UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act

Date of Report (Date of earliest event reported): July 22, 2021 (July 19, 2021)

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware	000-49908	83-1887078
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1111 Main Street, Suite 660
Vancouver, Washington 98660
(Address of principal executive offices, including zip code)

(360) 980-8524
(Registrant's telephone number, including area code)

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	None	None

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 7.01. Regulation FD Disclosure.

On July 19, 2021, CytoDyn Inc. (the "Company"), issued a press release announcing the preliminary results from its Phase 1b/2 trials and compassionate use with a total of 30 metastatic triple-negative breast cancer patients treated with leronlimab. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. On July 22, 2021, Company management, during a previously announced investment community webcast, discussed a summary of the preliminary data from the breast cancer trials and COVID-19 long-haulers trial, including a presentation of the empirical results from each, which are included in an Investor Presentation furnished as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

The press release and Investor Presentation described in Item 7.01 are furnished with this report as Exhibit 99.1 and Exhibit 99.2, respectively.

EXHIBIT INDEX

Exhibit	Description
99.1	Press release dated July 19, 2021
99.2	Investor Presentation dated July 22, 2021
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: July 22, 2021

By: /s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

CytoDyn Announces Preliminary Results from 30 mTNBC Patients Treated with Leronlimab. Decreases in CAMLs after 4 Doses of Leronlimab were Identified in Over 70% of Patients and were Associated with a 450% Significant Increase in Overall Survival at 12-Month Analysis

CytoDyn will seek FDA guidance on proceeding with an expedited regulatory plan for approval of leronlimab with existing FDA Fast Track designation for mTNBC

VANCOUVER, Washington, July 19, 2021 (GLOBE NEWSWIRE) — **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, announced today strong preliminary results from its Phase 1b/2 trials and compassionate use with a total of 30 metastatic triple-negative breast cancer (mTNBC) patients. Patients in Phase 1b/2 were treated with leronlimab in combination with carboplatin.

Key findings from the interim 12-month analysis include the following:

- 72% of patients had a decrease in CAMLs (cancer-associated macrophage-like cells) ~30 days after induction of leronlimab
- The decrease in CAMLs was associated with:
  - A ~300% increase in mean progression-free survival (mPFS)
  - A significant ~450% increase in overall survival (OS) at 12 months
- High CCR5 in tumor tissue biopsies may help to stratify patients likely to progress on leronlimab
- Decreases in CAMLs and CTCs (circulating tumor cells) appear to be related to slower progression and lower mortality
- CAMLs appear to identify populations that are responding to leronlimab

Daniel Adams, Director of Clinical Research & Development, Creatv MicroTech, Inc., stated, "While these are only interim results at the12-month point, our ability to rapidly monitor and identify patients that appear to respond to leronlimab using a single tube of blood is quite an encouraging finding. The fact that greater than 70% of patients saw positive changes in circulating tumor cells after a single dose of leronlimab was made even more informative by their dramatic increases in both progression-free survival and overall survival. The fact that a large group of patients taking leronlimab had an mPFS of approximately 6 months is well beyond that experienced with current treatment options available to these women, who typically have mPFS of approximately 2 months. This result is even more amazing as these women did not even reach mOS in 12 months, considering the typical mOS in this population is only 6 to 7 months."

Scott Kelly, M.D., CytoDyn's Chief Medical Officer and Chairman of the Board, commented, "We are very excited about these preliminary results and are eager to discuss the next regulatory steps based on this data. Based on leronlimab's mechanism of action, we believe these results may provide tangible hope for patients suffering from mTNBC, and potentially other forms of cancer. As we have said previously, we believe CytoDyn will evolve into an oncology-focused company as well as other potential indications."

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, added, "Today's results validate the strategic decision by CytoDyn to pursue leronlimab's potential cancer indications. We have built a team that is now advancing leronlimab towards potential marketing approval across many indications and therapeutic areas. The importance of this opportunity is tremendous, especially in patients with limited therapeutic options such as mTNBC."

About Leronlimab

The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat Human Immunodeficiency Virus (HIV) and metastatic cancer. The first indication is combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized IgG4 mAb that binds to CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including nonalcoholic steatohepatitis (NASH). Leronlimab has been studied in 16 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with HIV standard care in patients with multi-drug resistance to current available classes of HIV drugs).

Leronlimab, among various potential applications, is a viral-entry inhibitor in HIV/AIDS. It binds to CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab does not work on other strains of HIV (for example X4), however, R5 is the most dominant strain of HIV. Five clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies. Cancer research has shown CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control (for example, through angiogenesis). Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 97% in a murine xenograft model. As a result, CytoDyn is conducting two clinical trials, one, a Phase 2 in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second, a Phase 2, basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor plays a central role in modulating immune cell trafficking to sites of inflammation. After completing two clinical trials with COVID-19 patients (a Phase 2 and a Phase 3), CytoDyn initiated a Phase 2 investigative trial for post-acute sequelae of SARSCOV-2 (PASC), also known as COVID-19 Long-Haulers. This trial will evaluate the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, CytoDyn plans to pursue clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

CytoDyn is also conducting a Phase 2 clinical trial for NASH to evaluate the effect of leronlimab on liver steatosis and fibrosis. Preclinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH, which is a leading cause of liver transplant. About 30 to 40 percent of adults in the U.S. live with NAFLD, and 3 to 12 percent of adults in the U.S. live with NASH. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19, and oncology.

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a critical role in the ability of HIV to enter and infect healthy T-cells and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

CytoDyn successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies inHIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File in July 2020 and

subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. On July 1, 2021, CytoDyn announced that it had submitted a dose justification report to the FDA, an integral step in the resubmission process for its BLA. CytoDyn also completed a Phase 2b/3 investigative trial with leronlimab used as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it could support a label extension approval. Clinical results to date from two trials have shown that leronlimab can maintain a suppressed viral load in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen to once a week subcutaneous dose of leronlimab. Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

CytoDyn is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 long haulers, and a Phase 2 clinical trial for NASH. CytoDyn has already completed a Phase 2 and Phase 3 trial for mild-to-moderate and severe-to-critical COVID-19 patients, respectively, for which CytoDyn did not meet its primary or secondary endpoints except for the secondary endpoint in the critically ill subpopulation. More information is at www.cytodyn.com.

Forward-Looking Statements

This press release 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 specifically include statements about leronlimab, its ability to provide positive health outcomes, 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 determination of leronlimab's efficacy to treat HIV patients with multiple resistance to current standard of care, COVID-19 patients, and mTNBC patients, among other indications, by the U.S. Food and Drug Administration 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 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 Form10-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 press release.

CONTACTS

Investors:
Cristina De Leon
Office: 360.980.8524
ir@cytodyn.com

JULY 22, 2021

INVESTOR PRESENTATION

Vyrologix (leronlimab – PRO 140)

Forward-Looking Statements & Information

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 specifically include statements about leronlimab, its ability to provide positive health outcomes, 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 determination of leronlimab's efficacy to treat COVID-19 by the U.S. Food and Drug Administration 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 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.

Robust Pipeline – Leronlimab

1) Cancer program
    - mTNBC & Compassionate use
        - Testimonies
        - Follow up with FDA
    - Basket trial
2) COVID-19 Long-Hauler
    - Will send Phase 3 protocol to FDA
    - Bio marker data
3) COVID-19 trials in Brazil (different definitions)
    - Critical – 316 patients
    - Severe - 612 patients
4) COVID-19 (Philippines – India)
5) BLA submission process
    - Final timeline for completion (Oct-15-2021)
6) NASH trial
    - CT1 and PDFF + Biomarker
7) Biomarker Lab Dr. Chris Recknor

Cancer Program – Leronlimab

1) Cancer program
    - mTNBC & Compassionate use
        - Testimonies
        - Follow up with the FDA
    - Basket trial

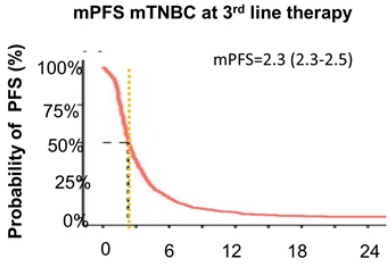
Preliminary Interim Task 1 Report:

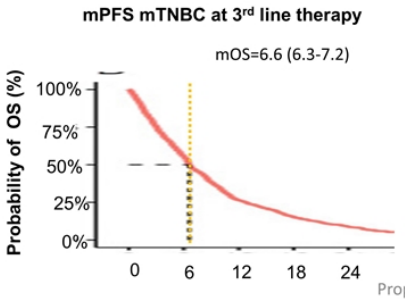
Pre-Analysis of mTNBC from Trial 756 (Compassionate Use) and Trial 706 (mTNBC)

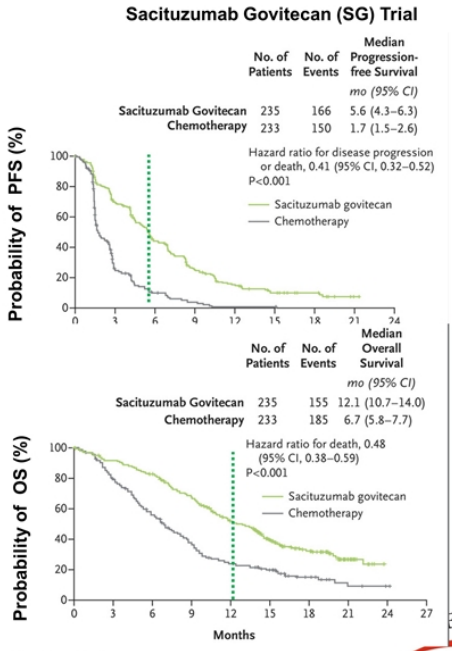
CytoDyn

July 15th, 2021

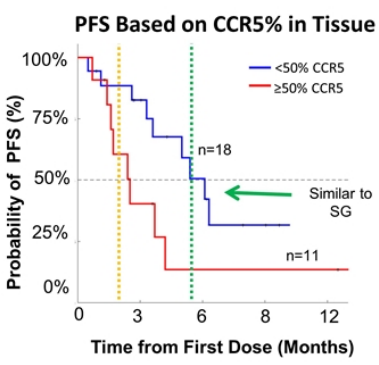
Overviewing mTNBC relapse clinical data
mPFS=1.5-2.6 : mOS= 5.8-7.7



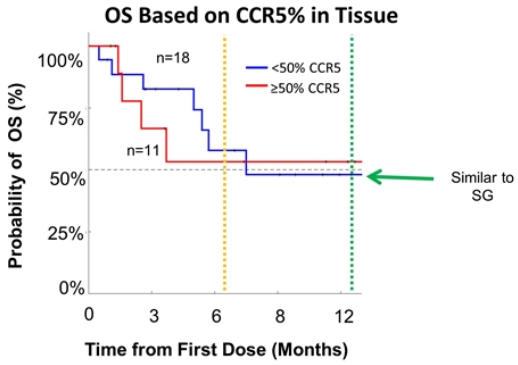




Comparing CCR5 expression from Tissue Samples



HR=3.0 (95%CI 1.0-9.1)
P=0.09112

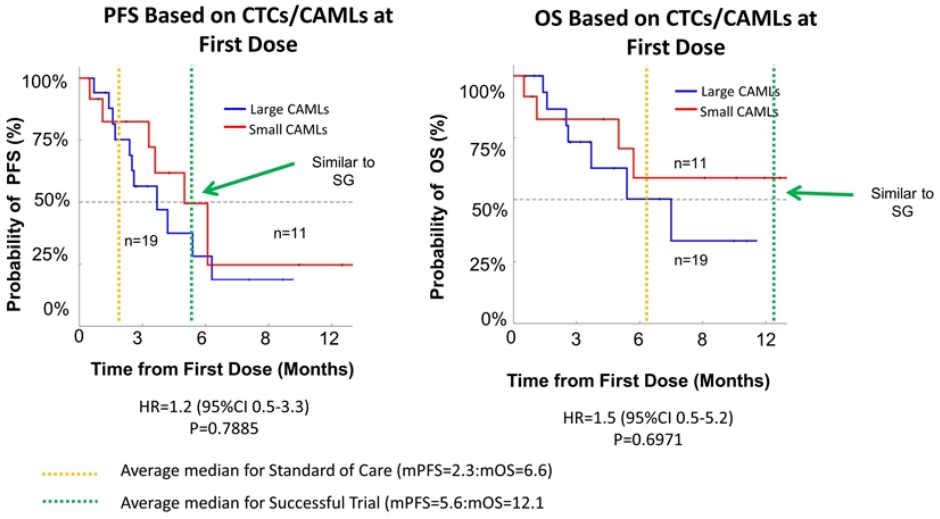


HR=0.8 (95%CI 0.2-2.9)
P=0.9767

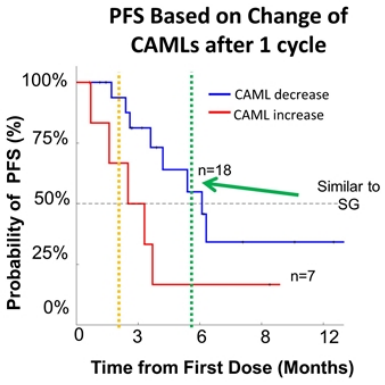
Average median for Standard of Care (mPFS=2.3:mOS=6.6)

Average median for Successful Trial (mPFS=5.6:mOS=12.1

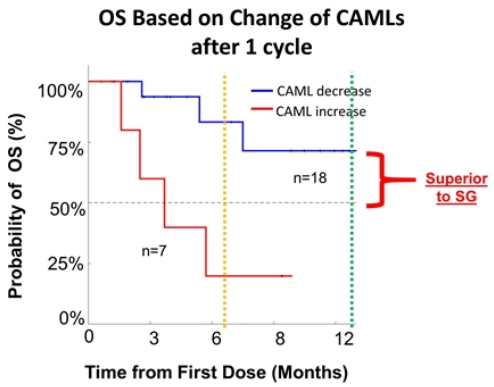
Circulating Stromal Cells (CAMLs) at First Dose



Change in Circulating Stromal Cells (CAMLs) at 30 days (1 full cycle)



HR=3.8 (95%CI 0.9-15.4)
P=0.1350



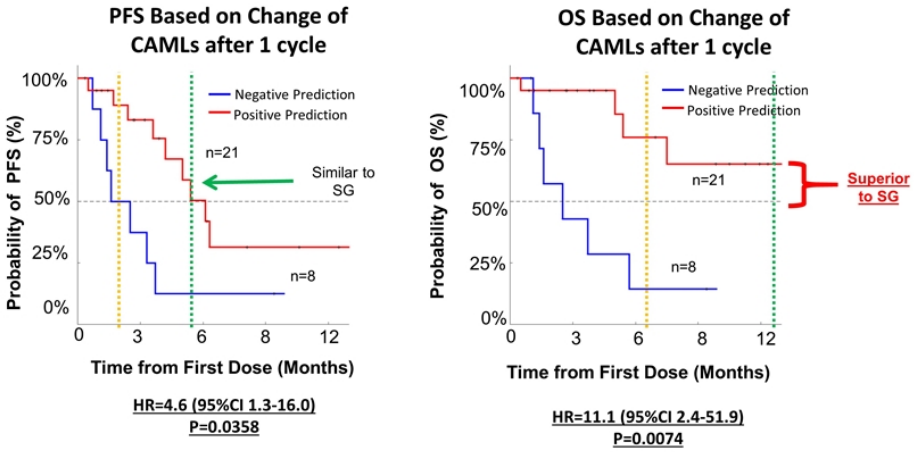
HR=15.4 (95%CI 2.2-1186.6)
P=0.0243

Average median for Standard of Care (mPFS=2.3:mOS=6.6)

Average median for Successful Trial (mPFS=5.6:mOS=12.1

CREATV BIO

Predicting Outcomes using LifeTracDx Algorithm Within 1 treatment cycle



Average median for Standard of Care (mPFS=2.3:mOS=6.6)

Average median for Successful Trial (mPFS=5.6:mOS=12.1

Summary

- **Goal of Interim Analysis is to compare PFS and OS in relation to Standard of Care (SOC) or Sacituzumab Govitecan (SG) Trial**
  - Goal one: Have a mPFS >2.3 (SOC) or >5.6 (SG)
  - Goal two: Have a mOS >6.7 (SOC) or >12.1 (SG)
- **CCR5 in Tissue Staining**
  - Low CCR5 in tissue partially predicted treatment response
  - Low CCR5 trended for better PFS, BUT had no effect on OS
  - mPFS for patients with <50% CCR5 in tissue was ~5.6 months
  - No difference was seen in mOS between high and low CCR5 expression
- **CAMLs and CTCs are Baseline (Prior to Induction)**
  - Prior to First dose of Leronlimab CTCs/CAMLs DID NOT predict for response
- **Decrease in CAMLs/CTCs after 1 cycle of Leronlimab (~30 days)**
  - 72% of patients had a decrease in CAMLs after 30 days
  - This decrease was associated with a significant ~300% increase in mPFS
  - Also associated with a significant 450% increase in overall (& median) survival at 12 months

Overall Summary

- High CCR5 may stratify patients likely to progress on Leronlimab
- Decreases in CAMLs/CTCs appear to be related to slower progression and lower mortality
- Leronlimab appears to have efficacy superior to standard of Care in specific populations
- CAMLs appeared to identify populations that are responding to Leronlimab
- Decreases in CAMLs after Leronlimab induction were seen in ~72% of patients which were associated with a significant 450% increase in overall survival at 12 months

COVID-19 Long-Hauler - Leronlimab

Responses to COVID-19

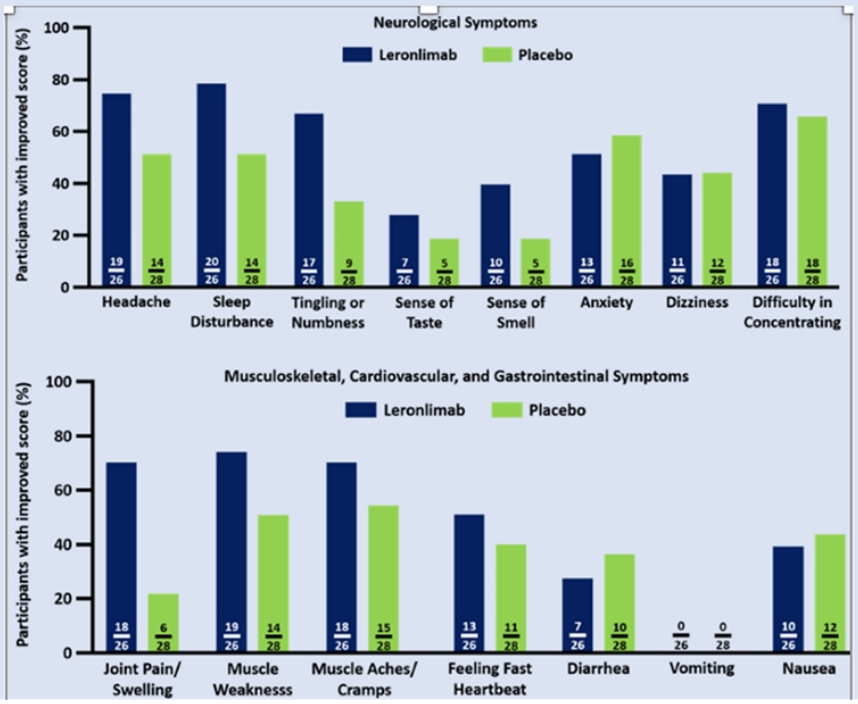
(1) Appropriate inflammation response balanced by appropriate healing.
A normal release of cytokines causes blood vessel walls to become leakier to promote healing of damaged tissue via inflammation.

(2) Inappropriately high inflammation
A cytokine storm may occur when too many pathogens enter the body at once, or if the body secretes the wrong type of cytokine early in the immune response, in which case the excessive cytokines can't accurately direct the immune system to clear out the pathogen. Because nearly every organ has cytokine receptors, almost every part of the body is susceptible to the negative effects of a cytokine storm. Excess cytokines cause blood vessels to become overly porous and result in low blood pressure. That, in turn, depletes organs of oxygen and could eventually cause death

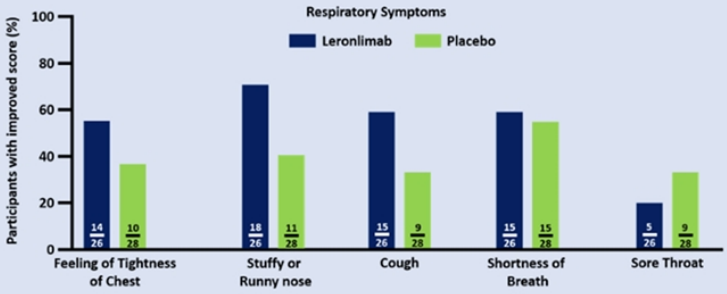
(3) Inappropriate low inflammation with inappropriately high healing.
Dysregulated immune function and to imbalance of cytokines
Possible reactivation of Virus EBV, HSV, etc./ disruption of normal commensal bacteria

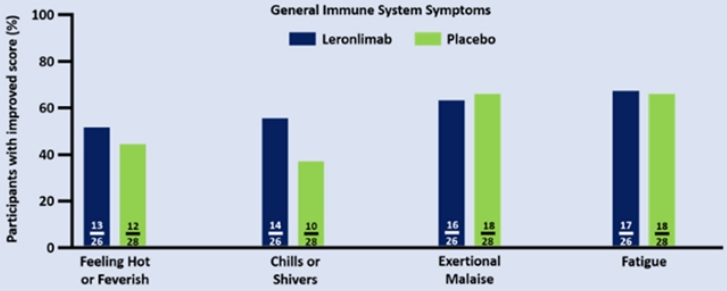
24 symptoms examined in the CD15 trial along with cytokine and cellular biomarkers

COVID-19 Long-Hauler – Leronlimab

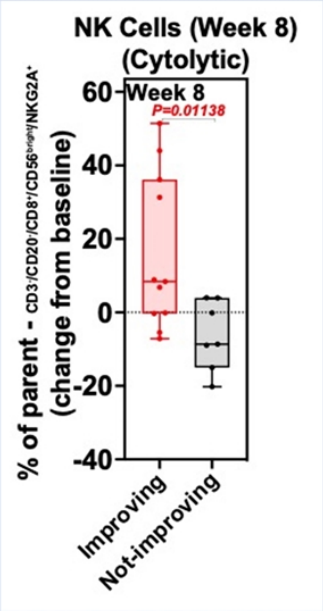


COVID-19 Long-Hauler – Leronlimab

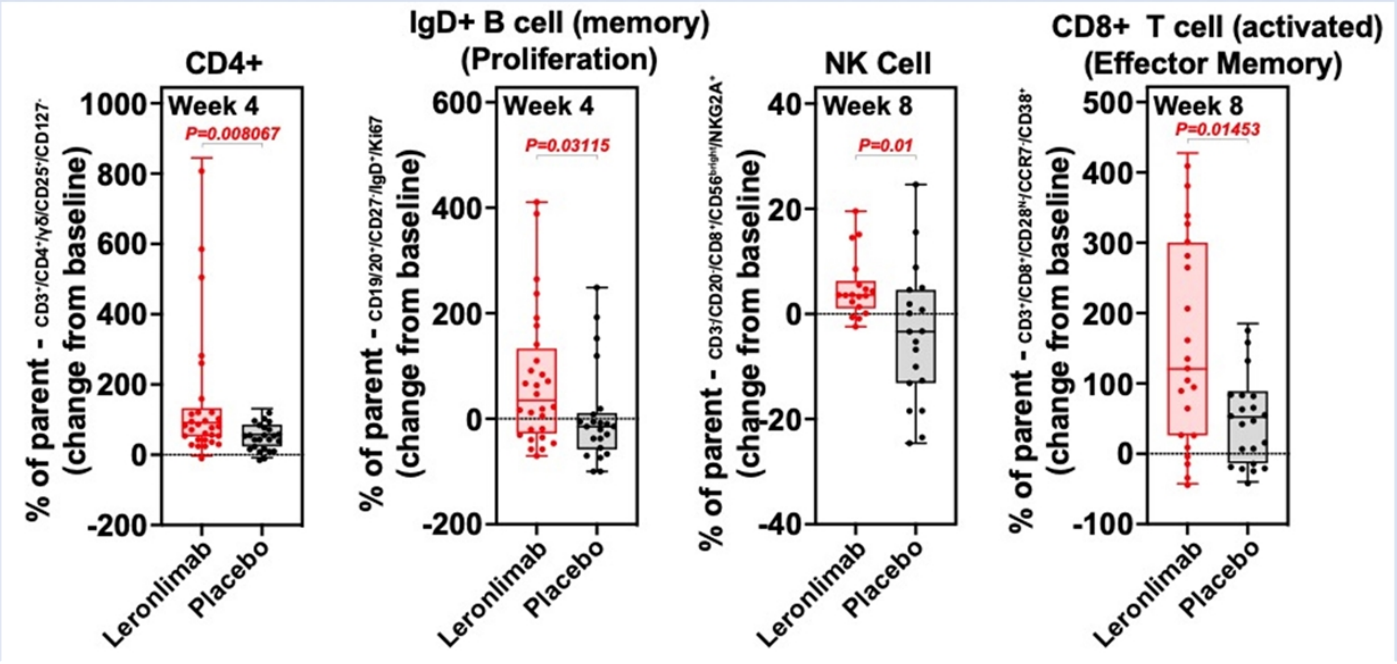




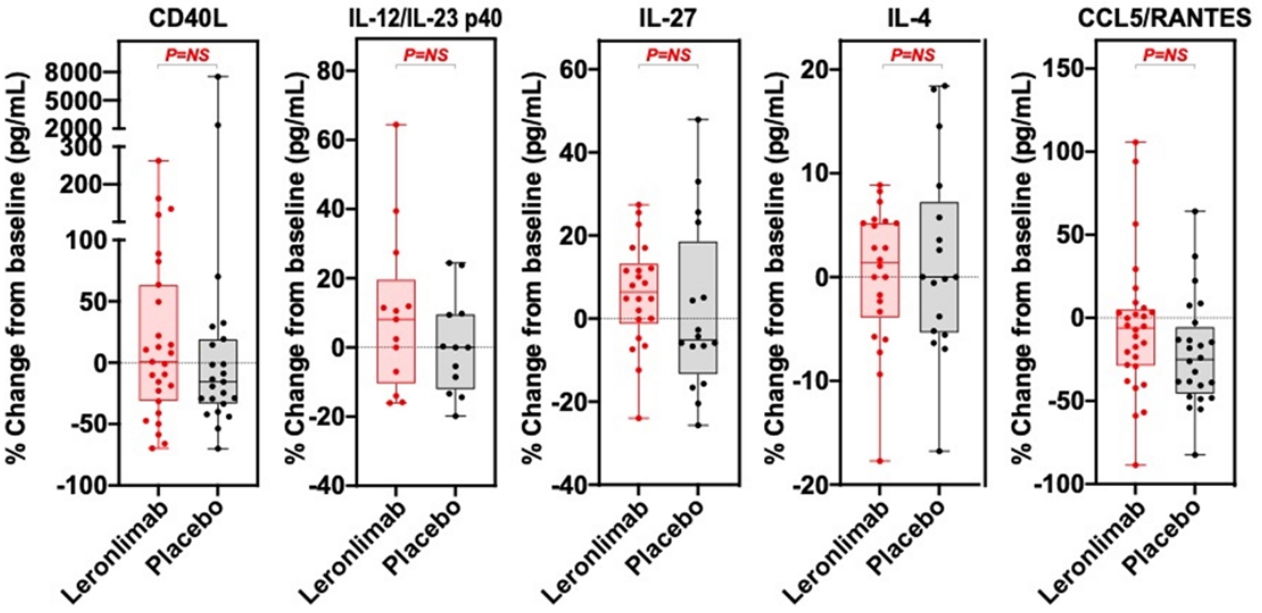
COVID-19 Long-Hauler – Leronlimab



COVID-19 Long-Hauler – Leronlimab

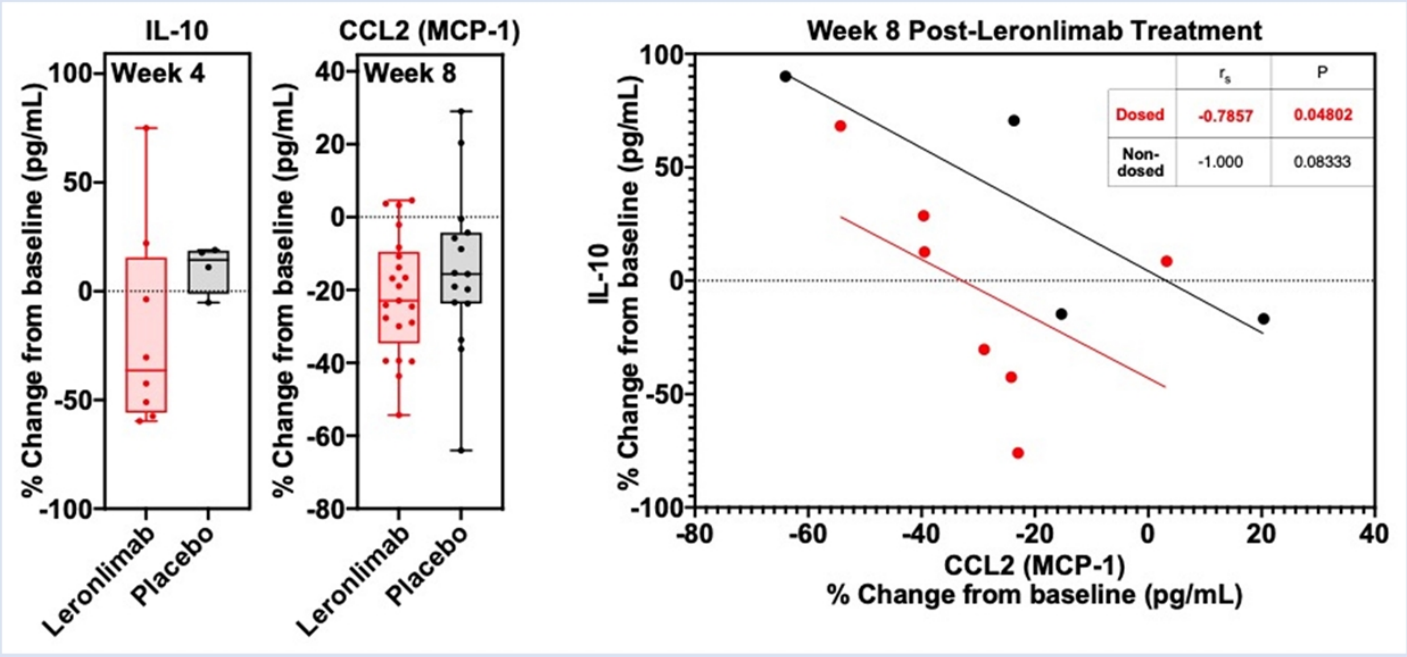


COVID-19 Long-Hauler – Leronlimab



Week 4

COVID-19 Long-Hauler – Leronlimab



COVID-19 Long-Hauler - Leronlimab

Results:

- Symptom improvement noted on daily diary
- Baseline dysregulated Immune function in control and treated groups
  - Down regulated T cells
  - Immune system shifted Th2
  - M2 monocyte polarization predominant up to 66%
- Biomarkers correlating with symptom improvement
  - Restoration of immune function
  - Immune system shifted Th1
  - M2 monocyte polarization reduced

COVID-19 Trials – Leronlimab

3) COVID-19 trials in Brazil (different definitions)
   Critical – 316 patients
   Severe - 612 patients
4) COVID-19 (Philippines – India)

COVID-19 Trials – Leronlimab

5) BLA submission process
Final timeline for completion (Oct-15-2021)

NASH Trial– Leronlimab

6) NASH trial
CT1 and PDFF + Biomarker

Diagnostic Lab for CytoDyn by Dr. Recknor – Leronlimab

7) Biomarker Diagnostic test Lab Dr. Chris Recknor
   a) Receptor Occupancy Test