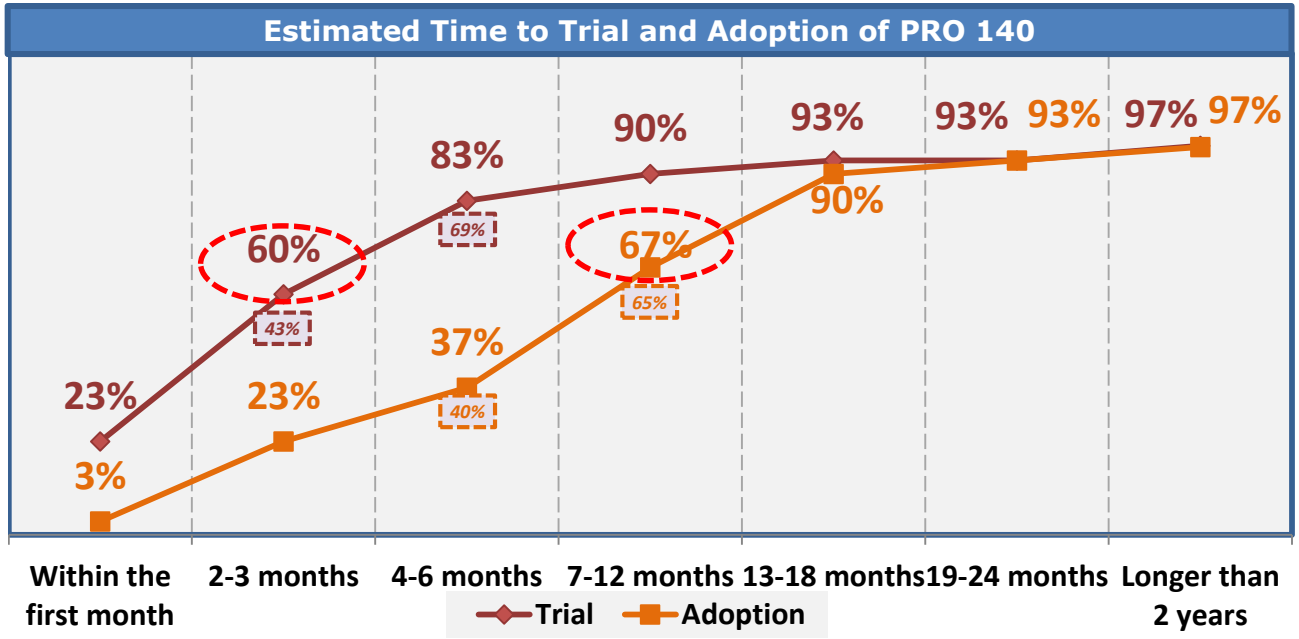
* Market size – BioVid Market Research: 2 class resistance ~ 5% to 20% ~ **70,000 to 280,000** patients

** Market size – BioVid Market Research: Monotherapy ~ 60% to 100% suppressed viral load among ~ **480,000 to 770,000**

HIV-U.S. Market Size - Research Report From BIOVID

Executive Summary

Most MDs will trial PRO 140 monotherapy within 3 months of launch, while 2 of 3 will adopt its use within the 1st year



Base size: Total Physicians (n=30)

Benchmark data based on BioVid's proprietary Demand database (full database)

U.S. Market Size - Research Report From BIOVID

Executive Summary

However, patients show a strong leronlimab (PRO 140) call to action

Patient Reactions to PRO 140 *(pre-video review)*	Monotherapy Patients	Combo Therapy Patients
PRO 140 is a **significant improvement** vs. current options	55%	55%
Highly likely to start a conversation with my doctor	70%	60%
Highly likely to try to find more information about PRO 140	65%	60%
Would schedule an appointment **within 3 months** to discuss PRO 140	70%	65%
Effort needed to make PRO 140 part of daily routine		
Very little/Moderate effort	**85%**	**95%**
A lot of effort	10%	5%
Way too much effort to take on	5%	0%
Level of concern about taking PRO 140 as instructed	5% 15% 40% 40%	5% 10% 25% 60%
Level of concern about taking PRO 140 long-term	5% 15% 35% 45%	5% 35% 35% 25%

- Monotherapy patients are slightly more likely to act upon their interest in PRO 140 by talking to their MD and/or searching for more product details on their own
- Both patient types see PRO 140 as requiring minimal effort to implement in their daily routine, and the majority do not have significant concerns with self-injecting PRO 140 once/weekly long-term

Very concerned
Somewhat concerned
A little bit concerned
Not concerned

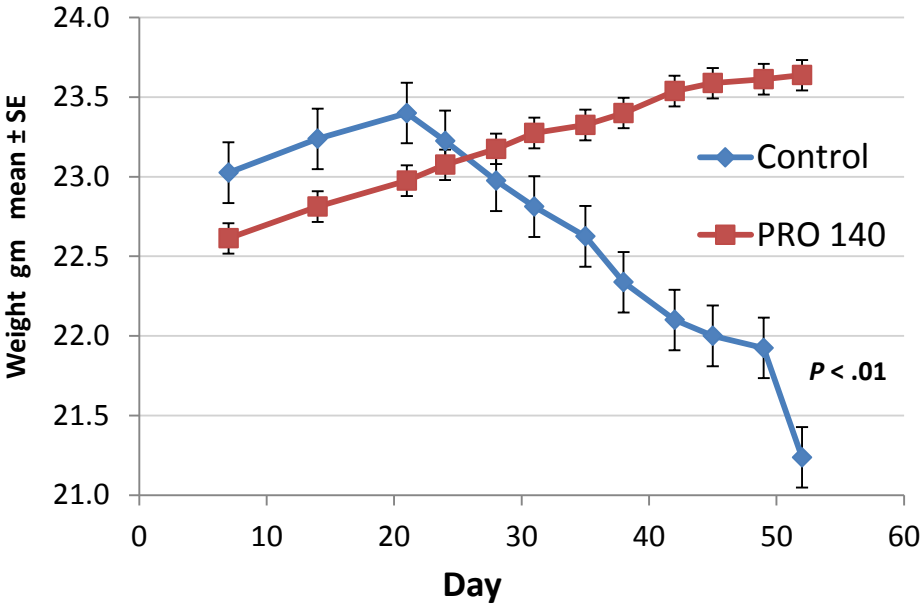
Base Size: Total Patients; Monotherapy Candidates (n=20); Combination Therapy Candidates (n=20)

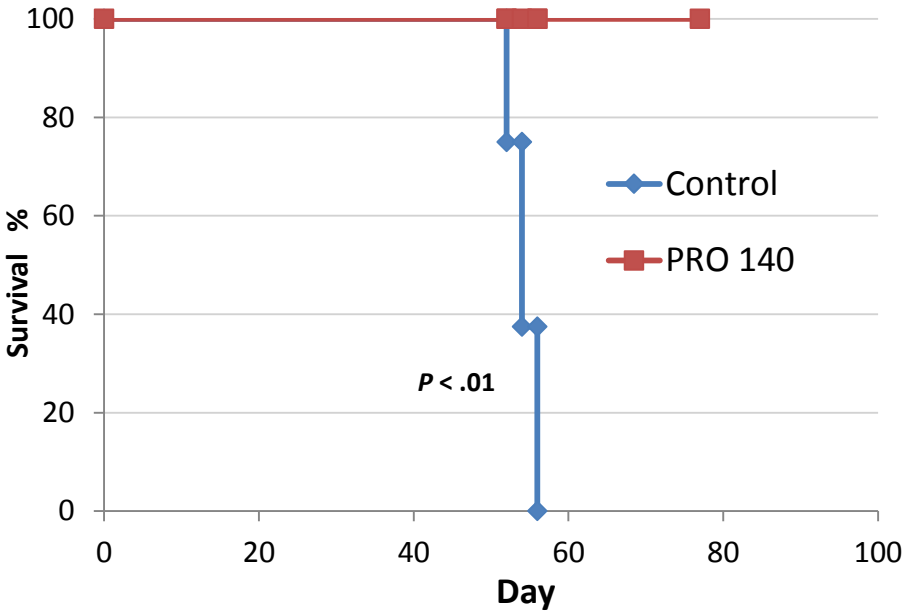
Leronlimab (PRO 140) Immunologic Indications

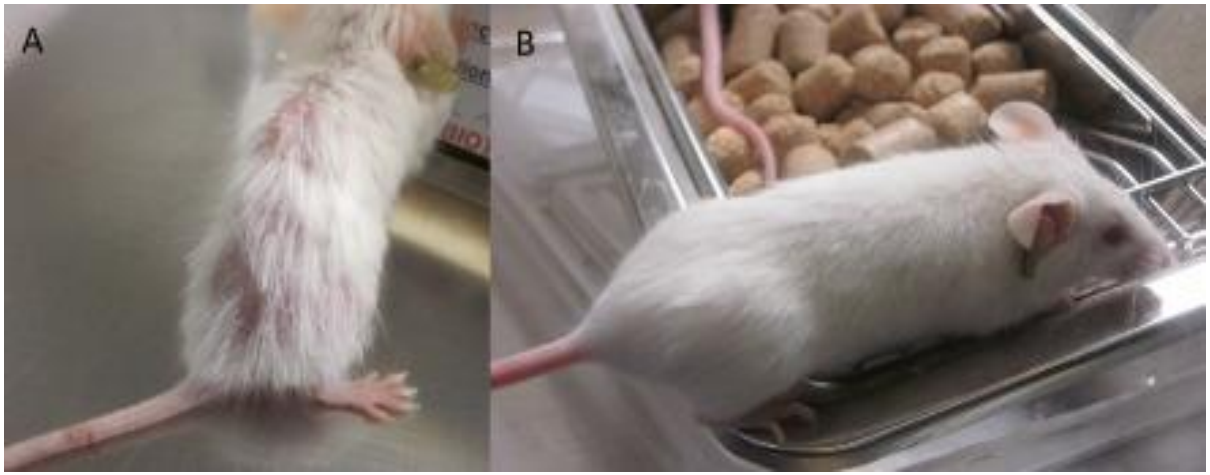
Additional potential PRO 140 applications

- **GvHD**
- **Cancer including tumor metastasis (Dr. Richard Pestell)**

Effect of leronlimab (PRO 140) on Xeno-GvHD
Human BM Transplanted Into Immuno-Deficient Mice







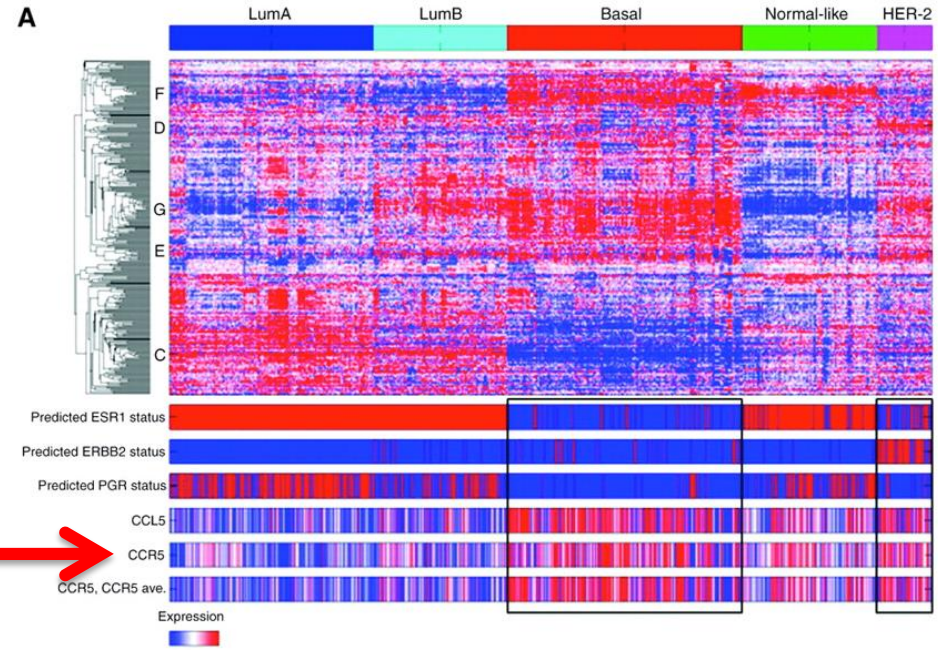
Expansion into Cancer Indications

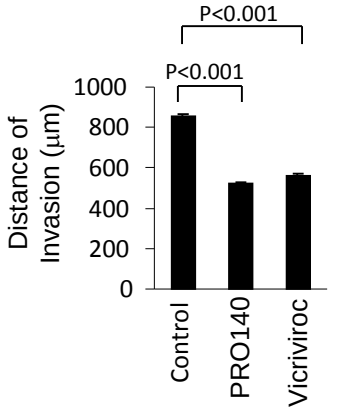
- Named world-renowned oncologist Dr. Richard Pestell to be Chief Medical Officer
  - Lead leronlimab (PRO 140) non-HIV development programs
  - Led 2 National Cancer Institute-designated cancer centers
    - Lombardi Comprehensive Cancer Center at Georgetown University
    - Sidney Kimmel Cancer Center at Thomas Jefferson University
- 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

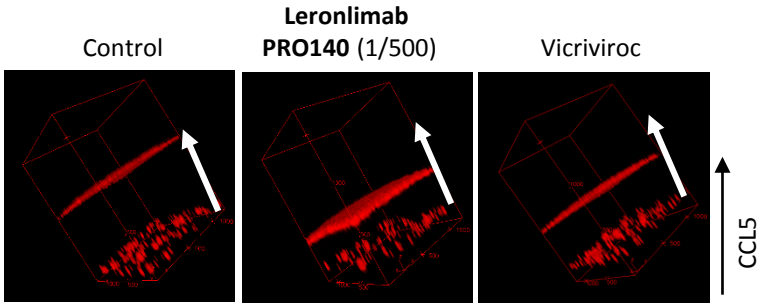
CCR5 is Expressed in >50% of Breast Cancer

– **Metastatic cancer**.

- 50% of breast cancers CCR5+
- Leronlimab(PRO 140) reduces breast cancer invasion

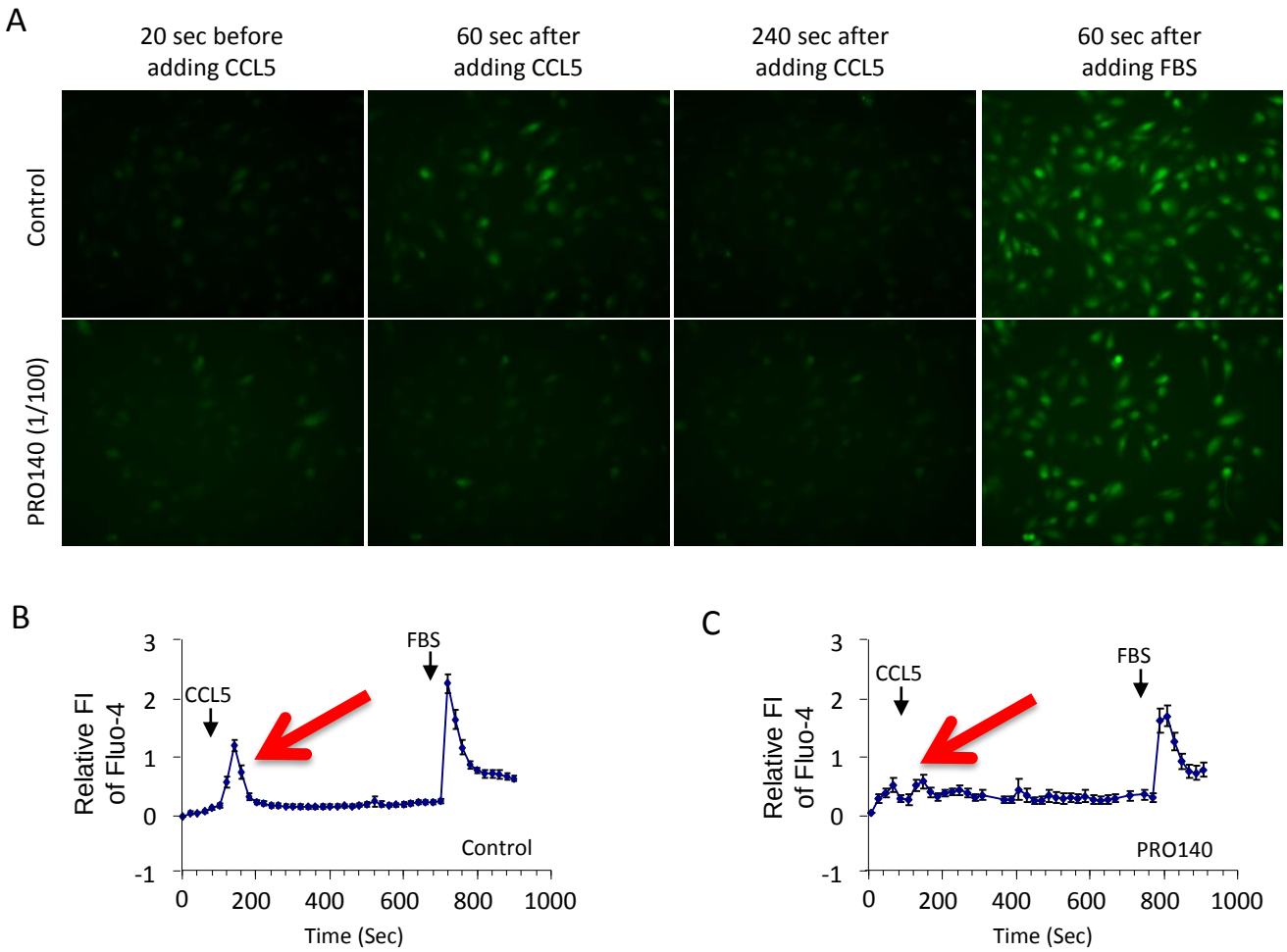






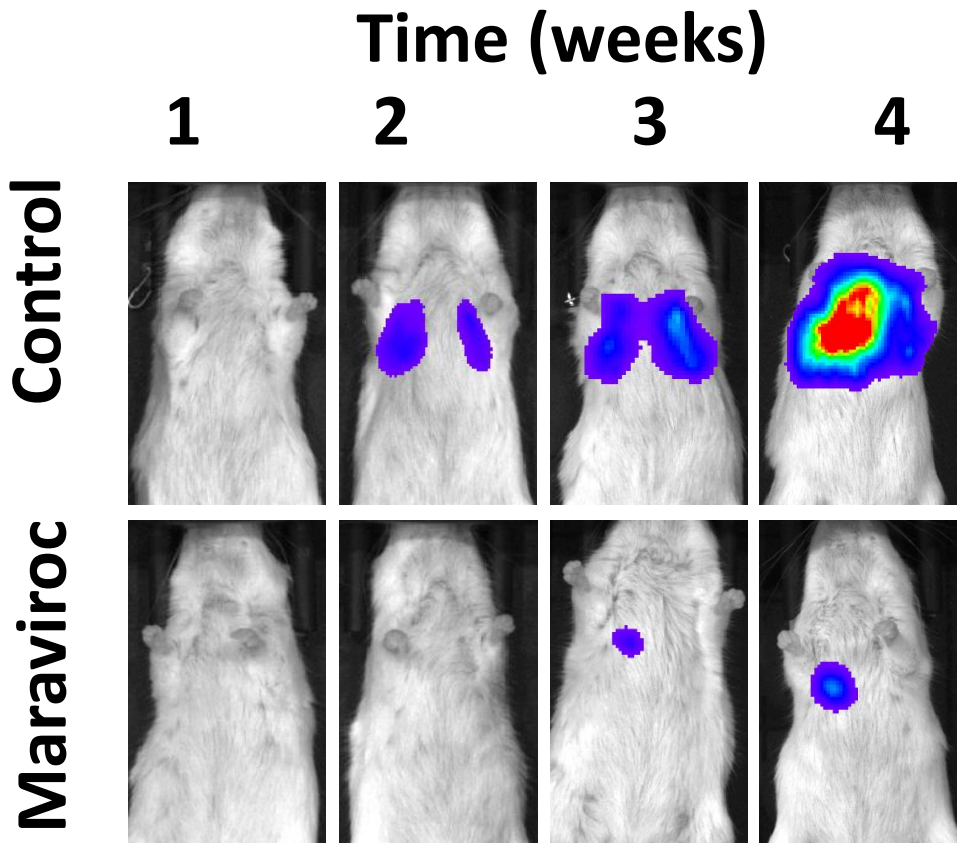
Professor Richard Pestell, PhD, MD

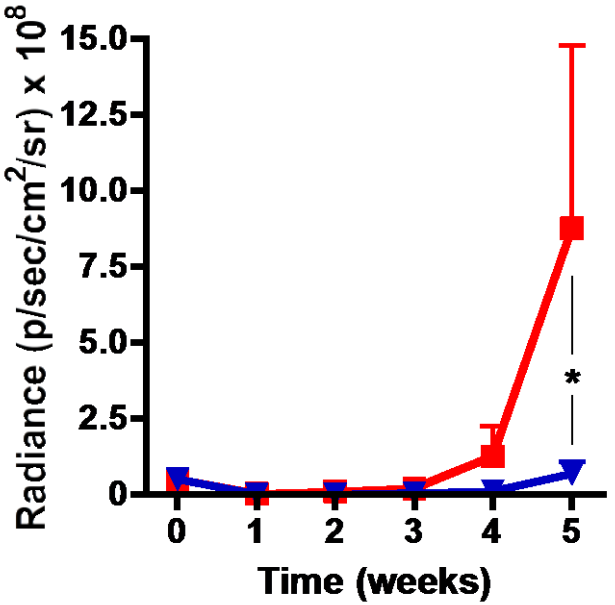
Leronlimab (PRO 140) Blocks Breast Cancer Ca^{+2} signaling



Professor Richard Pestell, PhD, MD

CCR5 Antagonists Block Breast Cancer Metastasis



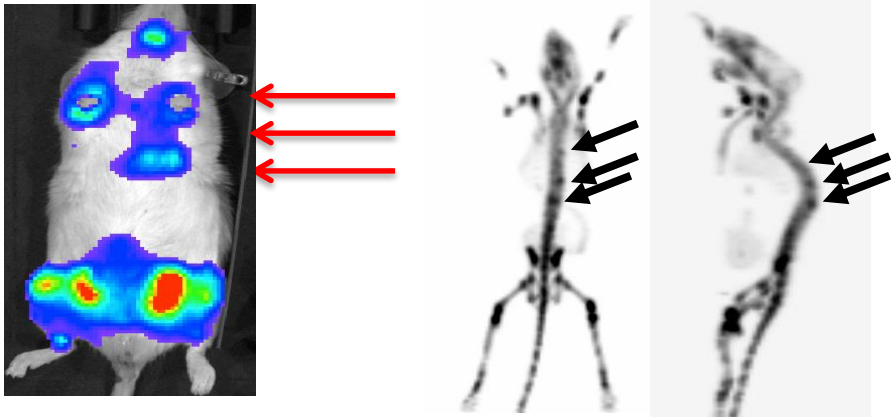


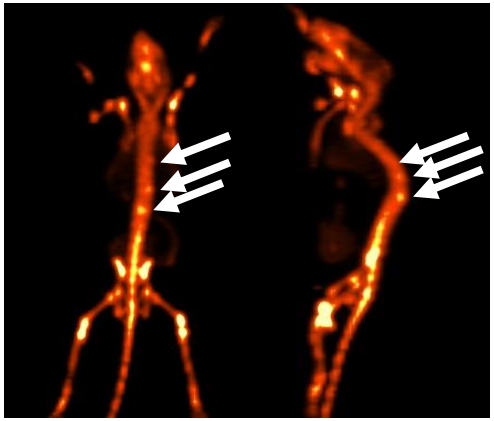
Professor Richard Pestell, PhD, MD

CCR5 Antagonists Block Prostate Cancer Metastasis

CytoDyn®

Control





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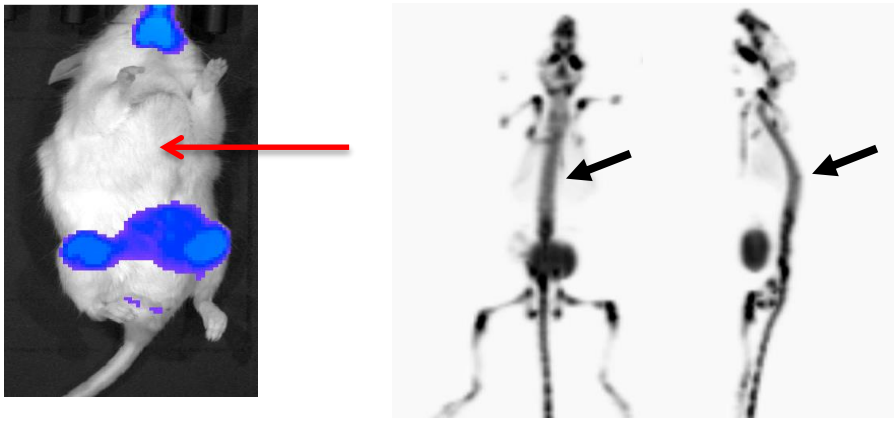
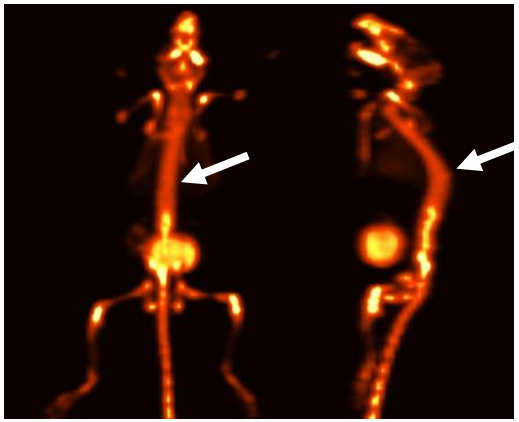
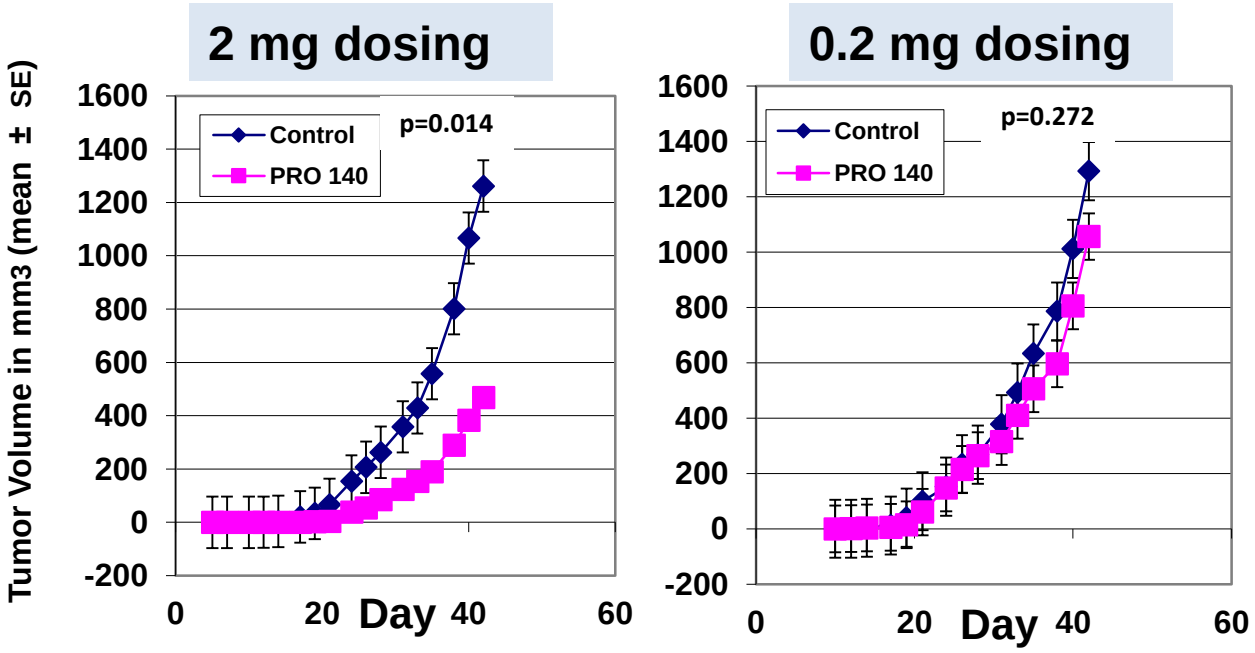




Leronlimab (PRO 140) Blocks Colon Cancer Growth in Mice

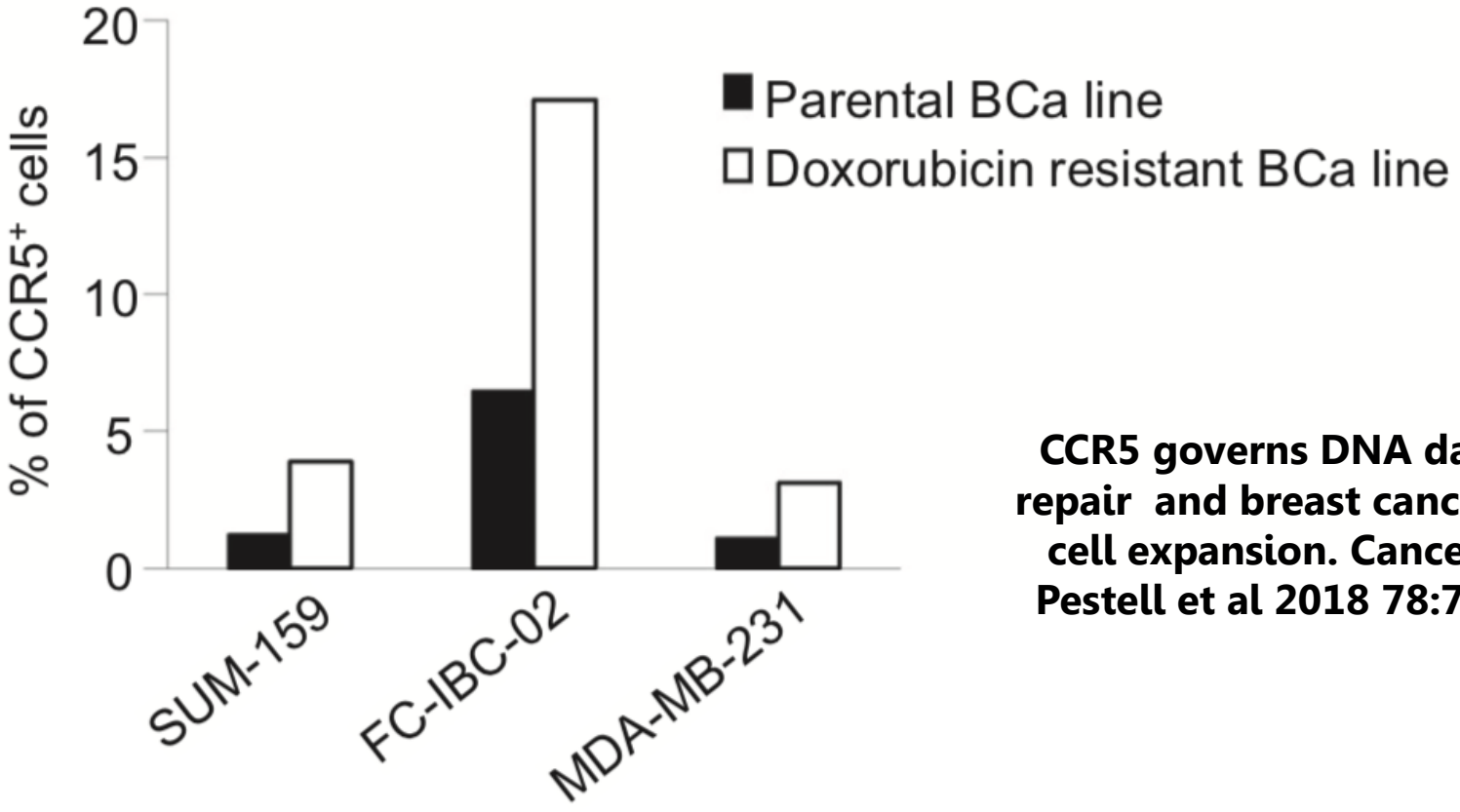
SW480 Human Colon Carcinoma Xenografts in NCr Nude Mice

PRO 140, 2 mg i.p. twice/week, started day 1, n=16 tumors/group



Daniel Lindner, M.D., Ph.D. – Cleveland Clinic

Chemotherapy Increases CCR5 Expression in Cancer Cells

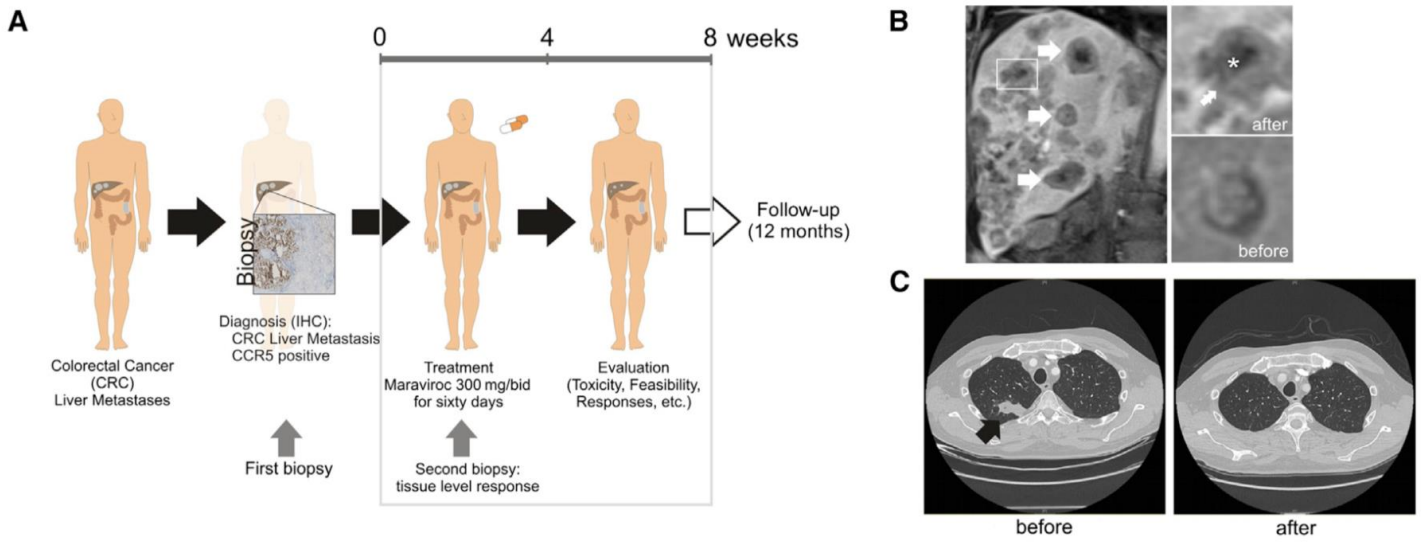


CCR5 governs DNA damage repair and breast cancer stem cell expansion. Cancer Res. Pestell et al 2018 78:7, 1657

Daniel Lindner, M.D., Ph.D. – Cleveland Clinic

Objective Tumor Response, Phase 1 Trial

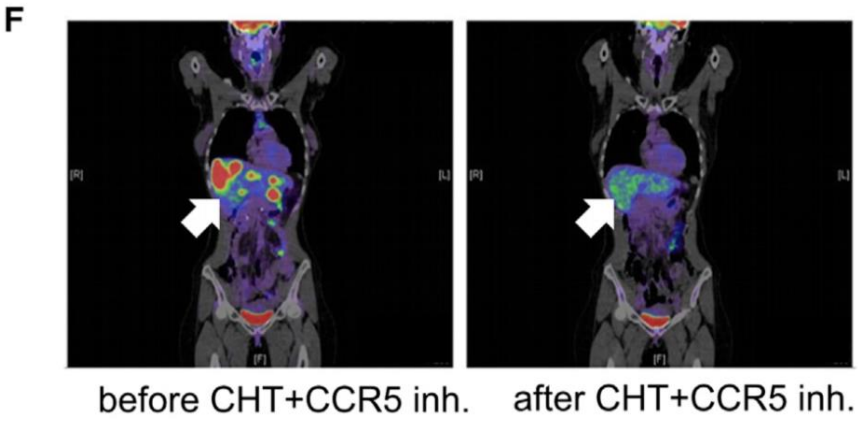
advanced-stage metastatic colorectal cancer who are refractory to standard chemotherapy, including regorafenib

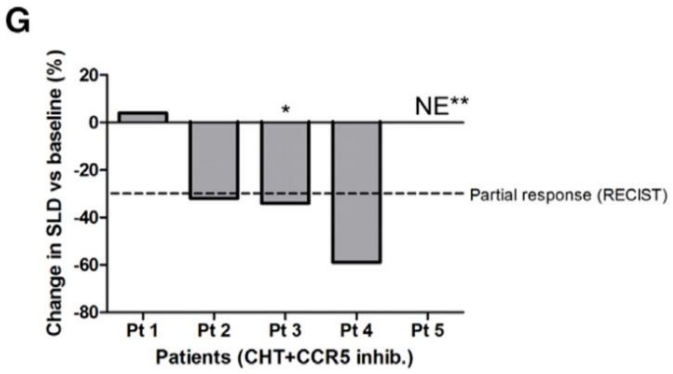


Tumoral Immune Cell Exploitation in Colorectal Cancer Metastases Can Be Targeted Effectively by Anti-CCR5 Therapy in Cancer Patients **Cancer Cell. 2016 587-601**

Objective Tumor Response, Phase 1 Trial

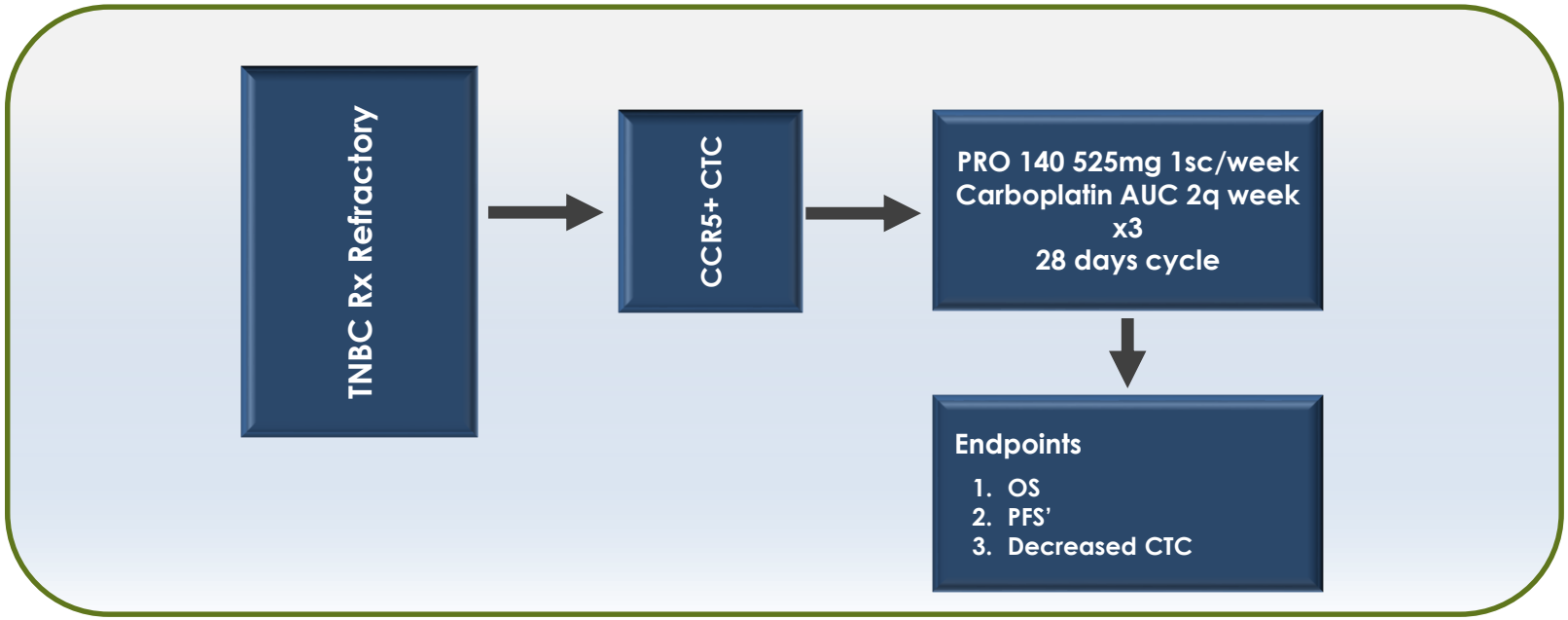
advanced-stage metastatic colorectal cancer who are refractory to standard chemotherapy, including regorafenib





Tumoral Immune Cell Exploitation in Colorectal Cancer Metastases Can Be Targeted Effectively by Anti-CCR5 Therapy in Cancer Patients **Cancer Cell. 2016 587-601**

Leronlimab (PRO 140) Breast Cancer Study



November 2018-March 2019
Phase II

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

Patents

Issued

1. **US Patent issued September 27, 201**6 as U.S. Patent No. 9,453,836. "Use of modulators of CCR5 in the treatment of cancer and cancer metastasis" US Provisional Patent Application Nos. 61/646,593 and 61/646,586 (Reference Nos. 010236-5002-PR & 010236-5002-PR1)

2. Australian issued Patent No. 2012225232, Title: Prostate Cancer Cell Lines, Gene Signatures And Uses Thereof. Ref. 140993.00105 AU. issued August 25, 2016 "Prostate Cancer Cell Lines, Gene Signatures And Uses Thereof: 61/450,767 Patent Methods and Compositions For The Diagnosis, Prognosis And Treatment Of Cancer Related Applications. 03/09/2011 and 09/03/2012, PCT/US2012/028546, agents file ref. 10236-5001WO issued patent.

Pending

1. CCR5 and cancer stem cells, 4/13/15, WO 2016/209926.

2. Circulating tumor cells and therapy, 2/12/15, US 15/738,020

Publications

CCR5 Governs DNA Damage Repair and Breast Cancer Stem Cell Expansion.
Jiao X, Velasco-Velázquez MA, Wang M, Li Z, Rui H, Peck AR, Korkola JE, Chen X, Xu S, DuHadaway JB, Guerrero-Rodriguez S, Addya S, Sicoli D, Mu Z, Zhang G, Stucky A, Zhang X, Cristofanilli M, Fatatis A, Gray JW, Zhong JF, Prendergast GC, **Pestell RG**.
Cancer Res. 2018 Apr 1;78(7):1657-1671. doi: 10.1158/0008-5472.CAN-17-0915. Epub 2018Jan 22.PMID: 29358169

CCR5 receptor antagonists block metastasis to bone of v-Src oncogene-transformed metastatic prostate cancer cell lines.Sicoli D, Jiao X, Ju X, Velasco-Velazquez M, Ertel A, Addya S, Li Z, Andò S, Fatatis A, Paudyal B, Cristofanilli M, Thakur ML, Lisanti MP, **Pestell RG**.
Cancer Res. 2014 Dec 1;74(23):7103-14. doi: 10.1158/0008-5472.CAN-14-0612.PMID: 25452256
Select item 237343214.

CCR5 antagonist blocks metastasis of basal breast cancer cells.
Velasco-Velázquez M, Jiao X, De La Fuente M, Pestell TG, Ertel A, Lisanti MP, **Pestell RG**.
Cancer Res. 2012 Aug 1;72(15):3839-50. doi: 10.1158/0008-5472.CAN-11-3917. Epub 2012 May 25.PMID: 22637726

Expanded Role for leronlimab (PRO 140) in Cancer

- Preclinical studies show PRO 140's ability to selectively target CCR5 receptor
- Dr. Pestell's preclinical research shows CCR5 receptor is vital in cancer cell invasion and metastasis
- Preclinical findings show PRO 140 as effective in blocking breast cancer invasion as small molecule CCR5 inhibitors (see CytoDyn press release dated 6/26/18)
- Leronlimab (PRO 140) could have advantage of less frequent dosing and improved safety profile compared with other small molecule CCR5 antagonists
- Completed acquisition of ProstaGene in mid-November 2018
- Planned IND filing to initiate Phase 2 trial in colon cancer

PRO 140 Important Milestones for HIV 2018/2019

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