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): January 5, 2021

CERECOR INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-37590		**45-0705648**
(Commission File Number)		**(IRS Employer Identification No.)**

540 Gaither Road, Suite 400, Rockville, Maryland 20850
(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (410) 522-8707

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
Common Stock, $0.001 Par Value	CERC	Nasdaq Capital Market

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 8.01. Other Events.

On January 5, 2021, Cerecor Inc. (the "Company") issued a press release announcing top line data from its proof-of-concept clinical trial of CERC-002 in patients with COVID-19 induced Acute Respiratory Distress Syndrome ("ARDS"). On January 5, 2021, the Company also posted on its website an informational presentation regarding this top line data. Copies of the press release and informational presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein in their entirety by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 5, 2021.
99.2	Informational Presentation.

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 hereunto duly authorized.

CERECOR INC.

Date: January 5, 2021

By: /s/ Christopher Sullivan
Christopher Sullivan
Interim Chief Financial Officer

Cerecor Announces Successful Proof of Concept Data for CERC-002, a Unique LIGHT-Neutralizing Antibody, in Patients Hospitalized with COVID-19 ARDS

- **COVID-19 ARDS patients treated with a single dose of the anti-LIGHT monoclonal antibody CERC-002 demonstrated robust improvement in the primary endpoint (proportion of patients alive and free of respiratory failure over the 28-day study period) compared to placebo (n=62, odds ratio [OR] = 2.62, p=0.059)**
- **A prespecified subgroup analysis of patients ≥ 60 years of age showed that CERC-002 treatment led to a greater than 3-fold increase in likelihood of avoiding respiratory failure and death compared to placebo (n=33, OR = 3.38, p=0.054)**
- **28-day mortality was reduced by approximately 50% in patients treated with CERC-002 (3 patients) vs. placebo (6 patients). There were a total of 4 COVID-19 related deaths in patients on CERC-002 vs. 9 on placebo as of December 2020. These data will be updated and analyzed at the 60-day timepoint**
- **Importantly, CERC-002 showed activity on top of corticosteroids in COVID-19 ARDS (>90% of patients in the trial received corticosteroids and >60% received remdesivir)**
- **CERC-002 dramatically and rapidly reduced serum free-LIGHT levels**
- **CERC-002 was well tolerated with no drug related SAEs and no clinically meaningful differences in immunosuppression or other SAEs between CERC-002 and placebo**
- **The company intends to meet with the FDA and believes that the data support the initiation of a registration trial and filing for Breakthrough Therapy Designation. Additionally, the company is continuing its program in severe pediatric-onset Crohn's disease and is exploring the applicability of CERC-002 in non-COVID-19 ARDS**

ROCKVILLE, Md. and CHESTERBROOK, Pa., Jan 05, 2021 -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare and orphan diseases, today announced results from its exploratory Phase 2 US-based randomized, double-blind, placebo-controlled proof of concept trial (NCT04412057) of the human anti-LIGHT (TNFSF14) monoclonal antibody CERC-002. All patients in this trial were hospitalized with COVID-19 associated pneumonia and mild-to-moderate acute respiratory distress syndrome ("ARDS"). A total of 83 patients (82 treated) were randomized 1:1 to receive standard of care at the sites plus either a single dose of 1,200 mg of CERC-002 or placebo subcutaneously. Due to the protocol allowing patients to receive high flow oxygen prior to randomization, 62 patients were included in the intention-to-treat (ITT) analysis of the primary endpoint.

The trial demonstrated robust improvement in the primary endpoint (proportion of patients alive and free of respiratory failure over the 28-day study period) compared to placebo in COVID-19 patients with ARDS treated with a single dose of the anti-LIGHT monoclonal antibody CERC-002 (n=62, OR = 2.62, p=0.059; the data trended towards statistical significance, p≤0.05). A prespecified subpopulation of patients ≥ 60 years of age showed similar improvement in the primary endpoint (n=33, OR = 3.38, p=0.054). CERC-002-treated patients in the subpopulation of patients ≥ 60 years of age also had a shorter average hospital stay compared with placebo-treated patients.

The data further showed a numerical mortality benefit favoring CERC-002 with 4 patients dying on active drug and 9 on placebo as of December 31, 2020. These data will be updated and analyzed at the 60-day timepoint.

Importantly, >90% of patients received concomitant systemic corticosteroids and >60% received remdesivir. Thus CERC-002 showed activity on top of corticosteroids in COVID-19 ARDS.

No drug-related serious adverse effects (SAEs) were reported in the trial, and there was no increase in infections in CERC-002 treated patients. The large majority of hospitalized COVID-19 patients had elevated LIGHT (TNFSF14) levels in their serum upon admission. Consistent with its targeted mechanism of action, CERC-002 dramatically and rapidly reduced LIGHT levels in nearly all treated patients, while patients on placebo saw a rise in LIGHT levels through Day 5. LIGHT levels were higher in the older patients who have a higher risk of death and respiratory failure. Moreover, these data demonstrate that corticosteroid therapy does not seem to affect serum LIGHT levels and that CERC-002 provides additional benefit on top of corticosteroid therapy.

“I would first like to thank the patients, their families, and the investigators for their participation in this important study,” said Jeff Wilkins, Chief Medical Officer of Cerecor. “We are very excited about these results as they demonstrate the therapeutic potential of CERC-002. In spite of recent advances in the treatment of COVID-19 ARDS patients, COVID-19 remains a global health threat, and this study demonstrates the potential for significant improvement for patients most at risk.”

Garry Neil, Chief Scientific Officer added, “Cytokine release syndrome remains a major cause of death and morbidity in COVID-19 ARDS. We and others have shown that the important immunoregulatory cytokine, LIGHT, plays a critical role in this syndrome – and that such patients have elevated LIGHT levels in their serum, roughly correlating with disease activity.[1] The data from this proof-of-concept study clearly demonstrate that neutralizing LIGHT with CERC-002 can improve clinical outcomes for COVID-19 ARDS patients, even when given to patients on concomitant steroids and remdesivir. In this study, CERC-002 was safe and well tolerated in sick, older, steroid-treated patients in the ICU. These data greatly increase our confidence in the mechanism of action and clinical utility of CERC-002, in COVID-19 ARDS and in other immune diseases. We believe we now have sufficient information to work with the FDA to design a registration trial for COVID-19 ARDS patients. We believe that these data also provide valuable insights that we can apply to other programs including our Crohn’s disease program.”

A presentation of these data updates can be found on the Investors section of the Cerecor website linked here.

CERC-002 (anti-LIGHT monoclonal antibody)

CERC-002 is a fully human anti-LIGHT or tumor necrosis factor superfamily member 14 (TNFSF14) monoclonal antibody licensed from Kyowa Kirin Co., Ltd. It is the only clinical stage anti-LIGHT therapy and has the potential to treat a number of LIGHT-associated immune diseases including cytokine storm-induced COVID-19 ARDS. It is currently in development for pediatric onset Crohn’s disease and cytokine storm induced COVID-19 ARDS. Cerecor has also developed a validated, high sensitivity serum/plasma free LIGHT assay in collaboration with Myriad RBM.

Role of LIGHT in Acute Inflammatory Response
LIGHT (homologous to **L**ymphotoxin, exhibits **i**nducible expression and competes with HSV **g**lycoprotein D for binding to **h**erpesvirus entry mediator, a receptor expressed on **T** lymphocytes) is a cytokine with inflammatory actions encoded by the TNFSF14 gene. LIGHT plays an important role in regulating immune responses in the lung, gut and skin. It stimulates T Cell and B Cell response as well as induces the release of other cytokines such as IL1, IL6, IL-8, IL-10, TNF and GM-CSF. It thus plays a key role in immune responses to viral pneumonia and other diseases.

About Cerecor

Cerecor is a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare and orphan diseases. The company is advancing its clinical-stage

pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases. The company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803, which are in development for congenital disorders of glycosylation and CERC-006, an oral mTORc1/c2 inhibitor in development for the treatment of complex lymphatic malformations. The company is also developing two monoclonal antibodies, CERC-002, and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for treatment of severe pediatric-onset Crohn's disease, and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)), and multiple myeloma (MM). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Disease Designation, which makes all four eligible for a priority review voucher upon FDA approval.

For more information about Cerecor, please visit www.cerecor.com.

Forward-Looking Statements

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Cerecor's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Cerecor's cash position and the need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic; and those other risks detailed in Cerecor's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

For media and investor inquiries

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Chief Commercial Officer
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[1] Perlin DS, Zafir-Lavie I, Roadcap L, et al Levels of the TNF-Related Cytokine LIGHT Increase in Hospitalized COVID-19 Patients with Cytokine Release Syndrome and ARDS. *mSphere*. 2020 Aug 12;5(4):e00699-20.

Exhibit 99.2

CERC-002: Double-blind, Placebo-controlled Proof-of-concept Trial in Patients with COVID-19 Mild to Moderate ARDS

January 2021

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Forward-Looking Statements

This presentation may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor, Inc. ("Cerecor") control, which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: its 2021 outlook; the development of product candidates or products; potential attributes and benefits of product candidates; strategic alternatives for neurological assets and Millipred; and other statements that are not historical.

These statements are based upon the current beliefs and expectations of Cerecor's management but are subject to significant risks and uncertainties, including: reliance on and integration of key personnel; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Cerecor's cash position and the need for it to raise additional capital; risks related to potential strategic alternatives for its neurology assets and Millipred; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and those other risks detailed in Cerecor's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

Executive Summary

Successful Proof of Concept for CERC-002 in Patients Hospitalized with COVID-19 ARDS

- Proof of concept demonstrated in hospitalized patients with COVID-19 related ARDS
  - COVID-19 patients treated with a single dose of CERC-002 demonstrated robust improvement in the primary endpoint (proportion of patients alive and free of respiratory failure over the 28-day study period) compared to placebo (n=62, odds ratio [OR] = 2.62, p=0.059)
  - A prespecified subgroup analysis of patients ≥ 60 years of age showed that CERC-002 treatment led to a greater than 3-fold likelihood of avoiding respiratory failure and death (n=33, OR = 3.38, p=0.054)
  - 28-day mortality was reduced by approximately 50% in patients treated with CERC-002 (3 patients) vs. placebo (6 patients). There was a total of 4 COVID-19 related deaths in patients on CERC-002 vs. 9 on placebo as of December 2020. These data will be updated and analyzed at the 60-day timepoint
  - Importantly, CERC-002 showed activity on top of corticosteroids in COVID-19 ARDS (>90% of patients in the trial received corticosteroids and >60% received remdesivir)
- CERC-002 was well tolerated with no appreciable differences in immunosuppression or other SAE between CERC-002 and placebo
- CERC-002 dramatically and rapidly reduced serum free-LIGHT levels
  - ~85% reduction in free LIGHT achieved in 1 day
- Plan to meet with the FDA regarding a registration trial and filing for Breakthrough Therapy Designation
- Additionally, the company is continuing its program in severe pediatric-onset Crohn's disease and is exploring the applicability of CERC-002 in non-COVID-19 ARDS

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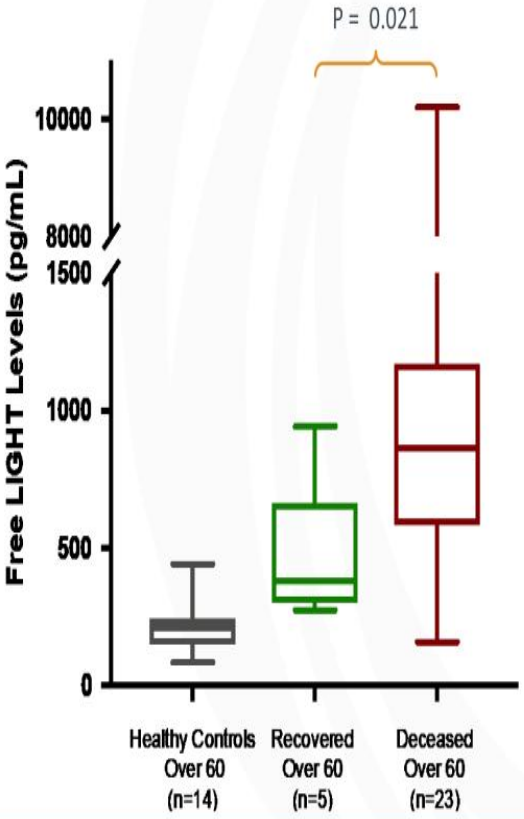
LIGHT is a Central Driver of COVID-19 Related Cytokine Storm

Clinical Trial Initiated After Compelling Biomarker Study Completed June 2020

Association Between Elevated LIGHT and Mortality Strongest in Patients Over 60



Key Implications

- In patients over 60, LIGHT levels were significantly higher in those that eventually died than in those patients that recovered (p=0.021)
- Observed mortality rate higher was higher for patients over 60 of age (82%) compared to patients <60 years (32%)

Elevated LIGHT levels in hospitalized COVID-19 patients were most strongly associated with mortality in patients over 60

1. Perlin et al. (2020) *mSphere*. 5(4):e00699-20.
2. Arunachalam *et al.* (2020) *Science*. 369(6508):1210-1220

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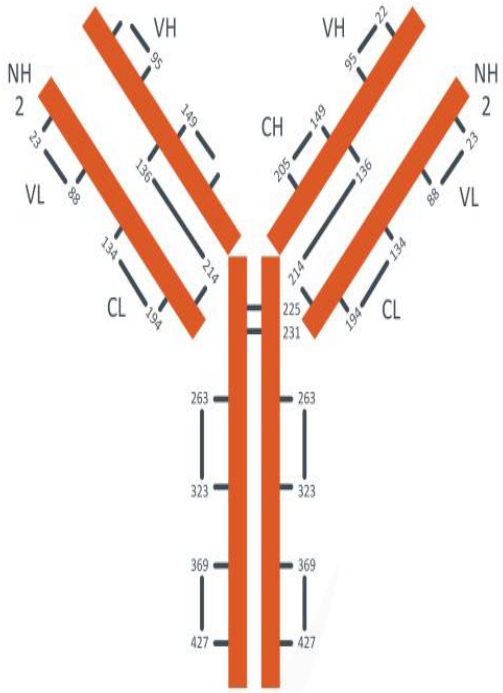
CERC-002: A Novel First-in-Class Anti-LIGHT (TNFSF14) mAb

The only known clinical stage anti-LIGHT antibody

- In-licensed from Kyowa Kirin Co.
- Positive toxicology profile
  - 8-week monkey toxicology study was well tolerated up to 100 mg/kg per week with NOAEL at 60 mg/kg
- Phase I trial successfully completed
  - Up to 1200 mg SQ in healthy volunteers (n=48) without significant toxicity
- Proprietary free LIGHT assay developed in collaboration with Myriad RBM enables a biomarker-based development approach



Discovered at La Jolla Allergy Institute and Licensed by Cerecor in 2016

SQ: Subcutaneous; NOAEL: No observed adverse effect level

CERC-002 Treatment of Cytokine Storm-Induced COVID-19 ARDS

Primary Endpoint: Respiratory Failure and Mortality Over 28 Days

Proof-of-Concept Trial Design

Randomized, Double-blind, Placebo-controlled, Multi-Center, Proof-of-Concept Clinical Trial of CERC-002 in Adults with COVID-19 ARDS

Inclusion Criteria

Hospitalized Patients with Documented COVID-19 Infection and Clinical Evidence of Pneumonia with Mild to Moderate ARDS

Enrollment (N=83)

1:1 Randomization

- **CERC-002 (16 mg/kg [maximum 1200 mg]) on Day 1 by SQ injection + Standard of Care at the site**
- **Placebo-matched SQ injection + Standard of Care at the site**

Primary Endpoint

- The proportion of patients treated with CERC-002 compared with placebo in addition to standard of care at site, alive and free of respiratory failure over 28 days
- 80% power to show an absolute difference of 25% between cohorts

Key Secondary / Exploratory Endpoints

- 1-month mortality
- Change in Pa02/Fi02 ratio
- Time to and duration of invasive ventilation
- LIGHT levels and other biomarkers of inflammation
- Viral load

PaO2 - Partial Pressure of Oxygen, FiO2 - Fraction of Inspired Oxygen

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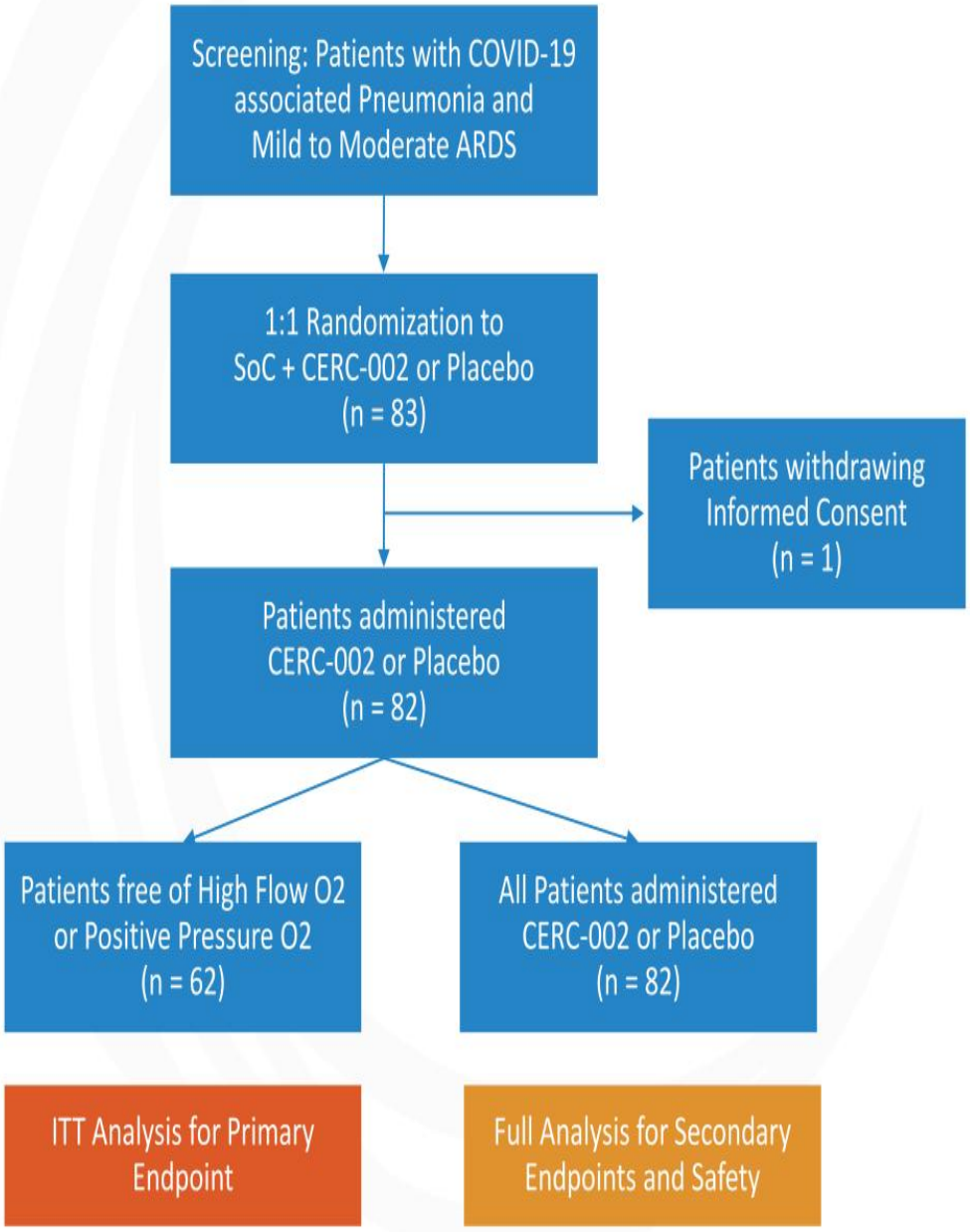
Patient Disposition Chart



Patient Demographics

Characteristic	CERC-002 (n=41)	Placebo (n=42)
Age		
Mean (SD)	59.2 (14.5)	58.1 (14.2)
Age Group		
< 60 years (n, %)	20 (48.8%)	21 (50%)
≥ 60 years (n, %)	21 (51.2%)	21 (50%)
Gender		
Male	25 (61%)	32 (76.2%)
Female	16 (39%)	10 (23.8%)
Free LIGHT Level at Baseline		
Mean (range) pg/mL	348 (63 - 667)	273 (37 - 703)
Race		
White	31 (75.1%)	37 (88.1%)
Black or African American	7 (17.1%)	3 (7.1%)
Asian	2 (4.9%)	0 (0%)
Other	1 (2.4%)	2 (4.8%)
Concomitant Medication		
Systemic corticosteroids	38 (92.6%)	37 (88.1%)
Remdesivir	27 (65.9%)	29 (69.0%)

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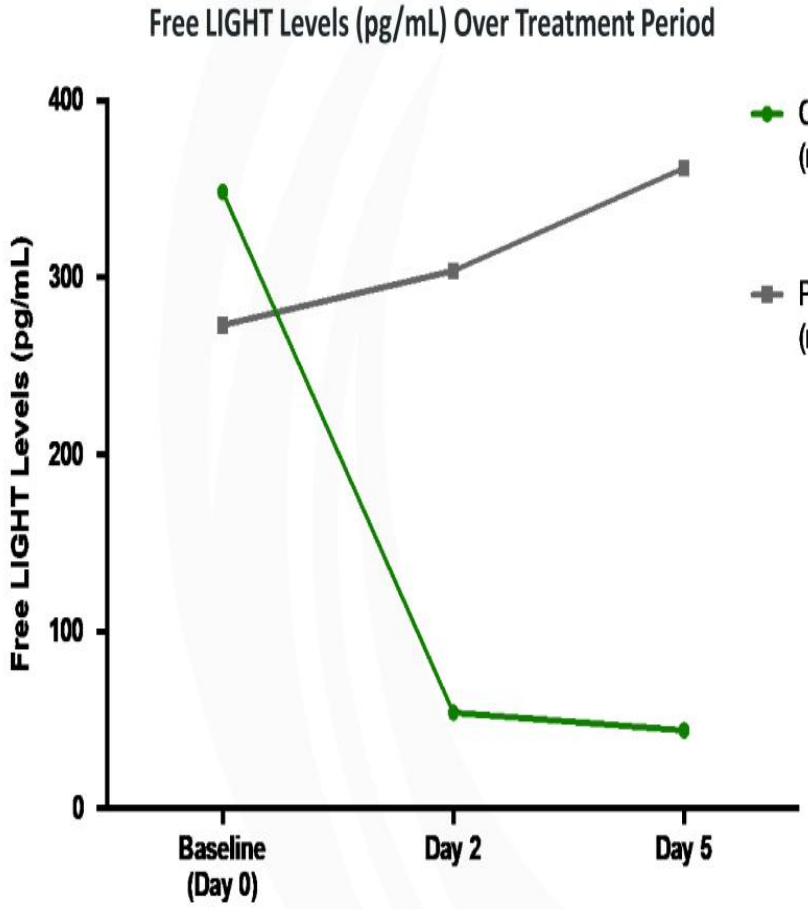
A Single Dose of CERC-002 Reduced Free LIGHT Levels Dramatically and Rapidly



- Mean free LIGHT levels were comparable at baseline across cohorts
- Mean free LIGHT levels were about 100 pg/mL higher in the patients ≥ 60 years-old
- Free LIGHT levels reduced quickly in the active cohort and increased in the placebo cohort
- The pharmacodynamic effect was on top of standard of care where approximately 90% of patients received systemic corticosteroids

Free LIGHT is inhibited by Day 1 and remains low

9| Data on file

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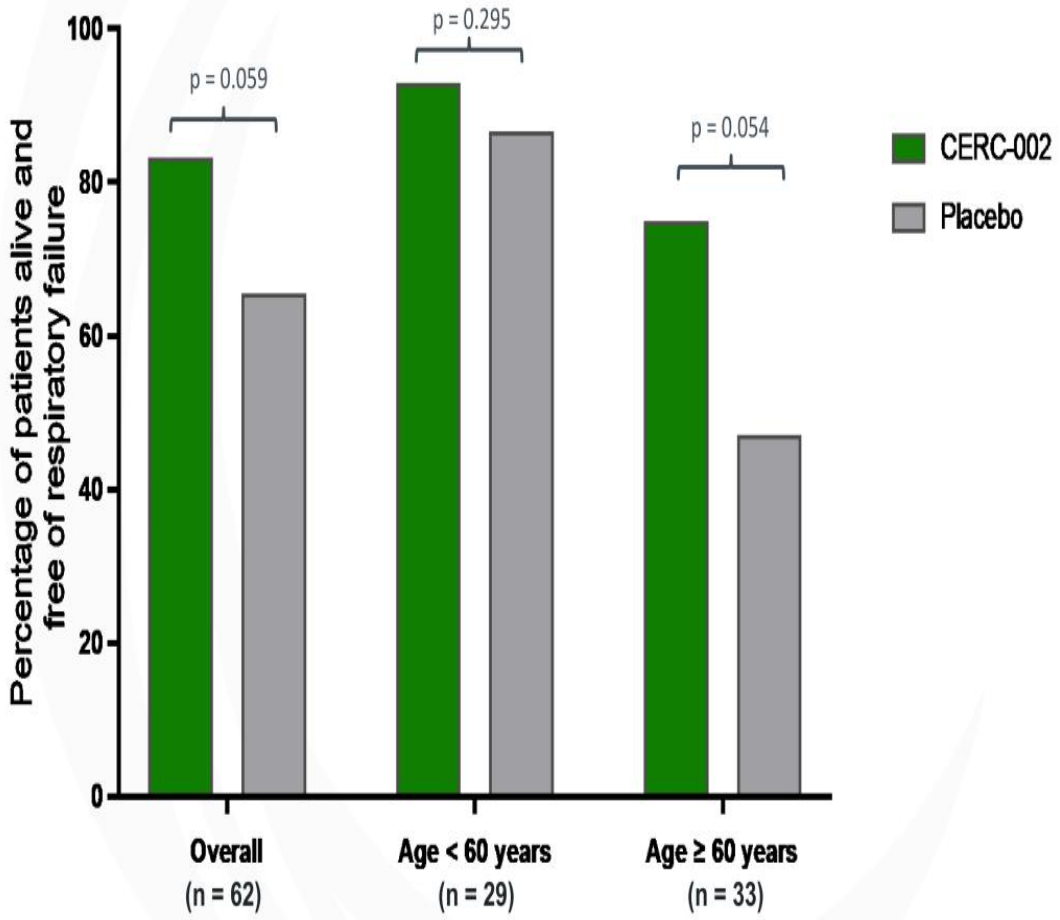
Robust Treatment Effect Demonstrated in Patients at Greatest Risk of Respiratory Failure and Death

Primary Endpoint: Percentage of patients alive and free of respiratory failure at Day 28

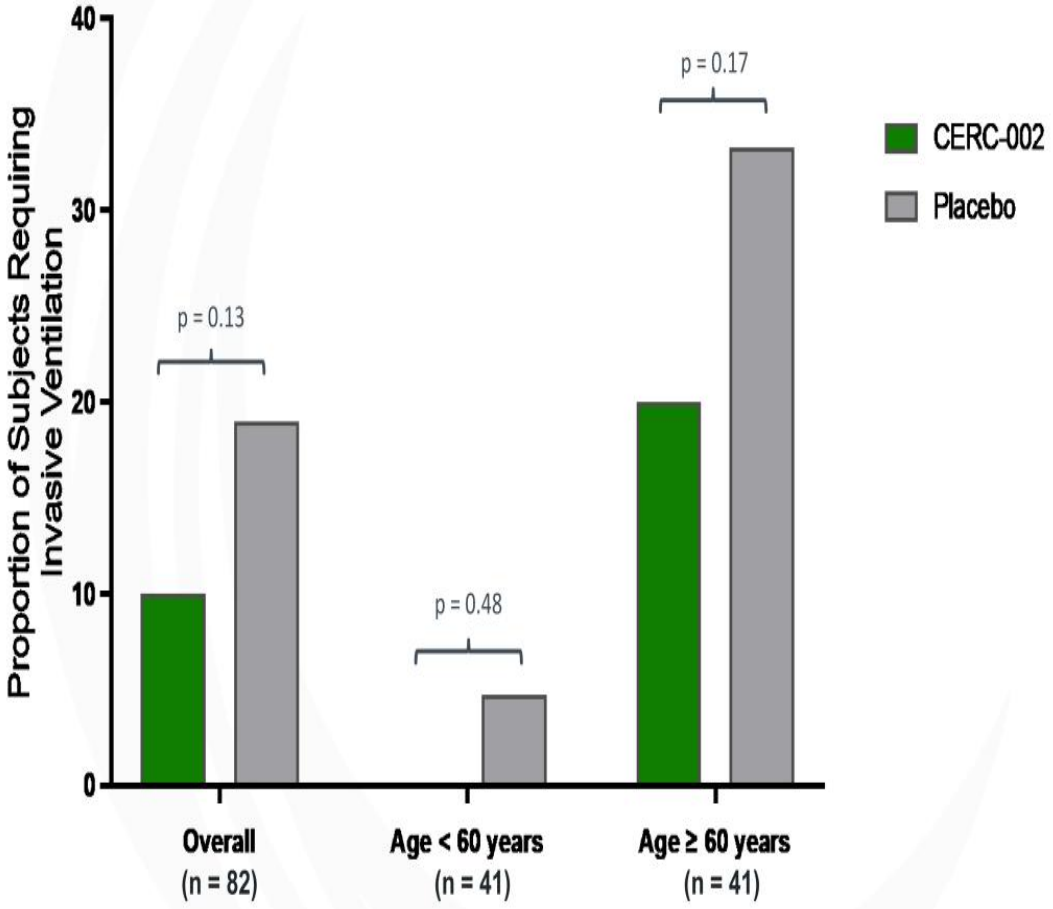


CERC-002 treatment led to a greater than 3-fold likelihood of avoiding respiratory failure and death in patients ≥ 60 years (OR: 3.38, 90% CI: 0.98 – 11.68)

10| Data on file

Clear trend of CERC-002 reducing the need for invasive ventilation; this effect is driven by events in the ≥ 60-year-old subset of patients

Proportion/Percentage of Subjects Requiring Invasive Ventilation



Patients ≥ 60 years treated with CERC-002 were twice as likely to avoid invasive ventilation (OR: 2.0, 90% CI: 0.61 - 6.6)

11| Data on file

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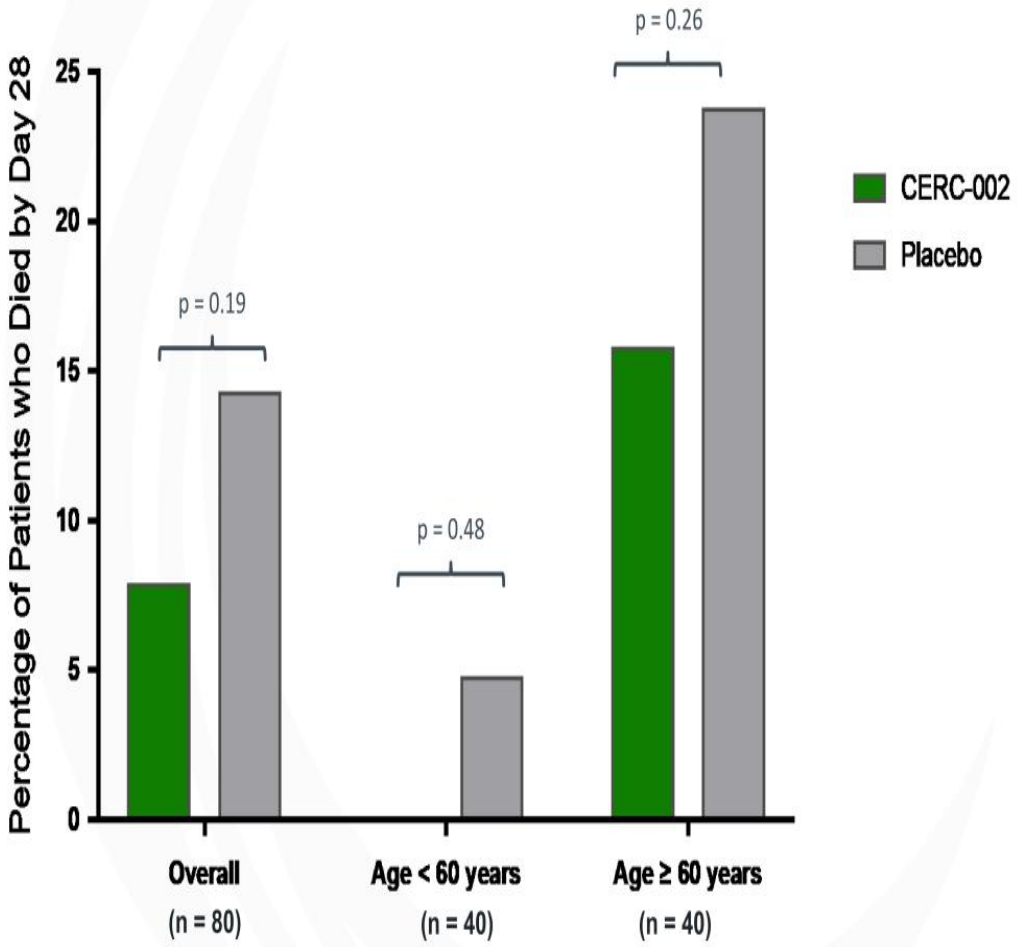
28-day mortality was ~50% lower in patients treated with CERC-002 (3 patients) vs. placebo (6 patients)

COVID-19 related deaths: 4 on CERC-002 vs. 9 on placebo (December 2020)



60-day follow up data in progress

 Data on file

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Safety and Tolerability

- CERC-002 was well-tolerated at a single dose of 16 mg/kg
- No serious adverse events attributable to CERC-002
- Majority of AEs judged to be mild or moderate
- No evidence of increased infections or adverse events related to immunosuppression

	CERC-002 N = 40	Placebo N = 42
Subjects with ≥1 AE (%)	16 (40%)	21 (50%)
Subjects with ≥ Drug-related AE	8 (20%)	6 (14.3%)
AEs > 5%		
Leukocytosis	6 (15%)	4 (9.5%)
Anemia	4 (10%)	3 (7.1%)
Hepatic enzyme increase	4 (10%)	2 (4.8%)
Acute kidney injury	3 (7.5%)	2 (4.8%)
Respiratory failure	3 (7.5%)	3 (7.1%)

 Data on file

Next Steps

- 60-day safety data expected 1Q 2021
- Plan to present full data at a future scientific meeting
- End of phase 2 meeting with FDA to discuss registration trial and filing for Breakthrough Therapy Designation
- Severe pediatric onset Crohn's disease – initial data 1Q 2021
- Currently exploring the applicability of CERC-002 in non-COVID-19 ARDS

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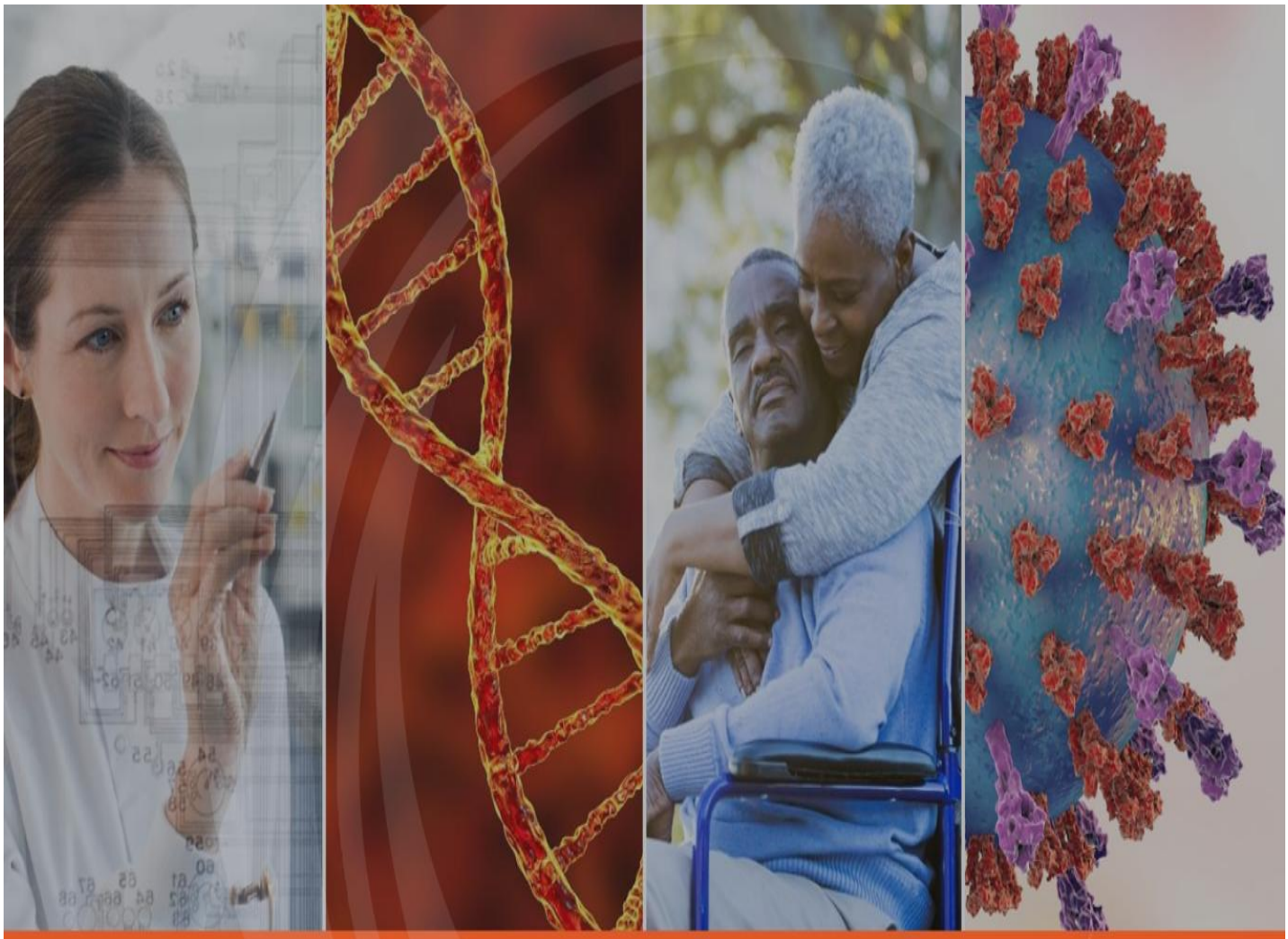

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