
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): June 21, 2021

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

000-49908
(Commission File Number)

83-1887078
(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 June 21, 2021, CytoDyn Inc. issued a press release and posted the press release and an investor presentation on its website in connection with an investor community webcast held on that date to discuss the results from the recently unblinded data from its COVID-19 long-haulers trial. Copies of the press release and investor presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Copies of the press release and investor presentation described in Item 7.01 are furnished with this report as Exhibits 99.1 and 99.2, respectively.

EXHIBIT INDEX

| <u>Exhibit</u> | <u>Description</u> |
|----------------|---|
| 99.1 | Press Release dated June 21, 2021 |
| 99.2 | Investor Presentation dated June 21, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURE

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: June 21, 2021

By: /s/ Antonio Migliarese

Antonio Migliarese
Chief Financial Officer



CytoDyn Inc. Announces Positive Preliminary Results of Unblinded Data from Long-Haulers Trial Showing Greater Improvement in Leronlimab Group over Placebo in 18 of 24 Symptoms

VANCOUVER, Washington, June 21, 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 preliminary results after unblinding the data from its COVID-19 long-haulers clinical trial.

The purpose of this clinical trial was to assess the safety and efficacy of leronlimab administered as weekly subcutaneous injection in subjects experiencing prolonged symptoms (> 12 weeks) of COVID-19. The primary outcome was change from baseline in daily COVID-19-related symptom severity score through Day 56. Secondary outcomes included progression (or worsening) of COVID-19-associated symptoms through Day 56 compared to baseline. Patient symptoms were self-reported daily throughout the 56-day evaluation period and reported electronically. The symptom scores were rated as severe, moderate, mild, and none.

Chris Recknor, M.D., CytoDyn’s Chief Operating Officer and Head of Clinical Development, commented, “We are very pleased with the preliminary results from our long-haulers trial, which showed a greater improvement in the leronlimab patient group over placebo in 18 of 24 COVID-19 symptoms. Although the study was not designed to show statistically significant differences due to the small sample size of 56 patients, clinically meaningful improvements in leronlimab over placebo were observed for cough, stuffy/runny nose, shortness of breath, tightness of chest, feeling of fast heartbeat, fatigue, muscle aches/cramps, muscle weakness, joint pain/swelling, chills/shivering, feeling hot or feverish, difficulty in concentration, sleep disturbance/insomnia, headache, dizziness, tingling/numbness, sense of taste, and sense of smell. Of the remaining 6 symptoms, sore throat, exertional malaise, anxiety, nausea, and vomiting had no clinically meaningful change. Diarrhea was worse in leronlimab treated compared to placebo. Biomarkers at multiple timepoints are being analyzed to help determine reasons for response and to provide better insight into the mechanism of action of leronlimab. As in other previous trials with leronlimab, no adverse safety signals were noted. Once our final analysis is performed, we will seek to hold discussions with the FDA regarding next steps.”

Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer, concluded, “Prior to the commencement of this trial, the FDA advised us that our long-haulers trial is considered an exploratory trial; thus, a follow-on trial will be necessary prior to potential approval. Our hope, following the FDA’s review of all data, is that the agency will grant us a Breakthrough Therapy designation and provide guidance for a Phase 3 trial protocol. It is important to note that we must await the review of regulatory agencies in the U.S. and abroad and their guidance on how to proceed forward. However, I am impressed with leronlimab’s performance in this trial by demonstrating a positive improvement for a significant number of symptoms for the benefit of patients suffering from COVID long-haulers. In my opinion, our hypothesis that leronlimab is an immune modulator has received a very positive boost from this trial. We look forward to providing more detailed results in our conference call today at 1pm PT.”

About Long-Hauler CD15 Trial

This CD15 trial was similar to a Phase 2 study with the purpose of exploring up to 24 symptoms for a hint of efficacy prior to initiation of a scientific confirmation study. Phase 2 studies in general, and this study

in particular, are limited because they set out to explore and do not pre-specify an appropriate primary endpoint. Also at this stage, precise biological variability for individual symptoms in this specific patient population is unknown. Consequently, the ranking of symptoms by superior leronlimab improvement relative to placebo could change. However, study results from this Phase 2 study can now be used to quantify that variability and use it to pre-specify endpoints to design a confirmatory study precisely.

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, amongst many things, 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 1b/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 SARS COV-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 2b pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn has been working diligently to refile 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. CytoDyn expects to refile its BLA in the first half of the calendar year 2021 or shortly thereafter. 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 keep the viral load suppressed 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 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 press release.

CONTACTS

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JUNE 21, 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) COVID-19 Long-Hauler
 - CD15 Exploratory Symptoms/Biomarkers
 - CD18 Phase 3: Biomarker/Symptoms/Autonomic/PFT
 - CD19 Phase 2: Biomarker after treatment
 - CD20 Phase 2: Biomarker/Cognitive
 - CD21 Phase 2: Biomarker/MRI fibrosis
- 2) COVID-19 trials
 - Critically ill
 - Severe
- 3) BLA submission
- 4) Cancer program
- 5) Cancer program
 - 1) mTNBC
 - 2) Basket trial
 - 3) Requesting Pre-BLA meeting with the FDA
- 6) NASH trial
 - CT1 and PDFF + Biomarker
- 7) Stroke
 - RTT data promising
 - Biomarker

CD-15: Long-Hauler Symptoms

Repeated Measures Statistical Analysis

- Models for the raw ordinal data would not converge.
 - This might be due to the study sample size and small cell sizes for each severity and treatment group combination.
- A model for daily change from baseline as a continuous variable was fit.
- Accounting for all daily data in a repeated measures model is thought to be a more precise method than only using a single day, however it was not pre-specified.
- Specifically, terms for treatment and a baseline covariate were included as fixed-effects with a repeated effect for time.
- Every symptom converged for this model.

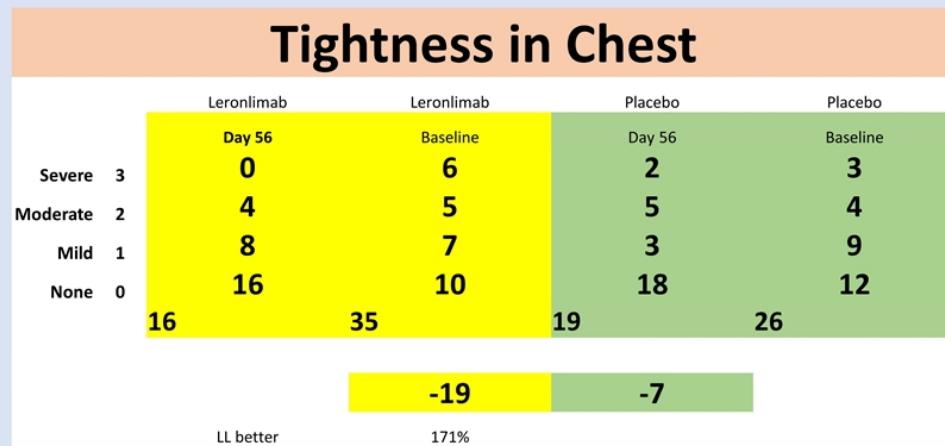
CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average

Joint Pain & Swelling

| | | Leronlimab | Leronlimab | Placebo | Placebo |
|----------|---|------------|------------|---------|----------|
| | | Day 56 | Baseline | Day 56 | Baseline |
| Severe | 3 | 0 | 2 | 1 | 3 |
| Moderate | 2 | 4 | 14 | 9 | 7 |
| Mild | 1 | 12 | 9 | 4 | 7 |
| None | 0 | 12 | 3 | 14 | 11 |
| | | 20 | 43 | 25 | 30 |
| | | | | -23 | -5 |
| | | LL better | | 360% | |

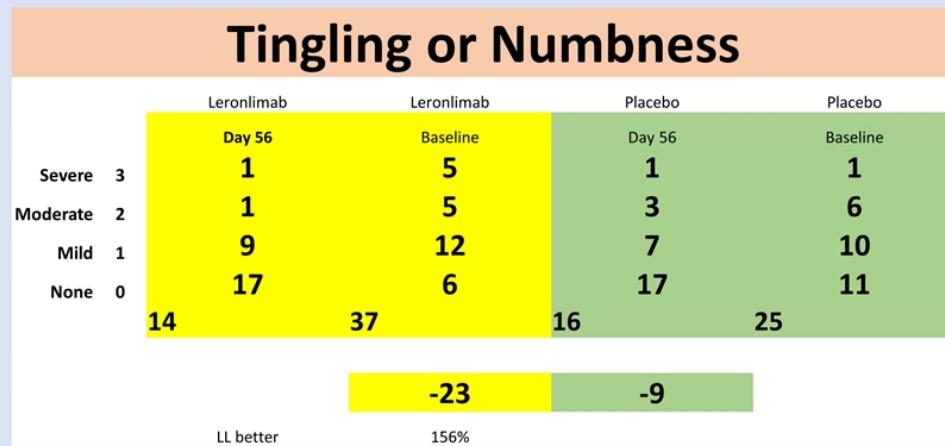
Repeated Measures p -value < 0.0001

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average



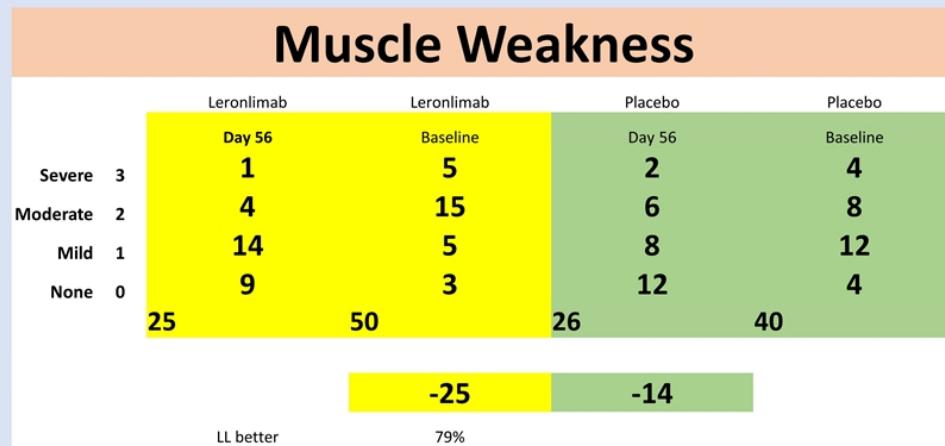
Repeated Measures p -value < 0.0001

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average



Repeated Measures p -value < 0.0001

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average



Repeated Measures p -value = 0.013

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average

Sleep Disturbance (Insomnia)

| | | Leronlimab Day 56 | Leronlimab Baseline | Placebo Day 56 | Placebo Baseline |
|----------|---|----------------------|------------------------|-------------------|---------------------|
| Severe | 3 | 2 | 10 | 4 | 8 |
| Moderate | 2 | 1 | 12 | 4 | 11 |
| Mild | 1 | 13 | 4 | 11 | 7 |
| None | 0 | 12 | 2 | 9 | 2 |
| | | 21 | 58 | 31 | 53 |
| | | | | -37 | -22 |
| | | LL better | | 68% | |

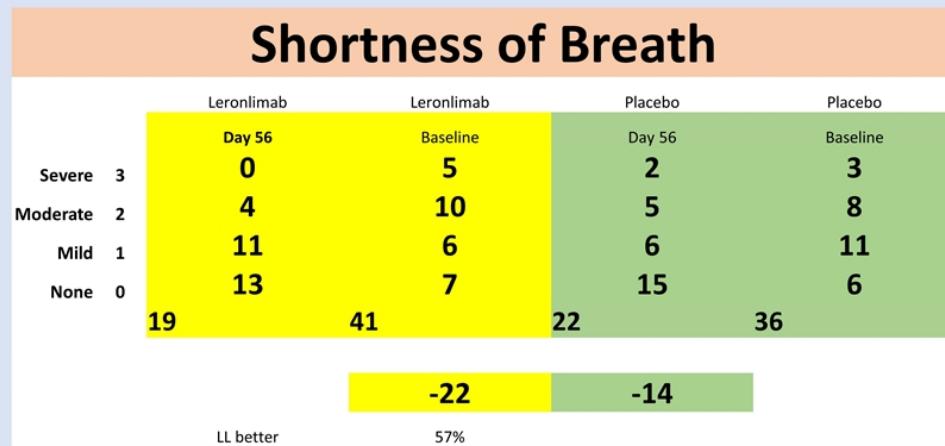
Repeated Measures p -value = 0.01

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average

| Headache | | | | |
|------------|----------------------|------------------------|-------------------|---------------------|
| | Leronlimab Day 56 | Leronlimab Baseline | Placebo Day 56 | Placebo Baseline |
| Severe 3 | 1 | 5 | 3 | 4 |
| Moderate 2 | 1 | 10 | 3 | 9 |
| Mild 1 | 12 | 10 | 6 | 8 |
| None 0 | 15 | 3 | 16 | 7 |
| | 17 | 45 | 21 | 38 |
| | | -28 | -17 | |
| | LL better | 65% | | |

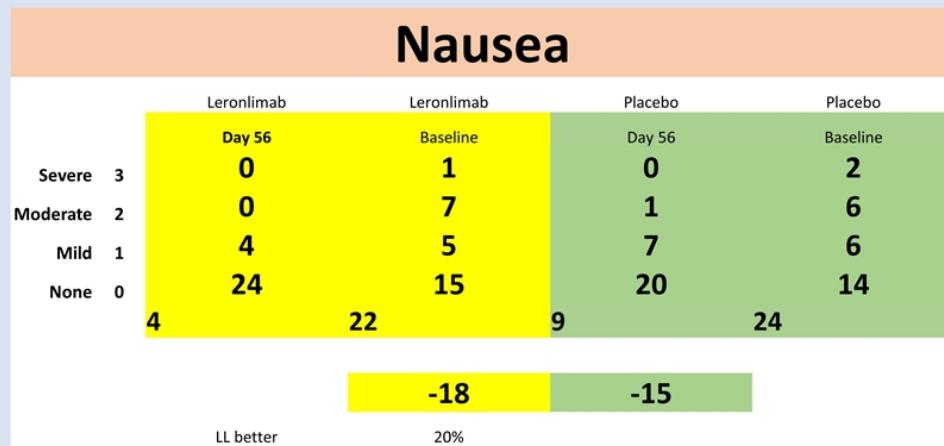
Repeated Measures p -value < 0.0001

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average



Repeated Measures p -value = 0.032

CD-15: Long-Hauler Symptoms
Primary Endpoint baseline thru day 56 Average



Repeated Measures p -value = 0.028

Robust Pipeline – Leronlimab

- 1) COVID-19 Long-Hauler
- 2) COVID-19 Critically ill
- 3) COVID-19 Severe

- 1) Brazil
- 2) India
- 3) Philippines
- 4) Other

Robust Pipeline – Leronlimab

Biomarker and Mechanism of Action

Laboratory work finding MOA of leronlimab for each indication
Dosage of leronlimab

Role of Leronlimab in HIV (Summary)

Monotherapy, PrEP and Cure

| Program | Status |
|------------------|---|
| HIV- Monotherapy | Phase 3, label expansion, protocol submitted to the US FDA |
| HIV - PrEP | One dose/month – Phase 2 – Animal study was very successful for use of leronlimab in PrEP for one dose per month. Publication has been submitted to journal and potential Phase 2 is to initiate in 2021. |
| HIV - Cure | 5 patients/Timothy Brown model – Phase 2 – This trial is currently searching for potential HIV patient who is in need of bone marrow transplant similar to Timothy Brown. If leronlimab can mimic the delta-32 during a bone marrow transplant by covering all the CCR5 receptor, then the result could be a cure. First patient injection could be 2021. |

Leronlimab Opportunity

Multiple Indications

BLA HIV

Draft Dose Justification Report **30-JUN-21**

Includes Virology Data Analysis

Receptor Occupancy Plan

CD02 and CD03 VF data with ADA and Population PK analysis

Completion to allow for rolling submission:

| | |
|--------------------------------------|-----------|
| BLA Module 1 Administrative | 15-Jul-21 |
| BLA Module 2 – CTD Summaries CMC | 30-Jul-21 |
| BLA Module 2 – CTD Summaries non-CMC | 01-Sep-21 |
| BLA Module 3 – Quality/CMC | 30-Jul-21 |
| BLA Module 4- Non-Clinical Reports | 15-Jul-21 |
| BLA Module 5- Clinical Reports | 15-Oct-21 |

Leronlimab Opportunity

Multiple Indications

Triple-Negative Breast cancer results in 4-6 months
NASH complete enrollment of initial 60 patients end of June
NASH enrollment for biomarkers and CT1/PDFF completion Q4 2021
Long-Hauler Phase 3 completion Q4 2021

Leronlimab Opportunity

Multiple Indications

2021

- 1) BLA submission completion
- 2) Critical COVID-19 completion
- 3) Severe-to-critical COVID-19 completion
- 4) Long-Hauler phase 3 results
- 5) HIV PrEP initiate
- 6) NASH trial results
- 7) MOA results with dosage finding (loading/normal dose)
- 8) Breakthrough Therapy designation for mTNBC filed

Leronlimab Manufacturing

Samsung BioLogics (Commercial Partnership)

Order for 2022 and 2023 at new facility at Samsung

Initial forecast made calendar 1Q20
Updated forecast provided quarterly

Order for 2022 and 2023 at new facility at Samsung



Contract minimum - 1 million vials/yr

Current inventory – 1.1 million vials

2022- 1 million vials minimum

2023 - 2 million vials minimum

- Deal signed April 2019
- Completion of first batch of clinical grade leronlimab in June 2020
- Completion of batches of commercial grade leronlimab in calendar 3Q20-4Q20

