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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): April 30, 2026**

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**CytoDyn, Inc.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-49908**  
(Commission File Number)

**83-1887078**  
(IRS Employer  
Identification No.)

**1111 MAIN STREET, SUITE 660  
VANCOUVER, Washington**  
(Address of Principal Executive Offices)

**98660**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 360 980-8524**

(Former Name or Former Address, if Changed Since Last Report)

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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:

- 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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	N/A	N/A

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.

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**Item 7.01 Regulation FD Disclosure.**

On April 30, 2026, at 1:00 p.m. (Pacific Time), CytoDyn Inc. (the “Company”) intends to hold an investor call and webcast to provide a corporate and clinical update. Instructions on how to access the investor call were included in a press release dated April 23, 2026, available on the Company’s website under Newsroom. Additional presentation materials relating to such call are furnished as Exhibit 99.1 and are incorporated herein by reference. The presentation materials will also be posted on the Company’s website under Investor Update Calls. All information in the presentation materials speaks as of the date thereof and the Company does not assume any obligation to update said information in the future except as may be required by law.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liabilities of that section, and the information shall not be deemed to be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Presentation Slides dated April 30, 2026</a> (furnished with this Form 8-K).
104	Cover Page Interactive Data File

**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.**

Date: April 30, 2026

By: /s/ Tyler Blok

Tyler Blok

Chief Legal Officer

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Leronlimab – A Novel Therapeutic in  
CCR5+ Immuno-Oncology

[CYTODYN.COM](http://CYTODYN.COM) / OTCMKTS: **CYDY**

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. Forward-looking statements may include statements about leronlimab, its ability to provide positive health outcomes, the Company's ability to develop a successful operating strategy and thereby create shareholder value, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. 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 regulatory determinations of leronlimab's safety and effectiveness to treat the diseases and conditions for which we are studying the product by the U.S. Food and Drug Administration (FDA) and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt and other payment obligations; (iv) the Company's ability to retain other key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third-parties; (vi) the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with applications for approval of the Company's drug product; (vii) the Company's ability to achieve approval of a marketable product; (viii) the design, implementation and conduct of the Company's clinical trials; (ix) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (x) the market for, and marketability of, any product that is approved; (xi) 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; (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiv) general economic and business conditions; (xv) changes in foreign, political, and social conditions; (xvi) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvii) 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 subsequent Form 10-Qs and Form 8-Ks, 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.

Any and all projections included herein are based on management estimates only. Adverse events could negatively impact the Company's ability to achieve such results.



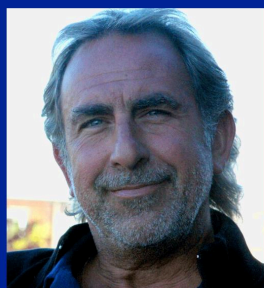
## Robert E. Hoffman

Chief Financial Officer

CFO of CytoDyn Inc. since May 2025.

An industry veteran with decades of financial and leadership experience. Prior to joining CytoDyn, served as President and CEO of Kintara Therapeutics, Inc. Other prior executive roles include; Heron Therapeutics, AnaptysBio, and Arena Pharmaceuticals.

Currently sits on the boards of Esperion Therapeutics, TuHURA Biosciences, and Fibrobiologics.



## Jacob Lalezari, M.D.





Chief Executive Officer

CEO of CytoDyn Inc. since November 2023.

37 years of industry experience, including nearly 20 years of experience with leronlimab.

Dr. Lalezari has been the CEO and Medical Director of Quest Clinical Research since 1996.

Dr. Lalezari has served as Principal Investigator for Phase I, II, and III clinical studies of new therapies for such viral diseases as HIV/AIDS, CMV, HPV, HSV, Hepatitis B and C, influenza, RSV, and COVID-19, including some historical trials conducted by CytoDyn.

-  Novel drug candidate with data supporting multiple Mechanisms of Action (MOA)
-  Well-tolerated with extensive safety database including more than 1,600 patients enrolled across 20+ clinical studies
-  Large market potential across mCRC, TNBC, and other solid tumors
-  Potential for multiple impacts in solid tumor oncology:
  - (i) leronlimab as a “Stand-alone” anti-cancer therapy; and
  - (ii) leronlimab as part of a “Prime and Pair” regimen with an immune checkpoint inhibitor (“ICI”) to create a pathway to sustained remission



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Colorectal Cancer  
("CRC")

### Title

CCR5-targeting Leronlimab With Oral Chemotherapy and VEGF-inhibitor Enriched Regimen Study (**CLOVER**)

### Design

Phase 2, open-label, randomized (350 vs 700mg) 60 patient study to explore safety and efficacy of leronlimab administered with Lonsurf and Avastin in patients with third line Microsatellite Stable (MSS) Metastatic Colorectal Cancer (mCRC).

### Lead Investigator

Pashtoon Kasi, M.D., M.S., Medical Director of GI Medical Oncology, City of Hope Orange County.

### Status / Enrollment:

*Target Enrollment complete*

Data and Safety Monitoring Board (DSMB) meetings took place in December 2025 and March 2026

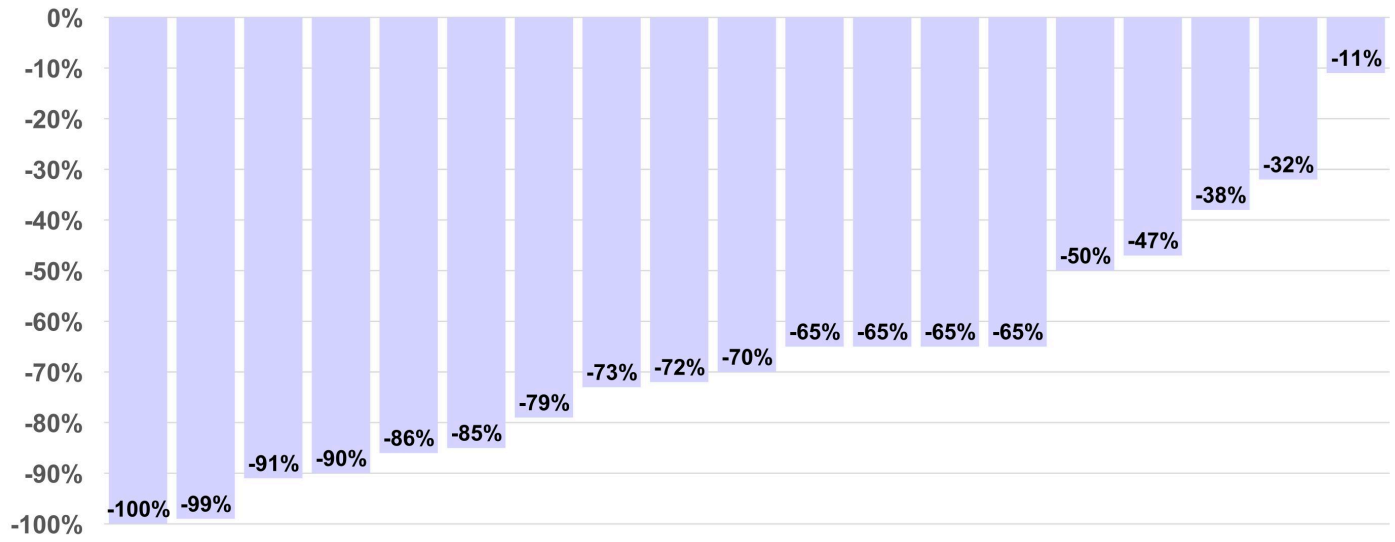
- Opened 700mg randomization arm
- No safety concerns

**Conference:** American Association for Cancer Research (AACR) Annual Meeting (April 2026)

**Poster ID:** 6466

**Presenter:** Dr. Pashtoon Kasi

**Figure 2: ctDNA Decline by Week 2 (% decline)**



- 1) 100% of screened patients (91/91) tested CCR5+
- 2) Well tolerated. No Grade 3 or 4 Adverse Events (AEs) or Serious Adverse Events (SAEs) related to leronlimab; no leronlimab-related dose or treatment-limiting toxicity
- 3) Early ctDNA declines in first 19 patients enrolled at City of Hope (100% of patients show declines in ctDNA; median decrease of 70% at week 2)
- 4) 15/22 (68%) patients with RECIST data available at Week 8 demonstrate shrinkage or classify as having stable disease
- 5) Early scan results correlate with ctDNA decreases
- 6) Numeric increases in PD-L1 observed in majority of patients
- 7) Principal Investigator reports patients responding clinically (better with less pain)

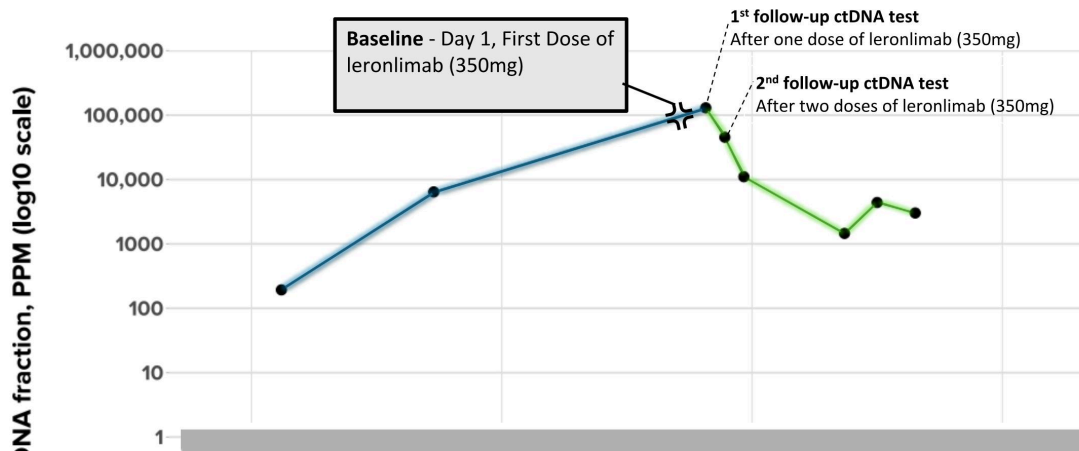


## Dr. Pashtoon Kasi, M.D., M.S.

Principal Investigator, CD-0-101

The Phase-2 CCR5-targeting Leronlimab With Oral Chemotherapy and VEGF-inhibitor Enriched Regimen Study (“CLOVER”)

Medical Director of GI Medical Oncology, City of Hope Orange County. Associate Clinical Professor, Department of Medical Oncology & Therapeutics Research. Rad Family Chair in Gastrointestinal Oncology.



**Patient No. 103-001**

Stable Disease

**ctDNA**  
-97%

*Tumor Volume*  
-21%

2025-12-31	Detected	3020 PPM
2025-12-17	Detected	4393 PPM
2025-12-05	Detected	1454 PPM
2025-10-29	Detected	11,036 PPM
2025-10-22	Detected	45,313 PPM
2025-10-15	Detected	129,734 PPM
2025-07-07	Detected	6422 PPM
2025-05-12	Detected	193 PPM

- On treatment:
- a) leronlimab (350mg week); and
  - b) backbone of Avastin and Lonsurf

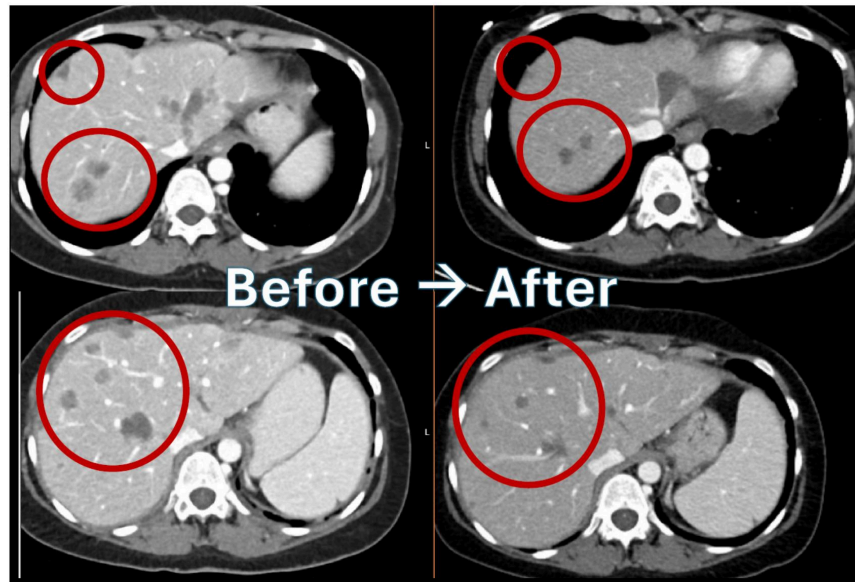
**Parts Per Million (PPM):** The number of tumor molecules observed per one million total molecules sequenced

**Liver scans**

City of Hope, CLOVER Study

“After” scans were taken 8 weeks post-treatment:

- a) leronlimab (350mg once/week); and
- b) backbone of Avastin and Lonsurf



<b>Patient No. 103-001</b>
Stable Disease
<b>ctDNA</b> -97%
<b>Tumor Volume</b> -21%

**Conference:** American Association for Cancer Research (AACR) Annual Meeting (April 2026)

**Poster ID:** 6466

**Presenter:** Dr. Pashtoon Kasi

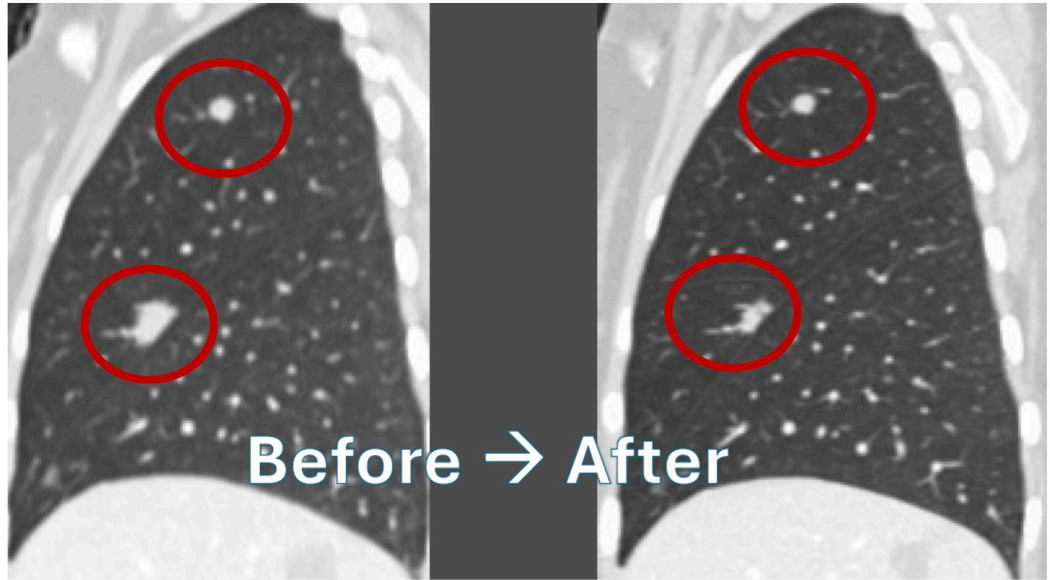
**Lung scans**

City of Hope, CLOVER Study

“After” scans were taken  
8 weeks post-treatment:

- a) leronlimab (350mg  
once/week); and
- b) backbone of Avastin and  
Lonsurf

<b>Patient No. 103-001</b>
Stable Disease
<b>ctDNA</b> -97%
<i>Tumor Volume</i> -21%



**Conference:** American Association for Cancer Research (AACR) Annual Meeting (April 2026)

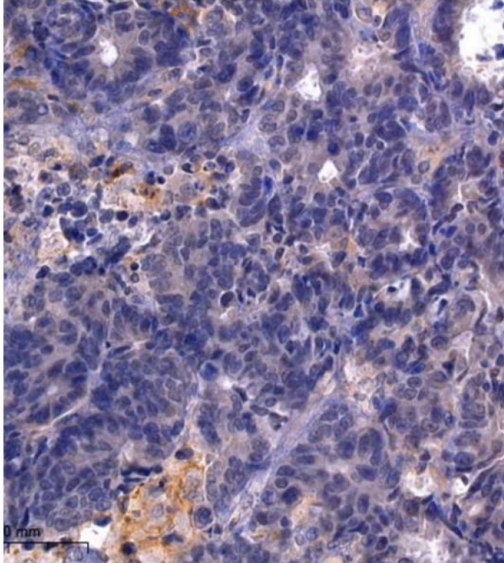
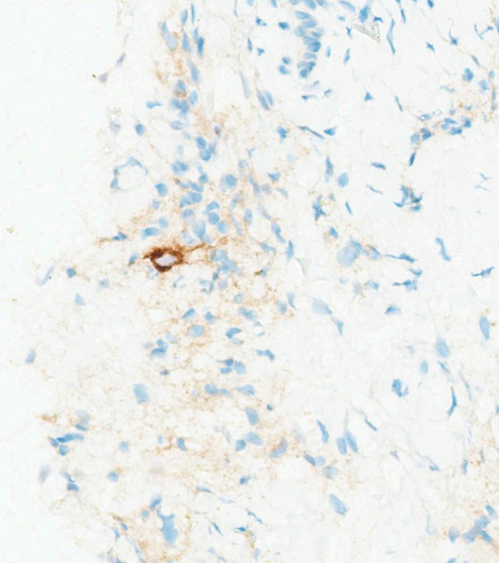
**Poster ID:** 6466

**Presenter:** Dr. Pashtoon Kasi

**PD-L1 Staining on Biopsy Tissue**  
City of Hope, standard of care

*Disclosure: The follow-up biopsy was taken at the discretion of the treating physician and this respective patient. The CLOVER study protocol only provides for a biopsy as part of the initial screening process, whether current or historical.*

**\*PD-L1 CPS (Pathology)**  
Proportion of cancer cells plus immune cells (lymphocytes and macrophages) with PD-L1 staining, relative to total number of viable cancer cells.

Baseline		Follow-up	
CPS Score*	1%	CPS Score*	5%
			

**Phase 3 Sunlight study - published May 3, 2023** <https://www.nejm.org/doi/full/10.1056/NEJMoa2214963>

- N = 246 patients
- Median Progression Free Survival (mPFS) = 5.6 months
- Median Overall Survival (mOS) = 10.8 months
- Overall Response Rate (ORR) = 6.1%, **no CRs**

**Meta-analysis of real-world data - published May 24, 2023** <https://pubmed.ncbi.nlm.nih.gov/37366880/>

- N = 437 patients
- Median Progression Free Survival (mPFS) = 4.5 months
- Median Overall Survival (mOS) = 11.1 months
- Overall Response Rate (ORR) = 2.7%

### 1) CLOVER – Phase 2 study in 3<sup>rd</sup> line or later, patients with MSS mCRC:

- Amendment #6:  
Study extension for stable patients; and  
Rollover arm for salvage therapy for patients with documented progression (Leronlimab 700mg + ICI).

### 2) A Phase 1/1b Single Arm Safety Lead in Study of Leronlimab (CCR5 Blockade) with Hepatic Arterial Infusion Pump Therapy Delivering Floxuridine (FUDR) and Concurrent Systemic Therapy in Patients with Colorectal Cancer Liver Metastases (CHAMP) – *IRB# 25965*

- CRC patients in earlier line of treatment;
- Jointly funded with City of Hope;
- Leveraging hepatic-protective and anti-tumor effects of leronlimab; and
- ctDNA results from patients on leronlimab monotherapy

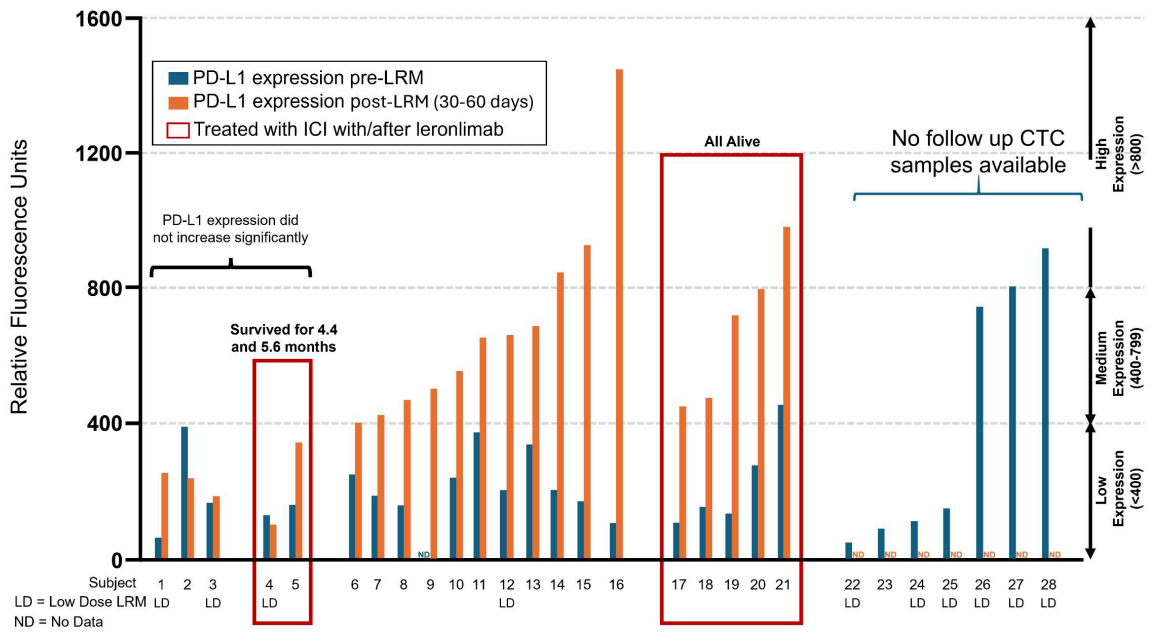
### 3) Leronlimab + ICI in patients with CRC



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Triple-Negative Breast Cancer  
("TNBC")

### Clinical Outcome(s): Survival Based on PD1/PD-L1 Inhibitors



Preclinical data: 98% reduction in metastasis in mice treated with leronlimab

\*Retrospective\* clinical data:

- Reduction of CTCs in 16/28 (57%) of patients
- Significant upregulation of PD-L1 on CTCs observed in:
  - 16/21 (76%) of patients irrespective of dose
  - 1/4 (25%) of patients who received 350mg
  - 15/17 (88%) of patients who received 525mg or 700 mg

Clinical outcomes:

- **5/5 (100%) of patients who upregulated PD-L1 *and* received an immune checkpoint inhibitor (“ICI”), are alive after 5+ years** (3/5 currently report no evidence of disease)
- For metastatic TNBC, the median overall survival is typically 11 to 13 months (<https://pmc.ncbi.nlm.nih.gov/articles/PMC11120599/>)
- 23/23 (100%) of patients who did not upregulate PD-L1 *or* did not receive an ICI, are deceased

**1) Phase 2 study of leronlimab with standard of care in 2<sup>nd</sup> line or later, HER2- patients with breast cancer**

*Part 1* – Dose escalation: safety, PK, ctDNA, and PD-L1

(Dr. Paula Pohlmann of MD Anderson to serve as Principal Investigator)

*Part 2* – Contribution of components (+/- ICI)

Adaptive study design in up to 120 patients

**2) Expanded access protocol for 2<sup>nd</sup> line or later, patients with mTNBC**

First patient dosed week of April 20, 2026

Prospective confirmation of PD-L1 induction

Externally funded for 1st 20 patients





**3) Neoadjuvant leronlimab in HER2- patients with breast cancer**

Exploring potential benefits of leronlimab as a monotherapy



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Clinical Priorities, Upcoming Milestones,  
Approach to Calendar 2026

-  Confirm stand-alone benefit of leronlimab plus backbone, through biomarker collection, Disease Control Rate (DCR), Overall Response Rate (ORR), Progression-Free Survival (PFS) and Overall Survival (OS).
-  Prospectively demonstrate leronlimab induction of PD-L1.
-  Prospectively demonstrate clinical benefit of adding an ICI to leronlimab in PD-L1-induced patients.
-  Identify optimal leronlimab dosing in oncology.

- ✓ **Close on Funding for Expanded Access Program** [1Q Calendar 2026]
- ✓ **Close \$17.5 Million Financing to Fund Continued Development of Leronlimab** [1Q Calendar 2026]
- ✓ **Present initial ctDNA readouts from mCRC study at AACR (San Diego)** [2Q Calendar 2026]
- ✓ **TNBC Expanded Access Program enrolls first patient** [2Q Calendar 2026]
- ✓ **Submission of protocol amendment(s) to FDA regarding inclusion and timing of ICIs in current Phase 2 mCRC (CLOVER) study** [2Q Calendar 2026]
- **Initiation of City of Hope investigator-initiated study in mCRC** [2Q/3Q Calendar 2026]
- **Initiation of dose escalation study in mTNBC** [3Q Calendar 2026]
- **Presentation at ESMO (Madrid, Spain)** [4Q Calendar 2026]
- **Presentation at ASCO GI (San Francisco)** [1Q Calendar 2027]

- **Confirm early safety and efficacy readouts; generate optimal data package(s)**  
[3Q Calendar 2026]
- **Presentation of updated biomarker and clinical data at ESMO** [October 2026]
- **Assemble data to support Fast-track and/or Breakthrough Therapy Designation(s)**  
[2H Calendar 2026]
- **Continued evaluation of strategic partnership opportunities** [2H Calendar 2026]