
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): October 16, 2026

CytoDyn, Inc.

(Exact name of Registrant as Specified in Its Charter)

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)

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. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On October 16, 2026, at a meeting held by the Board of Directors (the “Board”) of CytoDyn Inc. (the “Company”), which followed a number of discussions among members of the Board’s Nominating and Corporate Governance Committee and Jacob P. Lalezari, M.D. (“Dr. Lalezari”), the Company’s Chief Executive Officer, the Board appointed Robert E. Hoffman (“Mr. Hoffman”) as the Company’s Chief Executive Officer effective October 20, 2026. Mr. Hoffman will also continue to serve as the Company’s principal accounting officer. Also on October 16, 2026, Dr. Lalezari confirmed his resignation as the Company’s Chief Executive Officer effective October 20, 2026, and accepted a non-executive role with the Company as Head of Research and Translational Sciences.

Mr. Hoffman, age 60, has served as the Company’s Chief Financial Officer since May 15, 2025. From November 2021 to October 2024, Mr. Hoffman served as President, CEO, interim Chief Financial Officer and Chairperson of the board of directors of Kintara Therapeutics, Inc., a clinical stage biopharmaceutical company previously listed on Nasdaq and focused on the development and commercialization of new cancer therapies. Mr. Hoffman previously served as Senior Vice President and Chief Financial Officer of Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company, from April 2017 to October 2020; and as Chief Financial Officer of AnaptysBio, Inc. (Nasdaq: ANAB), a specialty pharmaceutical company, from July 2015 to September 2016. Mr. Hoffman is currently a member of the boards of directors of TuHURA Biosciences (Nasdaq: HURA), a clinical stage immuno-oncology company that acquired Kintara Therapeutics in October 2024; and Fibrobiologics, Inc. (Nasdaq: FBLG), a clinical stage company focused on treating chronic diseases. He previously was a director of Esperion Therapeutics, Inc. (Nasdaq: ESPR), a commercial stage biopharmaceutical company, from April 2025 until its acquisition in July 2026. Mr. Hoffman is a former member of the steering committee of the Association of Bioscience Financial Officers. Mr. Hoffman holds a B.B.A. from St. Bonaventure University.

There are no family relationships, as defined in Item 401 of Regulation S-K promulgated by the Securities and Exchange Commission (the “SEC”), between Mr. Hoffman and any of the Company’s other executive officers and directors. Other than the Employment Agreement between Mr. Hoffman and the Company effective May 15, 2025, there is no arrangement or understanding between Mr. Hoffman and any other person pursuant to which he was appointed as CEO of the Company. The Employment Agreement was included as [Exhibit 10.1](#) to the Company’s Current Report on Form 8-K filed with the SEC on May 6, 2025, and is incorporated herein by reference. There are no transactions in which Mr. Hoffman has an interest requiring disclosure under Item 404(a) of Regulation S-K promulgated by the SEC.

In connection with Mr. Hoffman’s appointment as Chief Executive Officer, on October 16, 2026, the Board’s Compensation Committee approved the following changes in his compensation for the fiscal year ending May 31, 2027, effective October 20, 2026: an increase in his annual base salary to \$525,000; an increase in his bonus target rate from 40% to 50%; and a grant of stock options under the Company’s Amended and Restated 2012 Equity Incentive Plan (the “Plan”) for the purchase of 2,500,000 shares at an exercise price equal to the higher of the closing prices for the Company’s common stock on October 16 and October 20, 2026, with a term ending on October 16, 2036, and vesting as to 25% on October 16, 2027, and the balance in equal monthly installments through October 16, 2030.

The Company and Dr. Lalezari have also entered into an agreement for his continued employment in his new role, which replaced his prior executive employment agreement. No changes were made in Dr. Lalezari’s compensation in connection with execution of the new agreement.

Item 7.01 Regulation FD Disclosure.

On October 19, 2026, the Company issued a press release announcing the appointment of Mr. Hoffman as the Company’s Chief Executive Officer and related information as described in Item 5.02 above. The press release is furnished as Exhibit 99.1 to this report. Also on October 19, 2026, the Company provided an investor webcast. The slide presentation included with the webcast, which has also been posted on the Company’s website, is furnished as Exhibit 99.2 to this report.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are furnished as part of this report.

Exhibit Number	Description
99.1	Press release dated October 19, 2026
99.2	Investor presentation slides, as presented on October 19, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 thereunto duly authorized.

CYTODYN INC.

Date: October 19, 2026

By: /s/ Tyler Blok
Tyler Blok
Chief Legal Officer

CytoDyn Appoints Robert E. Hoffman as Chief Executive Officer

Dr. Jacob Lalezari to remain with Company in scientific innovation and discovery role

VANCOUVER, Washington, October 19, 2026 -- CytoDyn Inc. (OTCQB: CYDY) ("CytoDyn" or the "Company"), a clinical-stage oncology company advancing leronlimab, a first-in-class humanized monoclonal antibody targeting the CCR5 receptor with therapeutic potential across multiple solid-tumor oncology indications, including colorectal cancer (mCRC) and metastatic triple-negative breast cancer (mTNBC), today announced the appointment of Robert E. Hoffman as Chief Executive Officer, effective October 20, 2026.

Mr. Hoffman takes over in place of Dr. Jacob Lalezari, who had served as Chief Executive Officer since November 2023. Dr. Lalezari will remain with CytoDyn as Head of Research and Translational Sciences, where he will focus on identifying and advancing new opportunities for leronlimab in solid-tumor oncology. The leadership transition comes as CytoDyn prepares for its next phase of clinical development, with a focus on advancing its oncology pipeline, pursuing regulatory milestones and exploring potential strategic partnerships.

"Robert's expertise is aligned with what's next for CytoDyn as we look to 2027 as a year of clinical results, regulatory progress, and renewed partnering opportunities," said Dr. Lalezari. "While our team executes the business plan to build on the very promising results from the CLOVER study, I will focus on identifying new opportunities for possible pursuits in solid-tumor oncology."

"We are entering a transformational period for the Company, with opportunities to build on the scientific and clinical progress achieved in recent years," said Mr. Hoffman. "Jay has played an instrumental role in advancing the Company and helping establish a clearer path forward for leronlimab. I am grateful for his leadership and look forward to continuing to work closely with him as we focus on clinical execution, financial discipline and positioning CytoDyn for its next stage of growth."

The Board of Directors appointed Mr. Hoffman as Chief Executive Officer in consultation with Dr. Lalezari, who supports the transition and intends to continue to support the Company's scientific efforts. In addition to assuming the CEO role, Mr. Hoffman will continue to serve as the principal accounting officer of the Company.

About Robert E. Hoffman

The Board of Directors appointed Robert E. Hoffman as the Company's Chief Executive Officer, effective October 20, 2026. Mr. Hoffman first joined CytoDyn on May 15, 2025, originally serving as its Chief Financial Officer. Mr. Hoffman is an industry veteran with decades of financial and leadership experience, having served in a number of biotech executive and board roles. Most recently, he was the President, CEO, interim Chief Financial Officer and Chairperson of the board of directors of Kintara Therapeutics, Inc. Prior to that, he served as Chief Financial Officer and Senior Vice President of Heron Therapeutics, Inc., Chief Financial Officer and Executive Vice President of Innovus Pharmaceuticals, Inc. and Chief Financial Officer of AnaptysBio, Inc. Mr. Hoffman started his career at Arena Pharmaceuticals, Inc., rising through the ranks to Senior Vice President, Finance and Chief Financial Officer. Mr. Hoffman currently serves on the board of directors of TuHURA Biosciences and Fibrobiologics, Inc., and has previously served as a director

of several public and private life sciences companies, including Esperion Therapeutics, Inc., ASLAN Pharmaceuticals Limited, Saniona AB, Kura Oncology, Inc., CombiMatrix Corporation, MabVax Therapeutics Holdings, Inc. and Aravive, Inc.

Mr. Hoffman is a former member of the steering committee of the Association of Bioscience Financial Officers. He also formerly served as a director and President of the San Diego Chapter of Financial Executives International and was an advisor to the Financial Accounting Standards Board from 2010 to 2020. Mr. Hoffman holds a B.B.A. from St. Bonaventure University.

About CytoDyn

CytoDyn is a clinical-stage oncology company dedicated to advancing leronlimab, a first-in-class humanized monoclonal antibody that targets the CCR5 receptor, a key regulator of immune function implicated in cancer, infectious diseases, and autoimmune disorders. Guided by a mission to improve patients' quality of life through therapeutic innovation, CytoDyn is committed to integrity, responsibility, and service as it works to bring transformative treatments to patients worldwide.

For more information, please visit www.cytodyn.com and follow us on LinkedIn.

Note Regarding Forward-Looking Statements

This news release may contain forward-looking statements relating to, among other things, the mechanism of action of leronlimab, clinical trial results, product development, market position, future operating and financial performance, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future events. For important information about these statements and our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review our Annual Report on Form 10-K for the fiscal year ended May 31, 2026, including the section captioned "Forward-Looking Statements" and in Item 1A, as well as subsequent reports filed with the Securities and Exchange Commission. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments except as required by applicable law.

Corporate Contact

CytoDyn Inc.
ir@cytodyn.com

Media Contacts

David Schull or Ignacio Guerrero-Ros, Ph.D.
Russo Partners, LLC
CytoDyn@russopartnersllc.com

CYTODYN INVESTOR UPDATE WEBINAR

THE WEBINAR WILL START SOON

Participants



Jacob Lalezari
M.D.

Chief Executive Officer of
CytoDyn



Robert E. Hoffman

Chief Financial Officer of
CytoDyn



Pashtoon M. Kasi
M.D., M.S.

Medical Director of GI Oncology,
City of Hope Orange County,
Irvine, California



Reny Aniline

Sr. Director of BioPharma
Business Development, Oncology
& RWD Solutions, Natera



The Next Generation of Monoclonal Antibody Therapy

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.



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 1, 2, and 3 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 multiple demonstrated mechanisms of action (MOA)
-  Large and growing market potential across CRC, TNBC, and other solid tumor indications
-  Well-tolerated with extensive safety database including approximately 1,700 patients enrolled in 20+ clinical studies across multiple therapeutic areas
-  Promising early readouts from CLOVER study in mCRC, strong retrospective clinical data in TNBC, and expectation of continued readouts supporting proposed MOA throughout calendar 2027
-  Potential for multiple therapeutic approaches in solid-tumor oncology:
 - i. “Stand-alone” anti-cancer therapy; and
 - ii. “Prime and Pair” – a combination approach with an immune checkpoint inhibitor to create pathway to sustained remission



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 700 mg) 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:

First patient dosed in June 2025; ***target enrollment completed in April 2026***

Primary Objective

- Evaluation of the [efficacy](#) of leronlimab in combination with current standard of care (Lonsurf and Avastin)

Primary Endpoint

- Objective Response Rate (ORR) – as assessed by responders in either arm (350 or 700 mg), or from the overall study population

Secondary & Exploratory Endpoints

- Assessment of the [safety and tolerability](#) of leronlimab with current standard of care (Lonsurf and Avastin)
- Evaluation of [changes in circulating tumor DNA \(ctDNA\)](#)
- Evaluation of patients who achieve complete response (CR), partial response (PR) or stable disease (SD); as well as progression free survival (PFS) and overall survival (OS)
- Investigator assessed overall response rate (ORR), based on local tumor assessments
- Evaluation of [changes in PD-L1 expression](#) on circulating tumor cells (CTCs)
- Evaluation of the efficacy of leronlimab with pembrolizumab in patients with documented progression during initial randomized phase of the study

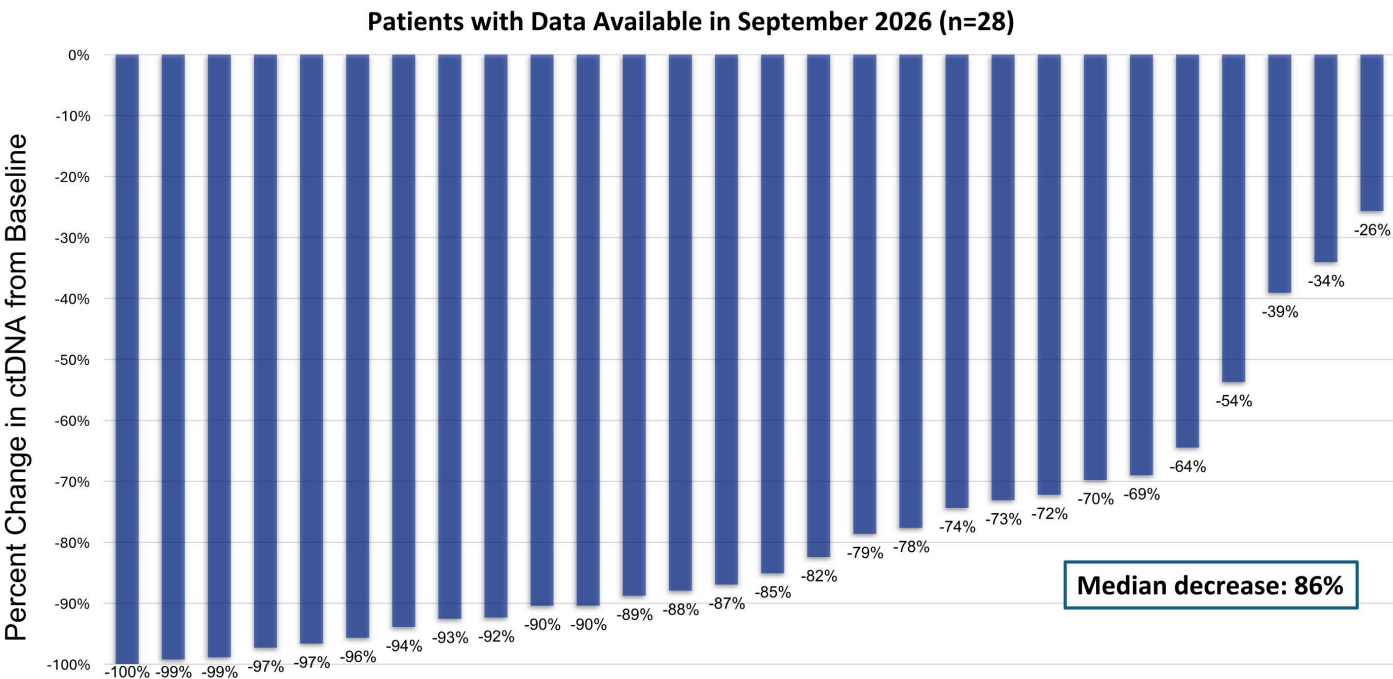
<i>Age</i>	350 mg (n=33)	700 mg (n=32)	Total (N=65)
Median Age (Years)	57 (38 -76)	57 (31 – 79)	57 (31-79)
Age <65	24 (72.7%)	21 (65.6%)	45 (69.2%)
Age ≥ 65	9 (27.3%)	11 (34.4%)	20 (30.8%)
<i>Primary Diagnosis</i>			
Colon Cancer	19 (57.6%)	17 (51.5%)	36 (55.4%)
Rectal Cancer	14 (42.4%)	15 (45.4%)	29 (44.6%)
<i>Prior Lines of Therapy</i>			
2	16 (48.5%)	15 (46.9%)	31 (47.7%)
≥ 3	17 (51.5%)	17 (53.1%)	34 (52.3%)
<i>Prior Avastin (bev) experience</i>	31 (93.9%)	25 (78.1%)	56 (86.2%)

*Results are based on a preliminary data cut. Final database cleaning, source verification, and query resolution are ongoing. As of September 2026, 22 of 65 subjects (34%) remain on study, reported outcomes may change up until database lock.

NOTES & OBSERVATIONS

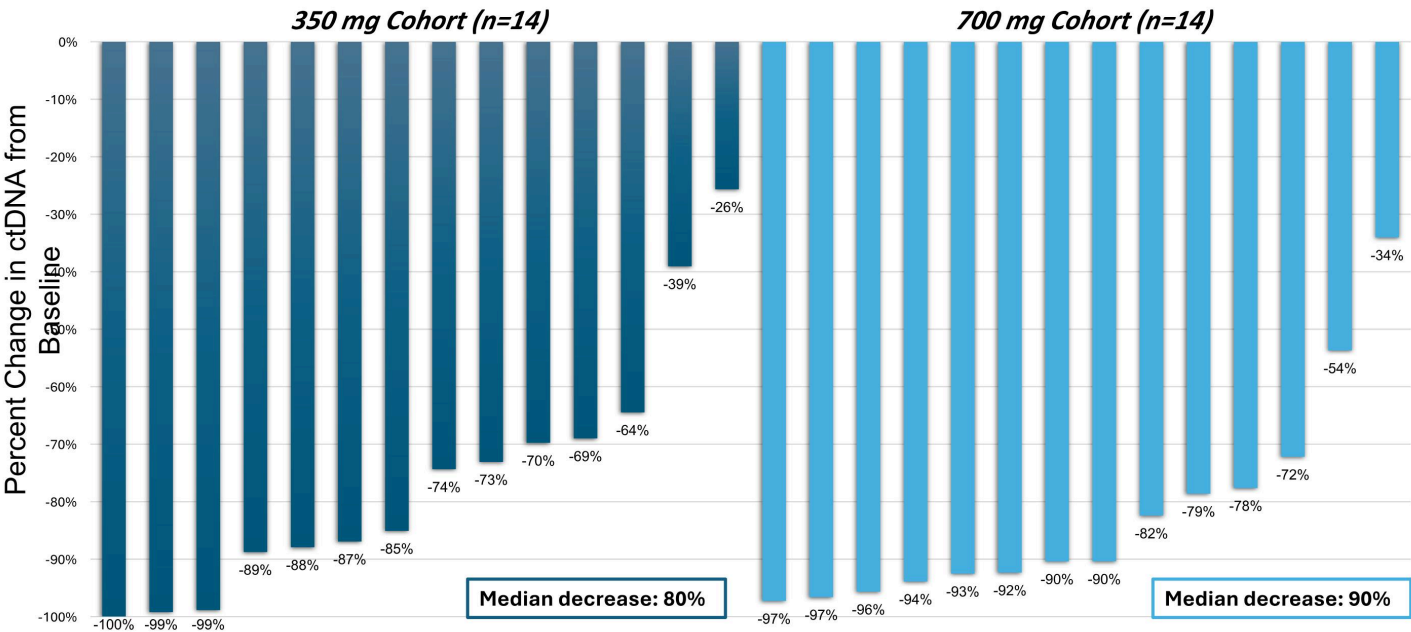
• 52.3% of CLOVER participants were receiving their 4th line of treatment (or later)

• 86.2% of CLOVER participants had previously attempted treatment with Avastin (bevacizumab) in a prior line of therapy

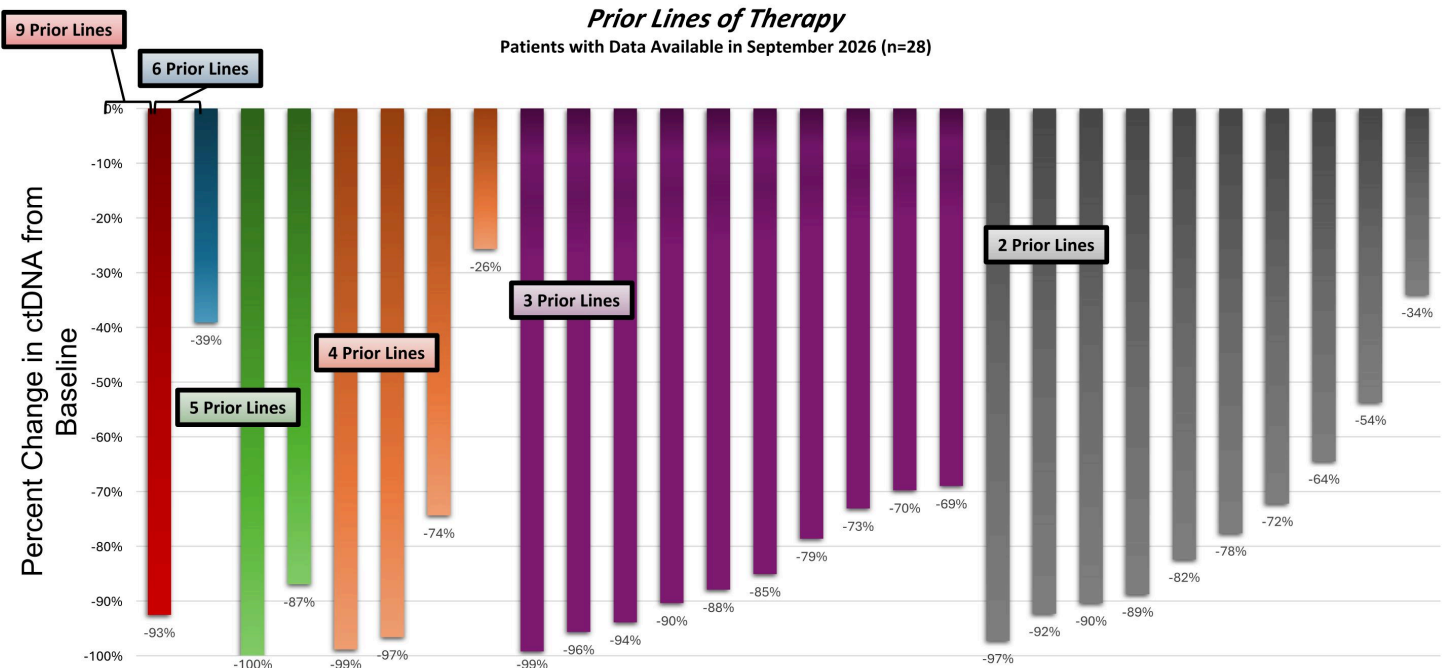


*Analysis includes all available Signatera Exome ctDNA measurements within seven days of starting treatment

Patients with Data Available in September 2026

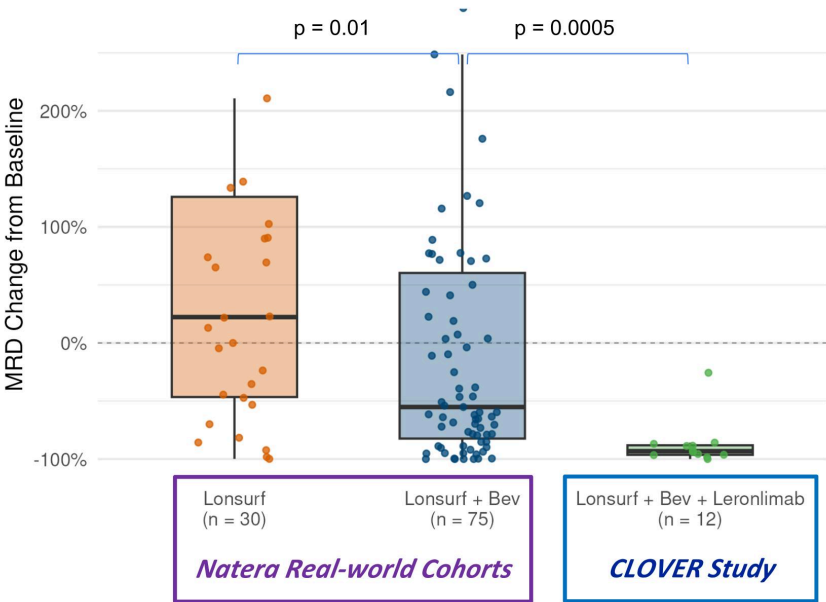


*Analysis includes all available Signatera Exome ctDNA measurements within seven days of starting treatment



*Analysis includes all available Signatera Exome ctDNA measurements within seven days of starting treatment

0-4 Weeks, Molecular Residual Disease (MRD) Change from Baseline



- 1) 96/96 (100%) of screened patients with an evaluable sample tested CCR5+, as determined by immunohistochemistry (IHC)
- 2) Well tolerated. No Serious Adverse Events (SAEs) related to leronlimab
- 3) Consistent ctDNA declines in 28 patients evaluated with *Signatera Exome**
- 4) 38/51 (74.5%) patients with scans available at Week 8 demonstrate shrinkage or classify as having stable disease
- 5) Numerical increases in PD-L1 observed in majority of patients
- 6) Investigators report patients responding well clinically – less pain & fewer hospitalizations
- 7) Three patients referred for curative-intent surgery

*Analysis includes all available Signatera Exome ctDNA measurements within seven days of starting treatment

As of August 2, 2023

Lonsurf & **Avastin**
(trifluridine/tipiracil) (bevacizumab)

Basis for FDA Approval of Avastin (August 2023):

The phase 3 SUNLIGHT study showed that adding Avastin to Lonsurf significantly improved overall survival and progression-free survival compared to Lonsurf alone.

Phase 3 SUNLIGHT study – published May 3, 2023

- **Lonsurf & Avastin** combination (n = 246)
- Median Progression Free Survival (mPFS) = 5.6 months
- Median Overall Survival (mOS) = 10.8 months
- Overall Response Rate (ORR) = 6.1%, **no Complete Responders**

Subsequent meta-analysis of real-world data – published May 24, 2023

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

<https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-trifluridine-and-tipiracil-bevacizumab-previously-treated-metastatic-colorectal-cancer>
<https://www.nejm.org/doi/full/10.1056/NEJMoa2214963>
<https://pubmed.ncbi.nlm.nih.gov/37366880/>

Patient Group Baseline

CLOVER Study*

Lonsurf & Avastin,
plus leronlimab (350 or 700 mg)

SUNLIGHT Study

Lonsurf & Avastin

*Results are based on a preliminary data cut. Final database cleaning, source verification, and query resolution are ongoing. As of September 2026, 22 of 65 subjects (34%) remain on study, reported outcomes may change up until database lock.

Age

	350 mg (n=33)	700 mg (n=32)	Total (N=65)	Lonsurf (n=246)	Lonsurf & Avastin (n=246)	Total (N=492)
Median Age (Years)	57 (38 -76)	57 (31 - 79)	57 (31-79)	64 (24-90)	62 (20-84)	NR
Age <65	24 (72.7%)	21 (65.6%)	45 (69.2%)	129 (52.4%)	146 (59.3%)	275 (55.9%)
Age ≥ 65	9 (27.3%)	11 (34.4%)	20 (30.8%)	117 (47.6%)	100 (40.7%)	217 (44.1%)

Primary Diagnosis

Colon Cancer	19 (57.6%)	17 (51.5%)	36 (55.4%)	181 (73.6%)	180 (73.2%)	361 (73.4%)
Rectal Cancer	14 (42.4%)	15 (45.4%)	29 (44.6%)	65 (26.4%)	66 (26.8%)	131 (26.6%)

Prior Lines of Therapy

1	– Not eligible for CLOVER –			15 (6.1%)	11 (4.47%)	26 (5.3%)
2	16 (48.5%)	15 (46.9%)	31 (47.7%)	224 (91.1%)	229 (93.1%)	453 (92.1%)
≥ 3	17 (51.5%)	17 (53.1%)	34 (52.3%)	7 (2.8%)	6 (2.4%)	13 (2.6%)

Prior Avastin (bev) experience

	31 (93.9%)	25 (78.1%)	56 (86.2%)	176 (71.5%)	178 (72.4%)	354 (72%)
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NOTES & OBSERVATIONS

- Similar patient age profile
- Comparable/lower prevalence of liver metastases in CLOVER
- Greater representation of rectal cancer in CLOVER
- More heavily pre-treated population in CLOVER
- Despite a more heavily pre-treated population and higher proportion of rectal cancer patients, baseline characteristics were otherwise broadly comparable to SUNLIGHT, supporting meaningful cross-study contextualization of clinical outcomes.

Reny Aniline

Natera



Sr. Director of BioPharma Business Development
Oncology & RWD Solutions

Natera™ is a global leader in cell-free DNA and precision medicine, dedicated to oncology, women's health, and organ health.



Following the strategic collaboration announced in June 2026, Signatera™, Natera's personalized assay for the detection of molecular residual disease (MRD), is being used to evaluate ctDNA dynamics and molecular response patterns in the CLOVER study (ClinicalTrials.gov Identifier: NCT06699836).

For more information on Natera, visit www.natera.com

Circulating tumor DNA for molecular response intelligence

What is ctDNA?

The diagram illustrates the process of ctDNA release and detection. It shows a blood vessel containing various components: RBCs (red circles), Macrophages (green stars), Normal Cells (blue circles), Tumor Cells (blue circles with internal structures), CTCs (blue circles with internal structures), Normal cfDNA (orange 'x' marks), and ctDNA (orange 'x' marks). A legend on the left identifies these components. A central illustration shows a blood vessel with tumor cells undergoing apoptosis, necrosis, and shedding, releasing ctDNA into the bloodstream. A test tube on the right shows the separation of Plasma, Leukocyte, and RBC layers. A source note at the bottom right reads 'Source: content.iospress.com'.

Circulating tumor DNA (ctDNA) is DNA shed into the bloodstream as cancer cells die

The advantages of ctDNA-based MRD detection:

- Real-time** — reflects live cancer activity as ctDNA has a half-life of <1 hour
- Quantitative and dynamic** — ctDNA levels track disease burden and changes over time
- Sensitive & specific** — demonstrated evidence of prognostic advantage of MRD vs. PET/CT

Real-World Comparator Arms for Earlier Efficacy Signals



CYTODYN

OPPORTUNITY

Clinical trials for new advanced-stage or metastatic therapies aim to demonstrate longer overall survival (OS) and progression-free survival (PFS).

Yet such approaches require randomized studies that are often expensive and time intensive.

Cytodyn partnered with Natera to benchmark its investigational therapy against a MIIRA-built comparator arm and assess an early efficacy signal vs. SOC using its CLOVER Phase 2 data.

Defining real-world comparator cohorts

Population Criteria

- mCRC
- 3L+
- Pre-treatment baseline ctDNA available
- 1+ MRD time points within first 4 weeks of treatment initiation

Timepoints

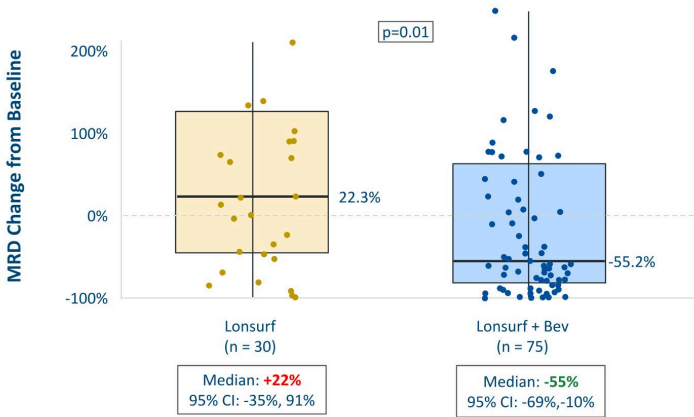
- **>3** average Signatera tests per patient (during entire duration of treatment)

RW Endpoints

- Molecular complete response (**mCR**): ctDNA clearance vs. baseline
- Molecular partial response (**mPR**): ctDNA reduction $\geq 90\%$ vs. baseline
- Molecular stable disease (**mSD**): ctDNA reduction of 0% to $<90\%$ vs. baseline
- Molecular progressive disease (**mPD**): ctDNA increase vs. baseline

Response analysis and validation of RW comparator arms in 3L mCRC

Response Analysis

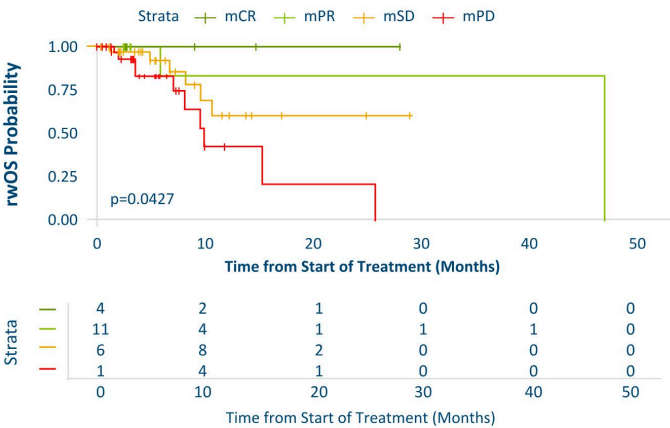


During first 4 weeks of treatment, duplet SOC showed deeper molecular response vs. monotherapy

- Lonsurf: median **22% increase** in ctDNA
- Lonsurf + Bev: median **55% decrease** in ctDNA

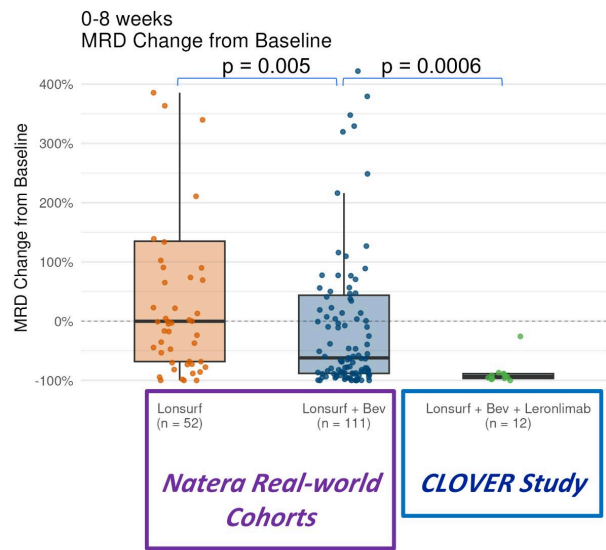
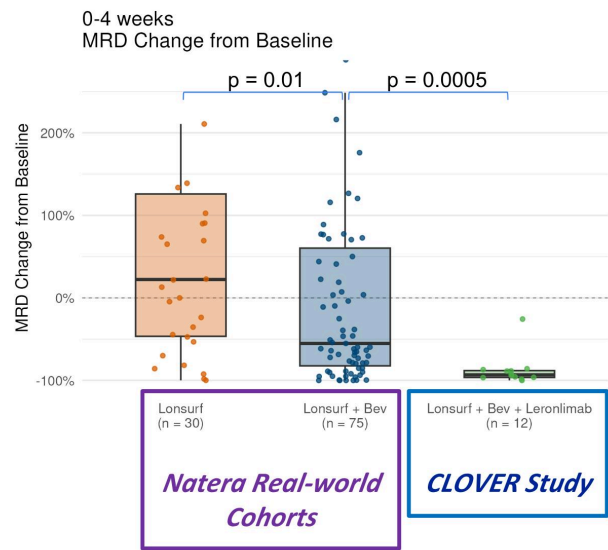
Response Validation

Risk Set Adjusted rwOS by Molecular Response (mCR/mPR/mSD/mPD)



Molecular responders (mCR and mPR) to either regimen had longer real-world overall survival (rwOS) vs. molecular non-responders (mSD and mPD)

Deeper molecular response observed in the CLOVER group, relative to Natera’s real-world comparator cohorts



Observed changes from baseline – MTM/mL (Mean Tumor Molecules per milliliter of plasma)

0-4 weeks treatment time window

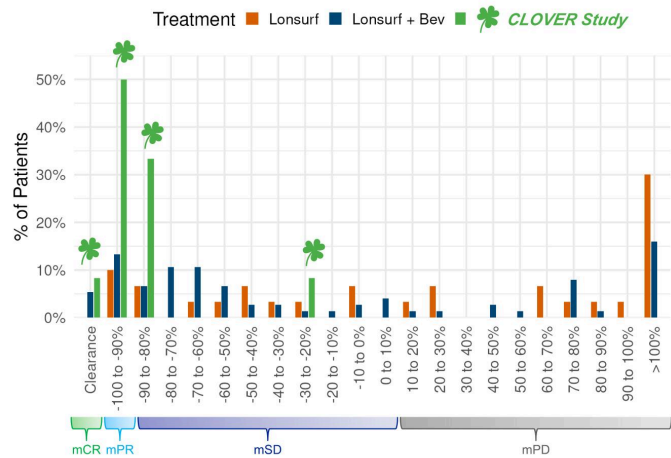
Regimen	N	Min	Q1	Median	95% CI (median)	Mean	Q3	Max	SD
Lonsurf	30	-99.87%	-46.59%	22.30%	-35.40% to 90.63%	435.76%	125.89%	9195.10%	1686.16%
Lonsurf + Bev	75	-100.00%	-82.38%	-55.19%	-68.51% to -9.76%	22.06%	60.33%	1264.78%	201.66%
<i>CLOVER Study</i> Lonsurf + Bev + Leronlimab	12	-100.00%	-96.30%	-93.22%	-96.60% to -86.93%	-87.44%	-88.16%	-25.67%	20.00%

0-8 weeks treatment time window

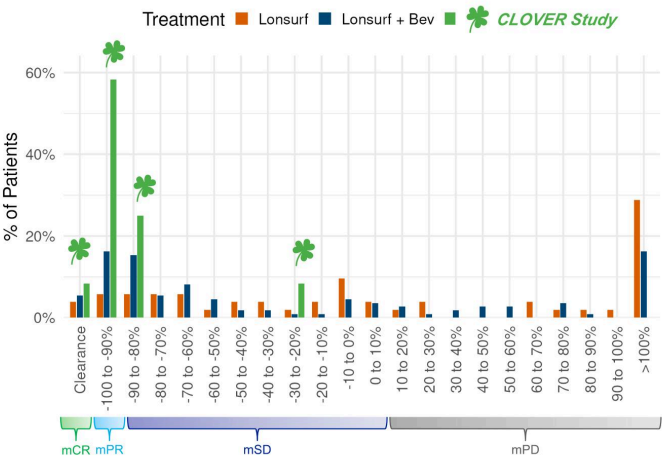
Regimen	N	Min	Q1	Median	95% CI (median)	Mean	Q3	Max	SD
Lonsurf	52	-100.00%	-68.16%	-0.24%	-35.40% to 69.34%	399.15%	135.00%	9195.10%	1474.67%
Lonsurf + Bev	111	-100.00%	-88.25%	-61.92%	-78.43% to -11.01%	103.79%	43.70%	4762.14%	621.94%
<i>CLOVER Study</i> Lonsurf + Bev + Leronlimab	12	-100.00%	-96.73%	-93.22%	-97.10% to -88.57%	-87.96%	-88.71%	-25.67%	20.05%

Deeper molecular response observed in the CLOVER group, relative to Natera’s real-world comparator cohorts

0-4 weeks
Distribution of MRD Change from Baseline



0-8 weeks
Distribution of MRD Change from Baseline



mCR – Molecular complete response: ctDNA clearance vs. baseline

mPR – Molecular partial response: ctDNA reduction ≥90% vs. baseline

mSD – Molecular stable disease: ctDNA reduction of 0% to <90% vs. baseline

mPD – Molecular progressive disease: ctDNA increase vs. baseline



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 1, 2, and 3 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.



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

City of Hope, Orange County

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.





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



- 1) What are your current clinical impressions as it relates to CLOVER participants at your site?
- 2) What are your thoughts on the ctDNA trends observed to date in the CLOVER study?
- 3) What is the current status of the rollover arm – patients that are to receive an immune checkpoint inhibitor with leronlimab at 700 mg?
- 4) Update on patients referred from CLOVER to pursue potentially curative surgery?



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Robert E. Hoffman

Chief Executive Officer – effective October 20, 2026



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 TuHURA Biosciences, and Fibrobiologics.





Upcoming Milestones,
Approach to Calendar 2026 & 2027

ESMO - European Society for Medical Oncology

October 23-27, 2026 | Madrid, Spain



- Additional clinical and ctDNA findings
- Additional follow-up and data maturity
- Real-world comparison data; further context of results relative to evolving mCRC treatment landscape

ASCO Gastrointestinal Cancers Symposium 2027

January 21-23, 2027 | San Francisco, California



- Further updates on clinical and biomarker outcomes
- Additional perspective on durability and consistency of findings
- Additional real-world comparison data; continued analysis of results relative to evolving mCRC treatment landscape

- ✓ **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]
- ✓ **Close on strategic data collaboration with Natera, Inc.** [2Q Calendar 2026]
- ✓ **Close \$16.2 Million financing to fund continued development of leronlimab** [3Q Calendar 2026]
- ❑ **Announcement/introduction to new head of regulatory affairs** [4Q Calendar 2026]
- ❑ **Initiation of dose escalation study in mTNBC** [4Q Calendar 2026]
- ❑ **Initiation of additional studies in CRC** [1H Calendar 2027]

- **Present durability of safety and efficacy from CLOVER Study – *ESMO and ASCO GI***
[4Q 2026 – 1Q 2027]
- **Assemble/present data package, subsequent communications with FDA**
[2H 2026 – 1H 2027]

- ✓ **Novel approach to immuno-oncology** – a first-in-class humanized monoclonal antibody targeting the CCR5 receptor with therapeutic potential across multiple solid-tumor indications
- ✓ **Well tolerated safety profile** – approximately 1,700 patient safety database
- ✓ **Strategic collaboration in place with Natera** – employing ctDNA-Guided Development and Molecular Response Analysis across development program

Large-market potential in metastatic colorectal cancer (mCRC)

- Metastatic Colorectal Cancer (mCRC) is a large and growing market in oncology – has the potential to exceed \$25B globally by 2030
- 2025 sales for Lonsurf totaled \$700+ million, with year-on-year growth reported at 6.2% in Q1 2026

Potential for expansion into other solid-tumor oncology indications (i.e. – triple negative breast cancer, glioblastoma, prostate cancer, pancreatic cancer, etc.)



Question & Answer Session

1111 Main Street, Suite 660, Vancouver, WA 98660
360-980-8524
ir@cytodyn.com

CYTODYN.COM / OTCMKTS:CYDY