Leronlimab (PRO 140)

HIV

(Combination therapy-Monotherapy-PreP -& Cure)

mTNBC

GvHD

Colon Cancer

NASH

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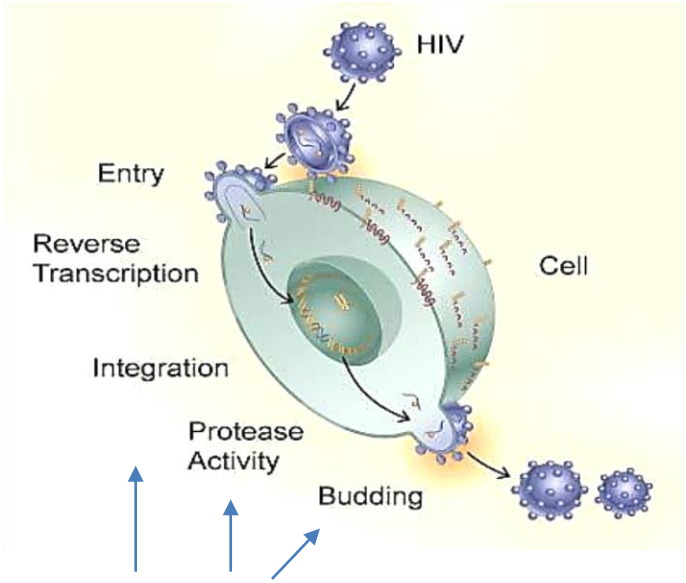
Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

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

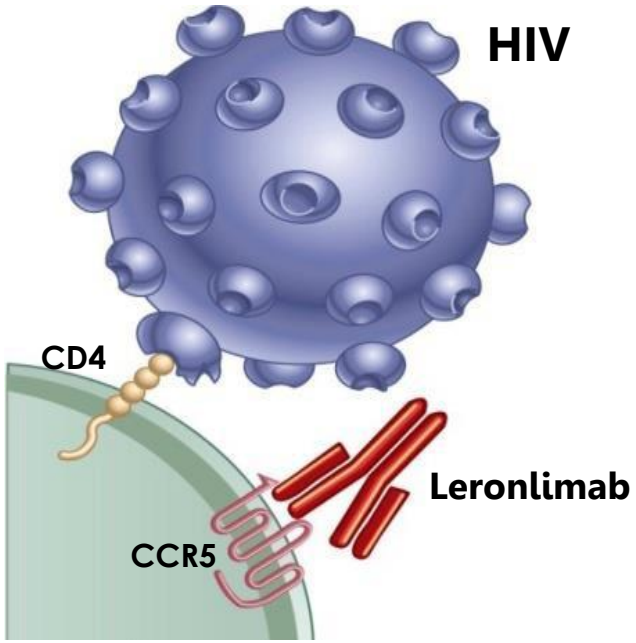
Humanized monoclonal antibody



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 >830 patients in 8 clinical trials	Side Effects	Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)
Negligible toxicity in 830 patients	Toxicity	Problems with short- and long-term toxicity
No drug resistance in patients on monotherapy for over 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

www.cytodyn.com
Stock: CYDY

CytoDyn Overview

HIV

PHASE 3 - Completed
World's first self-injectable for Unmet Medical Need Population

HIV

PHASE 3 - Monotherapy
150 patients reached about one year
A few at 5 years

GvHD

PHASE 2 – Initiated
Unmet Medical Need – ODD granted

mTNBC

PHASE 1b/2 – Initiated
Unmet Medical Need – FTD granted

Colon Cancer

PHASE 2
IND & Protocol has been filed w/FDA

NASH

PHASE 2
IND & Protocol to be filed w/FDA

Pre-clinical Studies

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

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	71%
525 mg	~31 weeks	95%
700 mg	~20 weeks	87%

- **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**

- **150 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**

	2020	2021
Number of Patients Treated, ART (N)	**788,374**	**815,875**
Single-Tablet Regimens (STRs)	**514,020**	**564,586**
NNRTI-based STRs	**152,945**	**150,121**
Atripla (efavirenz/emtricitabine/TDF)	51,244	18,765
generic efavirenz/emtricitabine/TDF	-	23,660
Complera (rilpivirine/emtricitabine/TDF)	14,979	13,054
Odefsey (rilpivirine/emtricitabine/TAF)	71,742	76,692
doravirine/lamivudine/TDF	14,979	17,949
INI-based STRs	**251,491**	**268,423**
Stribild (elvitegravir/cobicistat/emtricitabine/TDF)	18,133	17,133
Genvoya (elvitegravir/cobicistat/emtricitabine/TAF)	78,837	81,588
Triumeq (dolutegravir/abacavir/lamivudine)	35,477	34,267
dolutegravir/lamivudine	59,128	64,454
bictegravir/emtricitabine/TAF	59,916	70,981
PI-based STRs	**36,265**	**38,346**
Prezista STR (darunavir/cobicistat/emtricitabine/TAF)	36,265	38,346
NRTI-free STRs (Short- and Long-Acting)	**73,319**	**107,696**
dolutegravir/rilpivirine	45,726	61,191
cabotegravir/rilpivirine	27,593	46,505
Multiple-Pill Regimen Components	**274,354**	**251,290**
Fixed-Dose NRTI Backbones and NRTIs	**275,143**	**267,607**
Truvada (emtricitabine/TDF)	81,991	30,187
generic emtricitabine/TDF	-	51,400
Descovy (emtricitabine/TAF)	96,970	98,721
Epzicom (abacavir/lamivudine)	3,153	1,632
generic abacavir/lamivudine	22,863	17,133
Viread (TDF)	6,307	4,079
generic TDF	25,228	24,476
Other Fixed-Dose NRTI Backbones	3,153	3,264
Other NRTIs	35,477	36,714
NNRTIs	**25,228**	**22,029**
Sustiva (efavirenz)	788	816
generic efavirenz	2,365	2,448
Intelence (etravirine)	1,577	816
Edurant (rilpivirine)	1,577	816
MK-1439 (doravirine)	18,133	16,318
generic nevirapine	788	816
PIs	**137,965**	**128,500**
Prezista (darunavir)	3,942	2,448
generic darunavir	42,572	44,057
Prezcobix (darunavir/cobicistat)	18,133	16,318
Reyataz (atazanavir)	7,095	2,448
generic atazanavir	15,767	13,870
Evotaz (atazanavir/cobicistat)	13,402	12,238
Kaletra (lopinavir/ritonavir)	1,577	816
generic lopinavir/ritonavir	10,249	10,198
generic fosamprenavir	1,577	1,632
Other PIs	23,651	24,476
INIs	**111,161**	**100,353**
Tivicay (dolutegravir)	67,012	62,822
Isentress (raltegravir)	44,149	37,530
Number of Patients Treated, Add-on & Salvage Therapies (N)	**85,933**	**49,768**
Attachment, Entry, and Fusion Inhibitors	**18,921**	**17,949**
Fuzeon (enfurvitide) – Selzentry – Fostemsavir-Ibalizumab	-	-
Pharmacokinetic Enhancers (Boosters)	**67,012**	**31,819**

SCENARIO A

Add PRO 140 to any STR

Most Likely:

1) ~100% suppression rate
2) Very few switches
3) Adherence increases dramatically
4) Resistance almost zero
5) Side effect + toxicity added by PRO 140 is almost zero

SCENARIO B

Add PRO 140 to any 2 pill-combination or to any 1 pill

New HAART with 2 pill combination acting as STR like the above
Example: **Truvada + PRO 140**

or

2 combination that acts as HAART.
Example: **Dolutegravir + PRO 140**

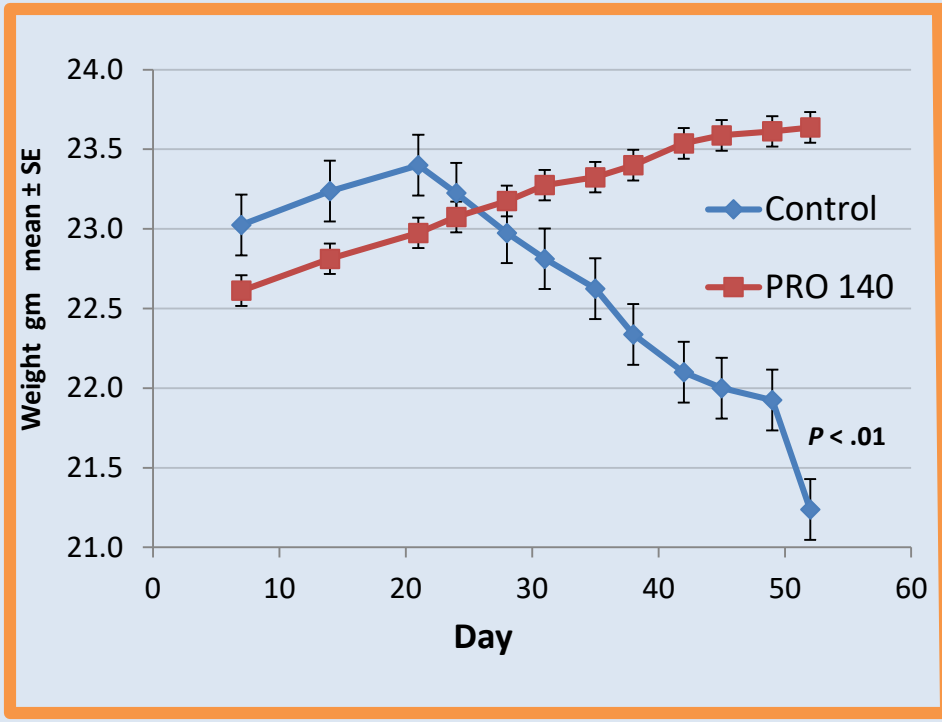
POSSIBLY: ~100% SUPPRESSION RATE

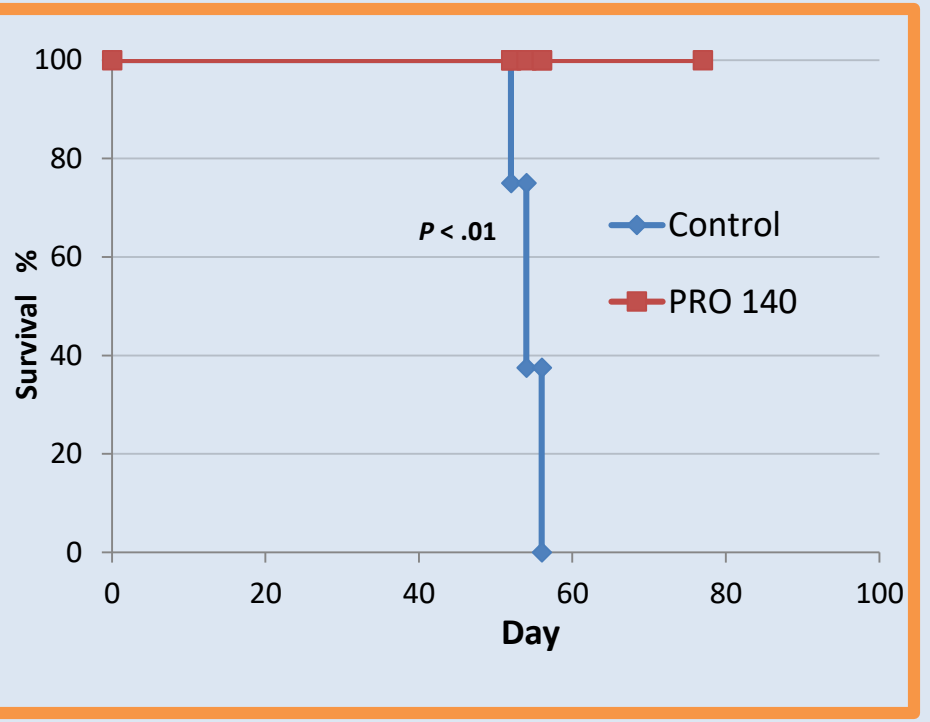
SCENARIO C

PRO 140 use as “add-on” to any combination

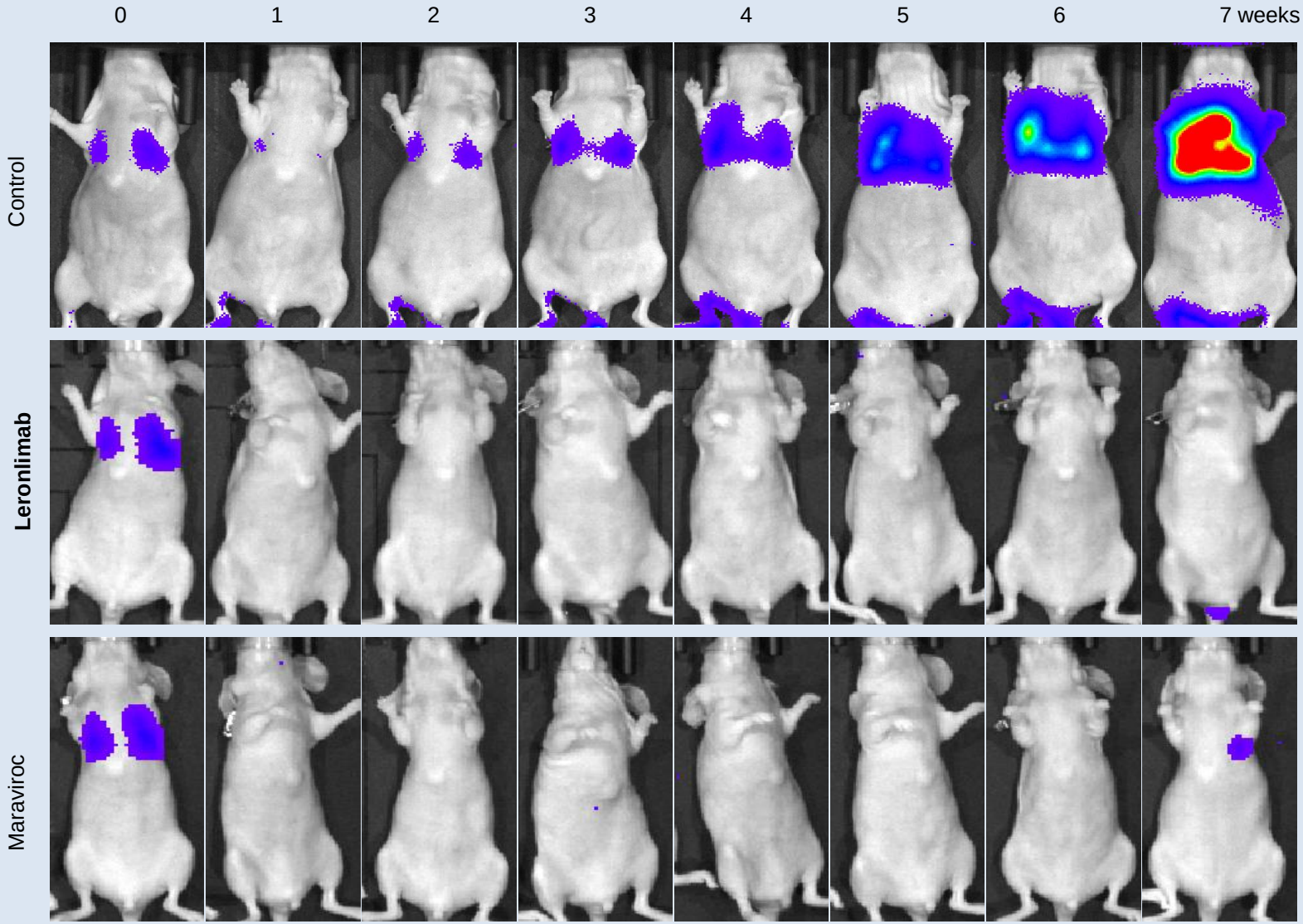
$1 billion worth of leronlimab (if evaluated @ $120,000/year/patient) first part with deferred payment plan
~$10 billion before 2027

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

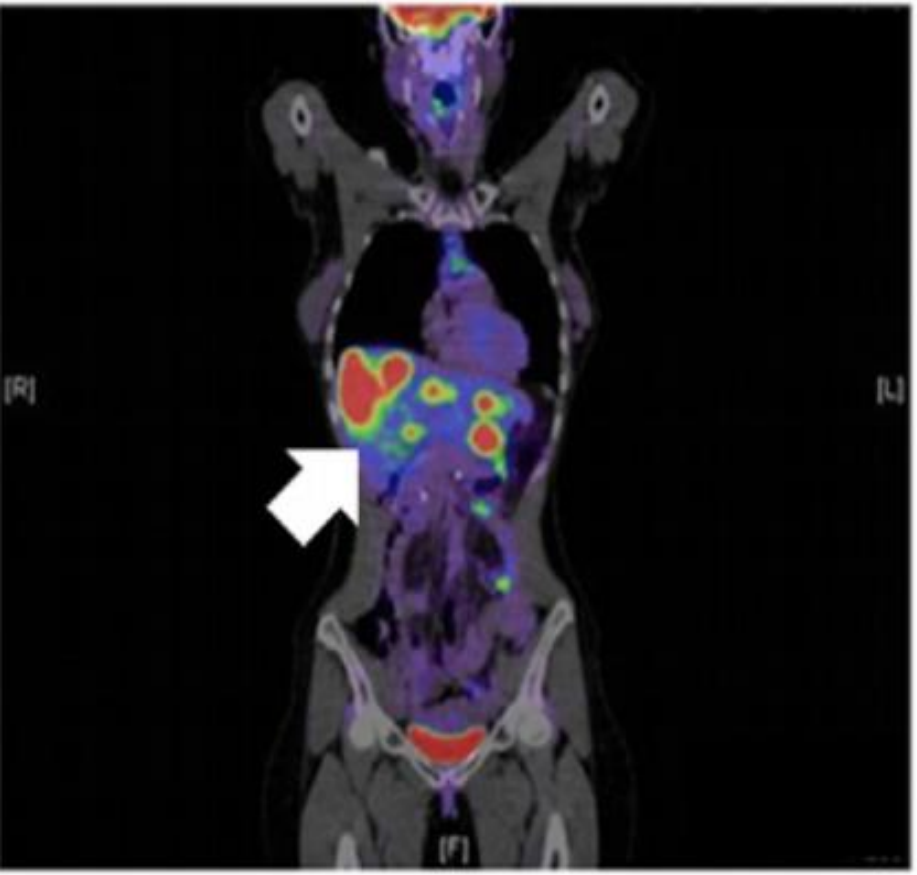




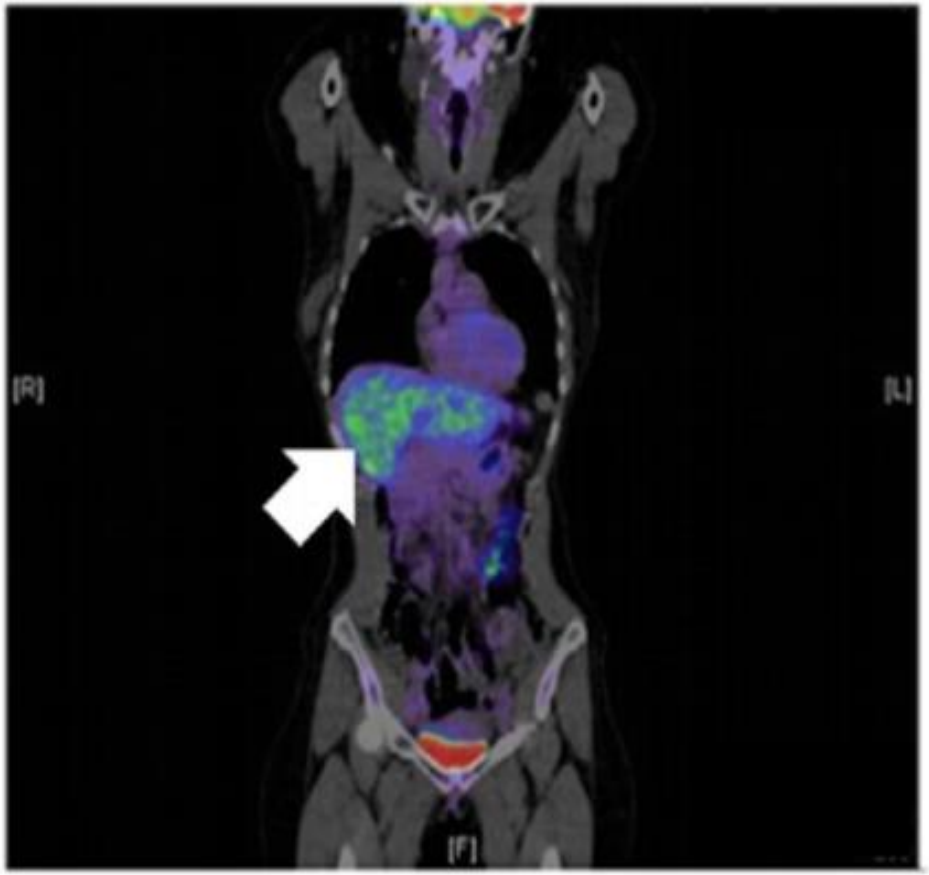
mTNBC – Mice study



Objective Tumor Response, Phase 1 Trial



before CHT+CCR5 inh.



after CHT+CCR5 inh.

NASH – Liver Fibrosis

2016

https://www.infectiousdiseaseadvisor.com/home/topics/gi-illness/hepatitis/research-focuses-on-ccr5-inhibition-and-liver-injury/

… an earlier study published by Kenneth Sherman, MD, PhD, professor of digestive diseases at the University of Cincinnati and colleagues in *Science Translational Medicine*.[1]

"It turns out that HIV and its evolution high-jacked that receptor and uses CCR5 as its primary way of binding to T-cells, entering them and killing them," Dr Sherman noted in a prepared statement about the research. "That's what causes AIDS. CCR5 is not just present on T-cells but also exists in the liver on the surface of hepatocytes and also in the liver on stellate cells. Stellate cells are the cells that produce scar tissue in the liver, which can lead to the development of cirrhosis. The focus of this grant is to look at how inhibition of CCR5 might influence the development of liver injury and/or the development of scar or cirrhosis in the liver."

2018

https://www.medicalnewstoday.com/articles/323891.php

A gene that helped protect our ancestors from a devastating plague outbreak may also help protect liver health in people with HIV, a new study finds.

PRO 140 Important Milestones for HIV and Cancer 2019

Milestones	Target Dates
BLA submission – HIV combination therapy – unmet medical need	2H2019
Revenue potential	1H2020
Initiate first ever monotherapy Phase 3 pivotal trial with self injectable	2H2019
Triple-Negative Breast Cancer study first patient injected	2019
Triple-Negative Breast Cancer study interim results	1H2020
GvHD First Patient Injection	4Q2019
IND-Protocol for colon cancer Phase 2	2019
IND-Protocol for NASH Phase 2	2019
Potential licensing or partnering	2H2019
Publication of combination therapy trial	2019