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

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported) May 28, 2020**

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**CERECOR INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of incorporation)

**001-37590**

(Commission File Number)

**45-0705648**

(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**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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.

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**Item 1.01. Entry into a Material Definitive Agreement.**

Cerecor Inc. (“Cerecor” or the “Company”) hereby reports that on May 28, 2020, Aevi Genomic Medicine, LLC, a wholly-owned subsidiary of Cerecor (“Aevi”), entered into an Amended and Restated Clinical Development and Option Agreement (the “New CDOA”) with Kyowa Kirin Co., Ltd., formerly known as Kyowa Hakko Kirin Co., Ltd (“KKC” and, collectively with Aevi, the “Parties”) relating to the development and potential commercialization of KKC’s first-in-class anti-LIGHT monoclonal antibody (the “Antibody”). The New CDOA replaces the Clinical Development and Option Agreement between the Parties effective June 6, 2016 (the “Prior CDOA”), which agreement was disclosed by Aevi in a Current Report on Form 8-K filed with the United States Securities and Exchange Commission (the “SEC”) on June 6, 2016 (the “June 6, 2016 8-K”) and redacted copy of which was filed on August 4, 2016 with Aevi’s Quarterly Report on Form 10-Q filed with the SEC for the fiscal quarter ending June 30, 2016.

The New CDOA retains all terms of the Prior CDOA, the summary of which contained in the June 6, 2016 8-K is incorporated by reference into this Current Report on Form 8-K, except that the Parties agreed to:

(1) eliminate certain rights of first negotiation and first refusal that would have been granted by KKC in favor of Aevi if Aevi exercised its option to obtain exclusive rights for the development, manufacture and commercialization of the Antibody”) in the treatment, prevention, and diagnosis of specified pediatric onset rare and orphan inflammatory diseases (including severe pediatric onset inflammatory bowel diseases such as Crohn’s disease and ulcerative colitis and other specified pediatric onset rare and orphan auto-immune diseases (collectively, the “Original Field”) (such option, the “Original Option”); and

(2) extend a time-based termination right in favor of KKC.

In addition to retaining the terms of the Prior CDOA with the changes mentioned above, the New CDOA grants Aevi the right to conduct a signal finding study testing the Antibody in the treatment of COVID-19 acute respiratory distress syndrome (the “COVID Study”). The COVID Study will be conducted under a new investigational new drug application filed by Aevi. The New CDOA also grants Aevi an additional option separate from the Original Option to obtain exclusive rights for the development, manufacture and commercialization of the Antibody in the treatment, prevention, and diagnosis of acute lung injury and acute respiratory distress syndrome (collectively, the “ARDS/ALI Field”) (such option, the “New Option”).

If Aevi exercises the New Option, Aevi will have the exclusive right to develop, manufacture and commercialize the Licensed Products globally in the ARDS/ALI Field pursuant to a pre-agreed license agreement attached to the New CDOA. Aevi will be responsible for the manufacture of the Licensed Products for use in clinical trials as well as for commercialization in the ARDS/ALI Field.

Upon exercise of the New Option, Aevi will be required to pay KKC an initial license fee in the low single-digit millions of dollars. The Company may pay KKC up to an additional \$14 million upon the achievement of certain regulatory milestones related to the Licensed Products in the ARDS/ALI Field. Aevi and KKC will split profits from the Company’s sales of Licensed Products in the ARDS/ALI Field with the Company being entitled to approximately 75% of such profits and KKC being entitled to approximately 25% of such profits. KKC will pay Aevi low double-digit royalties for sales of Licensed Products outside the ARDS/ALI Field. Aevi will be responsible for costs of development of Licensed Products in the ARDS/ALI Field. KKC will have the right to purchase the Licensed Products from Aevi for use outside the ARDS/ALI Field.

The New CDOA will expire if neither the Original Option nor the New Option are exercised during their applicable exercise period or if one of the options is exercised, then upon the expiration of the exercise period for the remaining option if such option is not exercised during such period. Upon any of the license agreements attached to the New CDOA becoming effective in connection with exercise of the relevant option, it will remain in effect so long as there are Licensed Products being commercialized by the Parties or until such license agreement is terminated pursuant to certain termination rights provided to each of the Parties. The New CDOA also contains early termination rights customary for this type of agreement.

The New CDOA (including the pre-agreed license agreements that become effective in connection with exercise of the Original Option and/or the New Option) will be attached as an exhibit to Cerecor's Quarterly Report on Form 10-Q for the fiscal quarter ending June 30, 2020 (the "Form 10-Q"). Cerecor intends to seek confidential treatment for certain terms of the New CDOA at the time of filing such agreements with the Form 10-Q.

The Company does not have any material relationship with KKC other than the New CDOA.

**Item 8.01. Other Events.**

On May 28, 2020, the Company issued a press release announcing that the Company has received clearance from the United States Food and Drug Administration to proceed with a clinical trial of CERC-002 in patients with COVID-19 induced Acute Respiratory Distress Syndrome (ARDS). On May 28, 2020, the Company also posted an updated investor presentation regarding this clearance and the clinical trial. Copies of the press release and investor presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein in their entirety by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated May 28, 2020.</a>
99.2	<a href="#">Investor Presentation.</a>

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: May 28, 2020

/s/ Christopher Sullivan

Christopher Sullivan

Interim Chief Financial Officer



## Cerecor Announces FDA Clearance of IND for CERC-002 in COVID-19 Induced ARDS

*Company to Initiate Multicenter, Placebo-controlled, Randomized Study in June  
Top-line Data Anticipated in Fourth Quarter 2020*

Rockville, MD – May 28, 2020 -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to proceed with a proof-of-concept clinical trial of its anti-LIGHT monoclonal antibody CERC-002 in patients with COVID-19 cytokine storm induced Acute Respiratory Distress Syndrome (ARDS). The study will assess the efficacy and safety of CERC-002. The first patient is expected to enroll in June and top-line data are expected in the fourth quarter of 2020.

The randomized, multi-center, double-blind, placebo-controlled trial will enroll approximately 82 subjects hospitalized with COVID-19 ARDS. The primary objective of the study is to demonstrate that treatment with CERC-002 results in fewer instances of respiratory failure and death versus the standard of care. Patients in the CERC-002 arm will receive a single dose of drug and be followed for 28 days. Key secondary endpoints include ICU length of stay, hospital length of stay and oxygen saturation at the end of study.

The scientific rationale for the study was driven by positive results from a recent biomarker study conducted with Hackensack Meridian Health Network demonstrating elevated levels of the inflammatory cytokine LIGHT in patients hospitalized with COVID-19 cytokine storm-induced ARDS. In the patients studied, LIGHT levels were significantly elevated in the serum of hospitalized patients with COVID-19 versus healthy controls ( $p$  value  $< 0.0001$ ). The highest LIGHT levels were found in patients who required ventilator support, particularly in patients over 60 years of age. Importantly, the data demonstrated elevated LIGHT levels were also strongly linked with mortality ( $p=0.02$ ). The data suggest that LIGHT may play a key role in cytokine storm that leads to ARDS. CERC-002 is a first in class monoclonal antibody targeted against the inflammatory cytokine LIGHT. It is the only anti-LIGHT therapy in clinical development and has the potential to be a treatment option for this patient population in critical need.

Cerecor's chief medical officer, Dr. H. Jeffrey Wilkins stated, *"There is an urgent need for therapies to help patients with COVID-19 ARDS given the ongoing spread of the SARS-CoV-2 and limited therapeutic options. With FDA clearance, we plan to initiate a clinical trial to evaluate anti-LIGHT antibody therapy in patients with COVID-19 cytokine storm-induced ARDS. The trial is designed to generate rapid and definitive results in the fourth quarter of 2020."*

### **CERC-002 (anti-LIGHT monoclonal antibody)**

CERC-002 is an anti-LIGHT (part of the Tumor Necrosis Super Family 14) fully human monoclonal antibody licensed from Kyowa Kirin Co., Ltd. in the clinic. It offers the potential to treat cytokine storm-induced COVID-19 ARDS in the near-term and broader ARDS indication beyond. It is currently being developed as a treatment for Pediatric Crohn's Disease and now cytokine storm induced COVID-19 ARDS. Cerecor has also developed a validated serum/plasma free LIGHT assay in collaboration with Myriad RBM. This assay has

shown to have high sensitivity and specificity for free LIGHT which has been shown to be elevated in patients with active Crohn's disease and with COVID-19 related ARDS.

### **Role of LIGHT in Acute Inflammatory Response**

LIGHT (homologous to Lymphotoxin, exhibits inducible expression and competes with HSV glycoprotein D for binding to herpesvirus entry mediator, a receptor expressed on T lymphocytes) is a cytokine with inflammatory actions encoded by the TNFSF14 gene. LIGHT has been shown to play a key role in the immune response to viral pneumonia. 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.

### **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies. The Company's pediatric rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 programs"), which are therapies for inborn errors of metabolism, specifically disorders known as Congenital Disorders of Glycosylation ("CDGs"). The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation ("ODD") to all three CERC-800 programs, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Still's Disease ("AOSD") and Multiple Myeloma ("MM"). CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations. CERC-002 is an anti-LIGHT monoclonal antibody being developed for the treatment of COVID-19 ARDS and Pediatric-onset Crohn's Disease.

For more information about Cerecor, please visit [www.cerecor.com](http://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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Investor Relations  
Chief Commercial Officer  
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623.439.2220 *office*



## Patient Inspired Science

Establishing a leading, pediatric rare and orphan disease-focused biopharmaceutical company to deliver impactful new medicines to patients





## Forward-Looking Statements

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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: our 2020 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 our 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.

## Highlights

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- Recent Merger of Cerecor and Aevi has created a rich pipeline of novel, 1<sup>st</sup> in class assets all with proven mechanistic rationale
- Only known anti-LIGHT mAb in the clinic, offers potential to treat cytokine storm-induced COVID-19 ARDS in the near-term and broader ARDS indication beyond
  - CERC-002 will enter the clinic in June and is expected to deliver definitive topline POC data in Q4 2020
- CERC-007 (anti-IL-18 mAb), unique molecular target, is expected to deliver initial data in multiple myeloma 4Q 2020 and POC data end of 1Q 2021; initial data in adult onset Still's Disease by 2Q 2021.
- CERC-800 series (substrate replacement therapy for congenital disorders of glycosylation, all orphan designated, Priority Review Vouchers eligible) will release data from CDG-FIRST 1H 2020
  - CERC-801 pivotal trial expected start 4Q 2020, top line data expected 4Q 2021
  - CERC-802 pivotal trial expected start 4Q 2020, top line data expected 3Q 2021
  - CERC-803 pivotal trial expected start 1H 2021, top line data expected 2H 2021
- CERC-006 (dual mTOR inhibitor), topline data expected 2Q 2021



# Clinical-Stage Pipeline

Core Research & Development Areas	Therapeutic Area	Program	Mechanism of Action	Lead Indication	Development Stage				
					Preclinical	Phase 1	Phase 2	Phase 3	Upcoming Milestone
Immunology	Inflammation	CERC-002	Anti-LIGHT mAb	ARDS					Initial Data 4Q 2020
		CERC-002	Anti-LIGHT mAb	Crohn's					Initial Data 1Q 2021
		CERC-007	Anti-IL-18 mAb	AOSD					Initial Data 2Q 2021
Oncology	Blood Cancers	CERC-007	Anti-IL-18 mAb	Multiple Myeloma					Initial Data 4Q20/1Q21
Rare Genetic Disorders	Complex Lymphatic Malformations	CERC-006	Dual mTOR inhibitor	Complex Lymphatic Malformations					Initial Data 2Q 2021
	Congenital Disorders of Glycosylation	CERC-801	D-Galactose replacement	PGM1-CDG					Initial data from CDG-FIRST 1H20
		CERC-802	D-Mannose replacement	MPI-CDG					
		CERC-803	L-Fucose replacement	LADII-CDG					

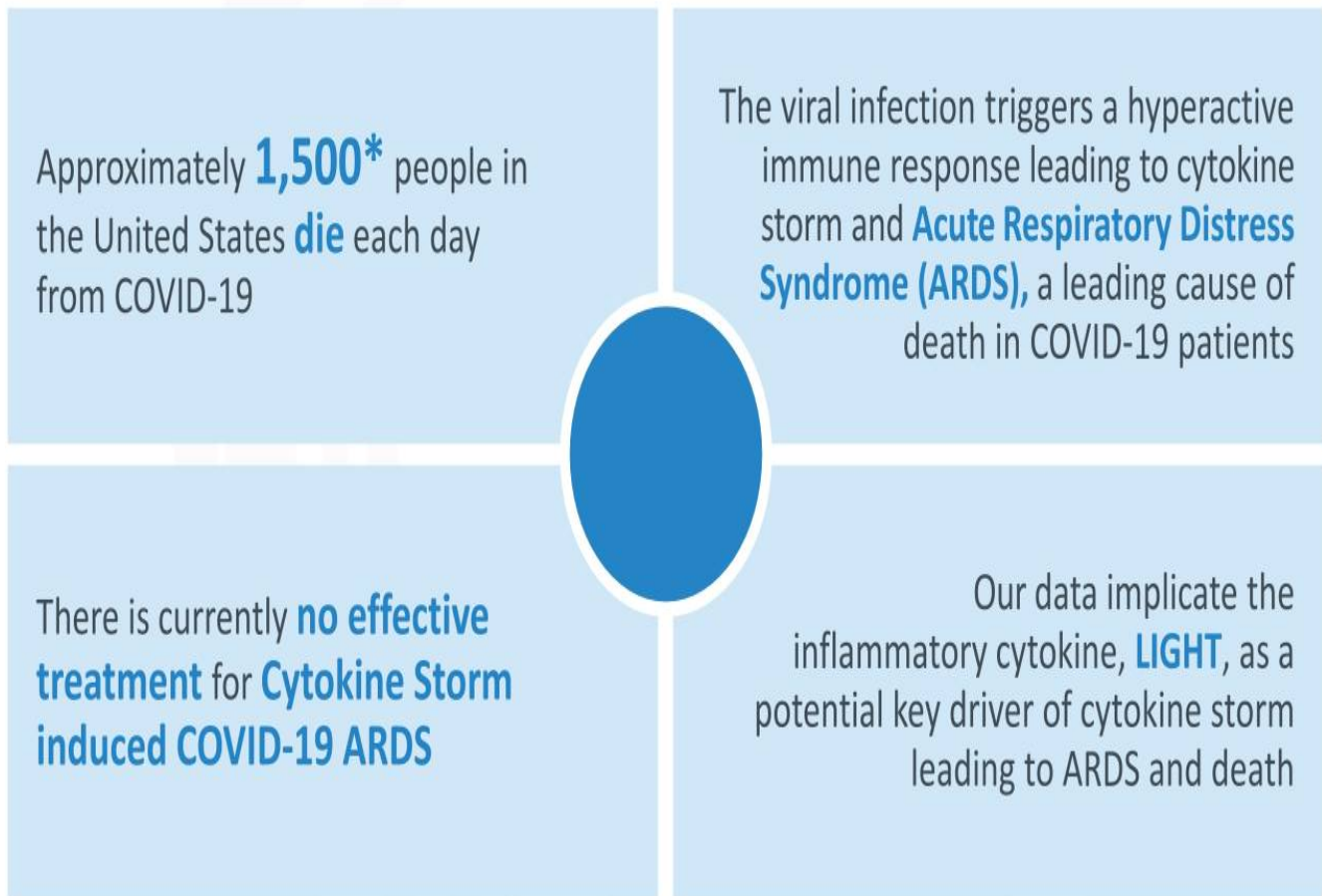
**CERC-002**

Anti-LIGHT monoclonal antibody in clinical studies for  
COVID-19 ARDS



# The Impact of Cytokine Storm Induced COVID-19 ARDS

The outbreak of coronavirus disease 2019 (COVID-19) has created a global health crisis



**CERC-002 is the only know therapeutic currently in clinical development that inhibits the inflammatory cytokine LIGHT**

6 | \*Data from Bloomberg COVID Tracker April 2020



# LIGHT is a Potential Key Driver of Inflammation in the Lung

## LIGHT Impacts Lung Function

frontiers  
in Immunology

ORIGINAL RESEARCH  
published: 19 March 2018  
doi: 10.3389/fimmu.2018.00676



### TNFSF14 (LIGHT) Exhibits Inflammatory Activities in Lung Fibroblasts Complementary to IL-13 and TGF- $\beta$

Ricardo da Silva Antunes<sup>1</sup>, Amit K. Mehta<sup>1</sup>, Lisa and Michael Croft<sup>1,2\*</sup>

<sup>1</sup>Division of Immune Regulation, La Jolla Institute for Allergy and Immunology, San Diego, CA, USA; <sup>2</sup>Department of Medicine, University of California San Diego, La Jolla, CA, USA

The cytokine TNFSF14 (homologous to Lymphotoxin- $\beta$  and competes with HSV Glycoprotein D for binding to CD27) has been shown to promote development of lung tissue remodeling in the pulmonary fibrosis (PF), and systemic sclerosis. In the present report, we show that TNFSF14 and its receptors for LIGHT, are constitutively expressed in lung fibroblasts and

OPEN ACCESS

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Università degli Studi di  
Salerno, Italy

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*J Immunol.* 2018 April 15; 200(8): 2894–2904. doi:10.4049/jimmunol.1701499.

### The TNF superfamily molecule LIGHT Promotes the Generation of Circulating and Lung-Resident Memory CD8 T Cells following an Acute Respiratory Virus Infection

Pritesh Desai<sup>1</sup>, Vikas Tahiliani<sup>1</sup>, Tarun E. Hutchinson<sup>1</sup>, Farhad Dastmalchi<sup>1</sup>, Jessica Stanfield<sup>1</sup>, Georges Abboud<sup>1</sup>, Paul G. Thomas<sup>2</sup>, Carl F. Ware<sup>3</sup>, Jianxun Song<sup>3</sup>, Michael Croft<sup>4</sup>, and Shahram Salek-Ardakani<sup>1</sup>

<sup>1</sup>Department of Pathology, Immunology & Laboratory Medicine, University of Florida, Gainesville, FL, USA

<sup>2</sup>Department of Immunology, St. Jude Children's Research Hospital, Memphis, TN, USA

<sup>3</sup>Department of Microbiology and Immunology, The Pennsylvania State University College of Medicine, Hershey, PA, USA

<sup>4</sup>Division of Immune Regulation, La Jolla Institute for Allergy and Immunology, La Jolla, CA, USA; and Department of Medicine, University of California San Diego, La Jolla, CA, USA

Recent peer-reviewed publications implicate LIGHT in viral pneumonia and acute lung fibrosis



# Hyperactive Immune Response Leads to Cytokine Storm

Cytokine storm induced ARDS is a major driver of poor COVID-19 outcomes

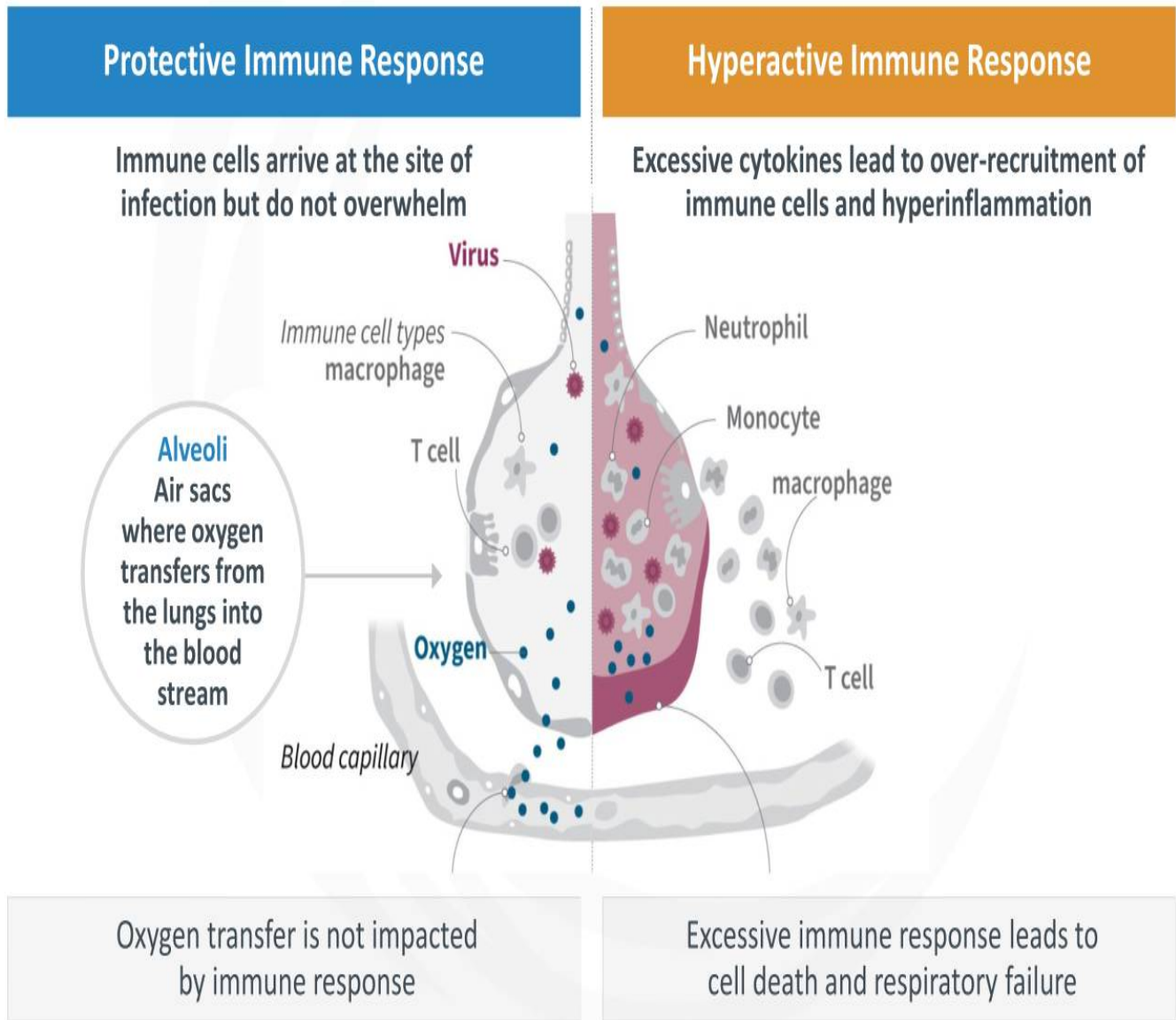


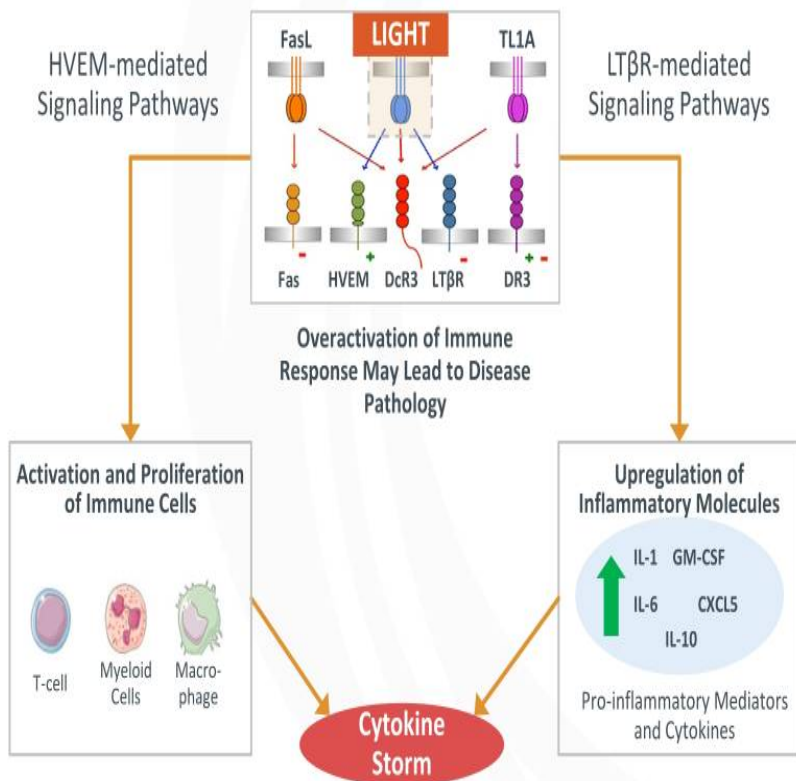
Figure adapted from AFP Graphics

8 | <https://twitter.com/AFPgraphics/status/1246330114171961358/photo/1>



# LIGHT is Potentially a Key Driver of the Inflammatory Response in Cytokine Storm in ARDS

## LIGHT Releases Inflammatory Cytokines and Activates both T Cells and B Cells



- Highly expressed in **neutrophils and macrophages** and induces airway inflammation. It also appears to **exacerbate pulmonary fibrosis** in patients who recover from ARDS
- A critical factor in **COVID-19 cytokine storm**, pulmonary failure and longer-term pulmonary fibrosis and in **broader ARDS etiologies**

Recent biomarker data from hospitalized COVID-19 patients demonstrates elevated LIGHT levels, implicating its role in COVID-19 ARDS



# LIGHT Linked to Ventilation and Mortality in Hospitalized COVID-19 Patients

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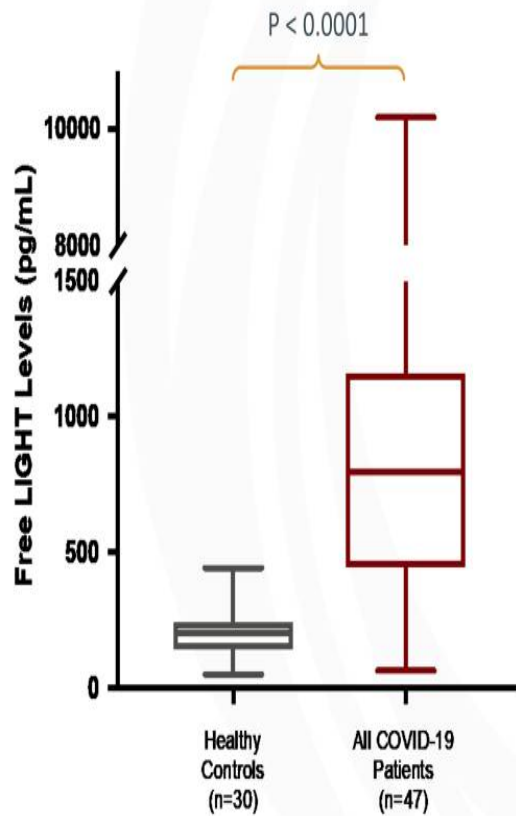
## Very Recent Data Implicate LIGHT in COVID-19 ARDS

- Free LIGHT levels are significantly elevated in the serum of hospitalized patients with COVID-19, with the greatest statistical significance in patients who are ventilated
- Elevated free LIGHT levels are associated with mortality in ventilated patients infected with COVID-19
- The association between LIGHT levels and mortality is strongest among hospitalized patients over 60, a high-risk group for negative outcomes related to COVID-19

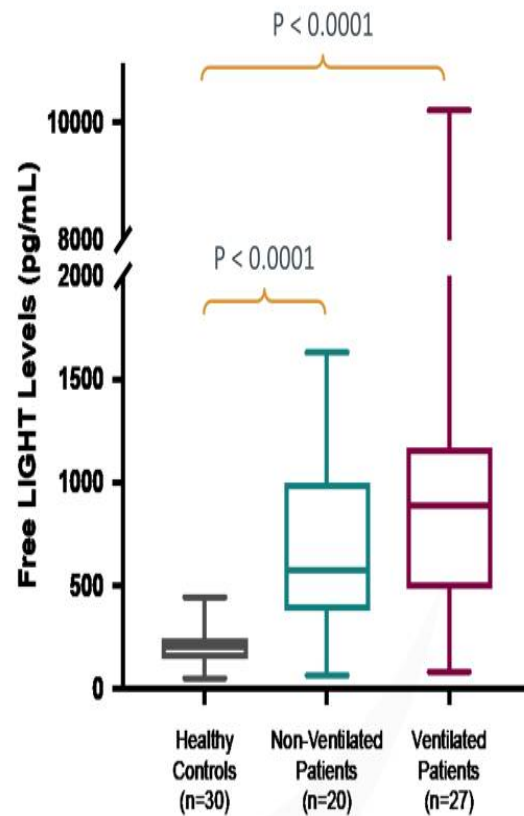
**Reducing LIGHT levels using CERC-002 may prevent severe ARDS and reduce the extent of mechanical ventilation required in patients that develop ARDS**

# LIGHT is Significantly Elevated in Hospitalized COVID-19 Patients

## LIGHT Levels in Hospitalized COVID-19 Patients



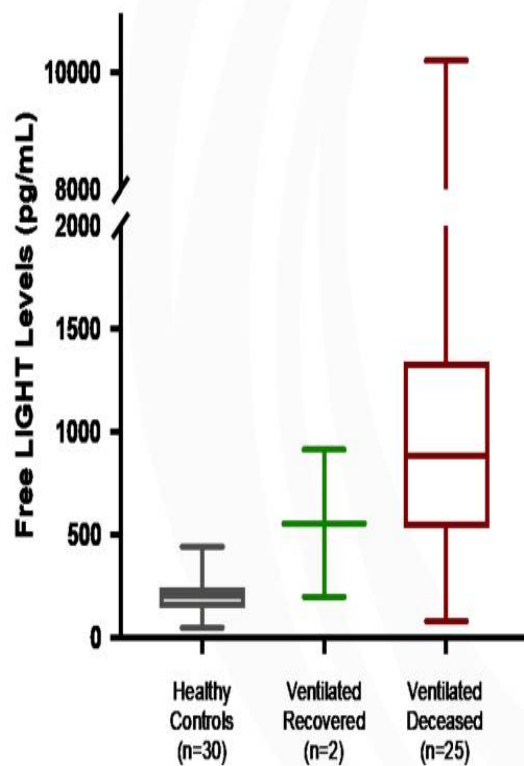
## LIGHT Levels in Both Non-Ventilated and Ventilated Patients



Free LIGHT levels are significantly elevated in serum of hospitalized patients with COVID-19, suggesting that it plays a key role in underlying disease pathophysiology

# Elevated LIGHT Levels are Linked to Mortality in Ventilated Patients

## Elevated LIGHT Levels Associated with Increased Mortality in Ventilated Patients



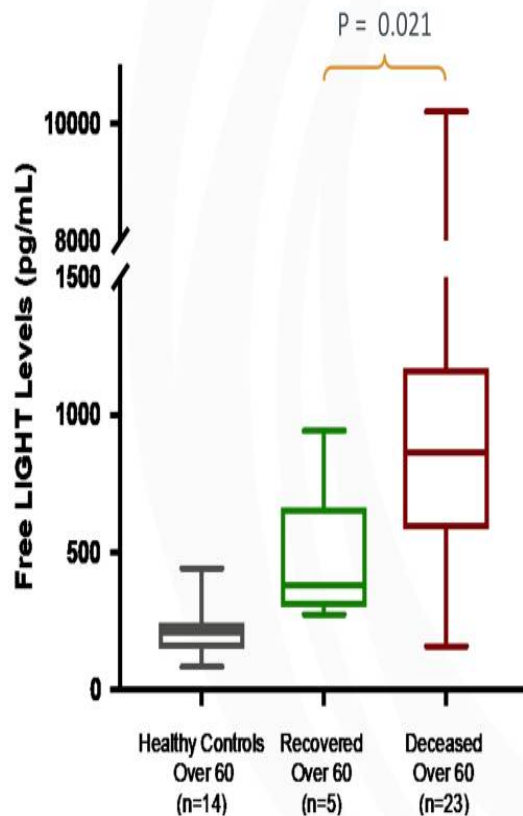
## Key Implications

- In ventilated patients, LIGHT levels were higher in those patients that eventually died than in those patients that recovered. This did not reach statistical significance because of the small number of survivors (n=2)
- Observed mortality rate was higher for ventilated patients (93%) compared to non-ventilated patients (20%)

Elevated LIGHT may be a predictor of mortality in COVID-19 ARDS patients, most notably in those being treated with invasive mechanical ventilation

# Elevated LIGHT is Most Strongly Linked to Mortality in Patients 60+

## Association Between Elevated LIGHT and Mortality Strongest in Patients Over 60



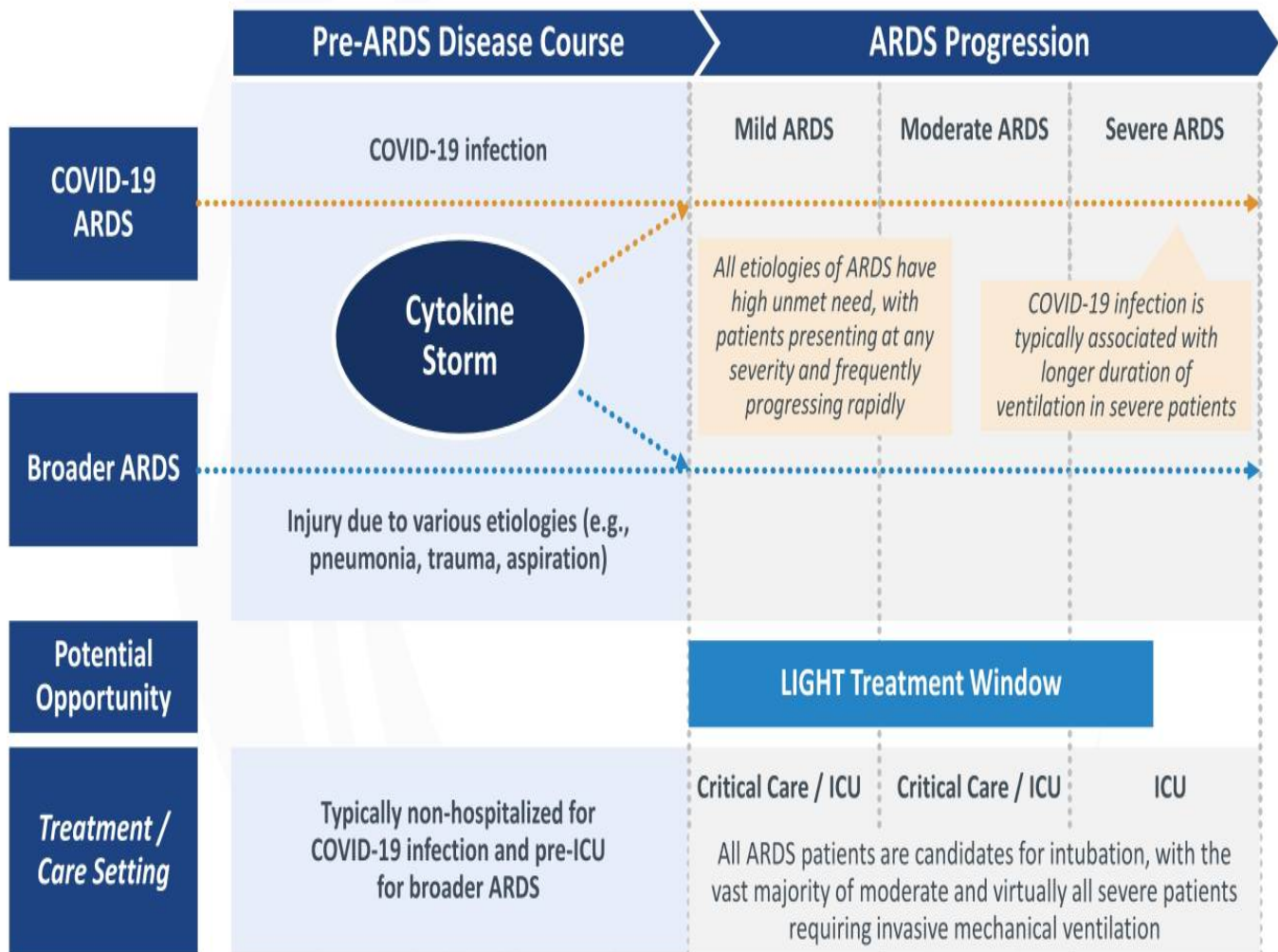
## Key Implications

- 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

# Cytokine Storm Drives ARDS Across Etiologies

Patients may progress rapidly and often require invasive mechanical ventilation



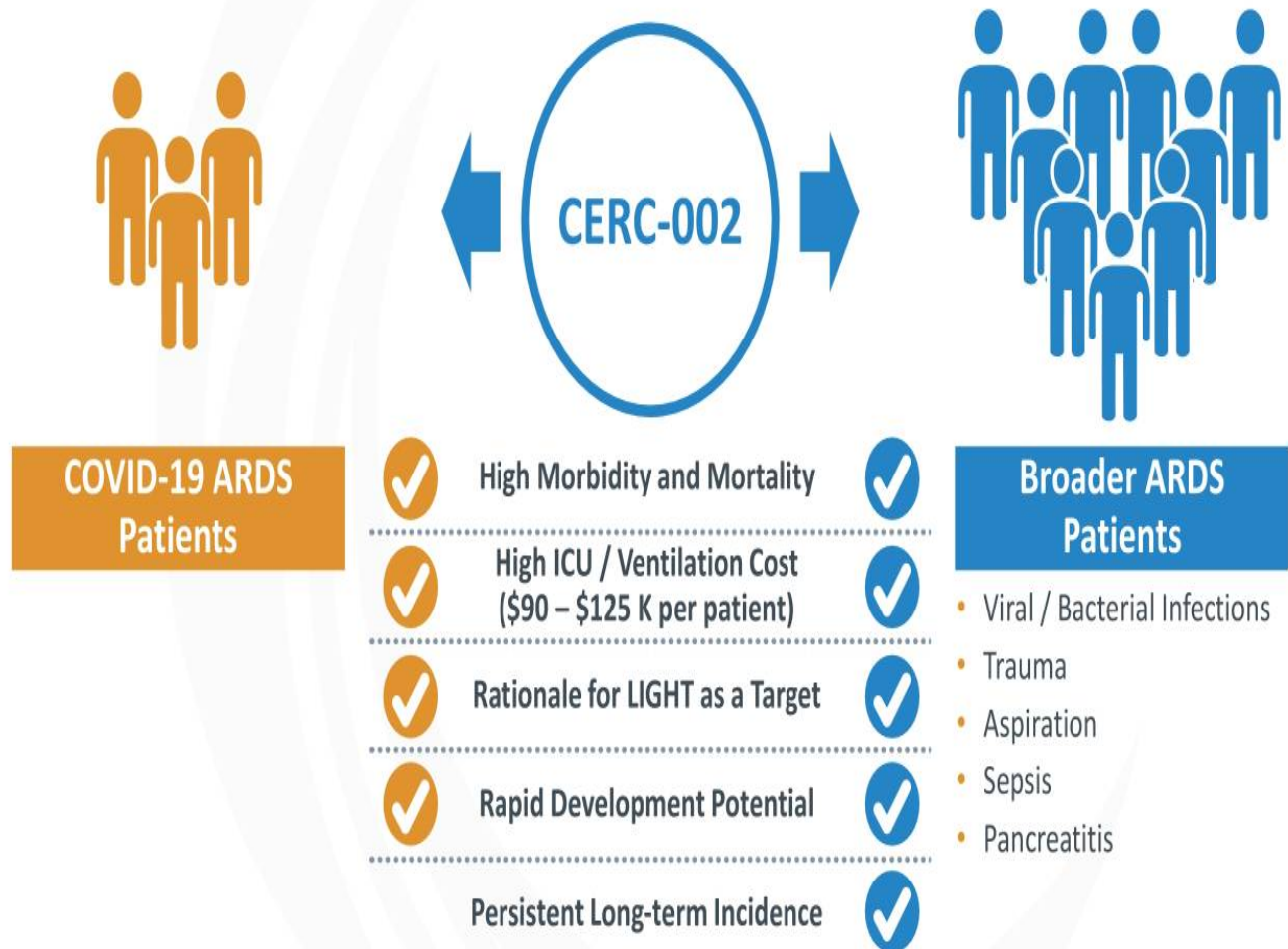
Reducing LIGHT levels may limit the proportion of patients requiring invasive mechanical ventilation, which drives high cost of treatment and low quality of life in ARDS

14 | Source: Physician Interviews; Papazian et al. Ann. Intensive Care 2019; Bhatraju et al. NEJM 2020.



# Potential Beyond COVID-19 ARDS

CERC-002 may be applicable to the broader ARDS population



**CERC-002 has the potential to treat the underlying disease of cytokine storm induced ARDS**

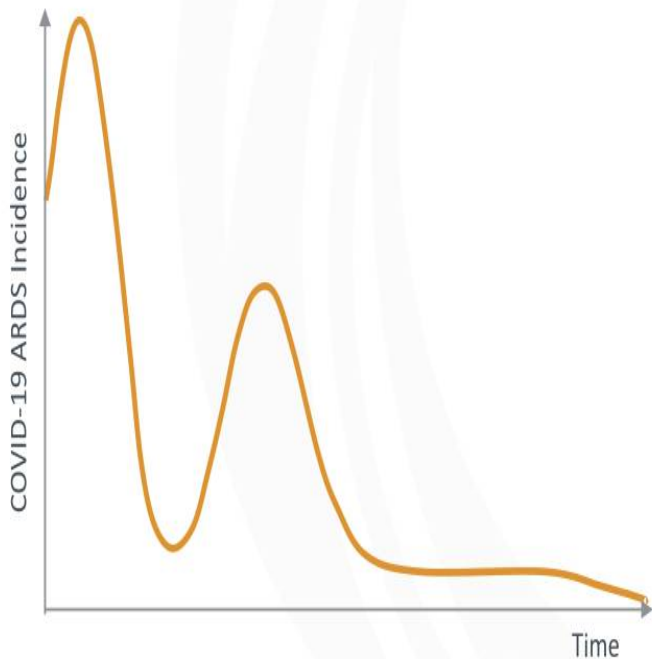
15 | Source: Chueng. Am J Respir Crit Care Med. 2006; Dasta. Crit Care Med. 2005; Hamel. Am J Med; 2000; Bice. Semin Respir Crit Care Med. 2013; ClearView Analysis. MV: Mechanical Ventilation.



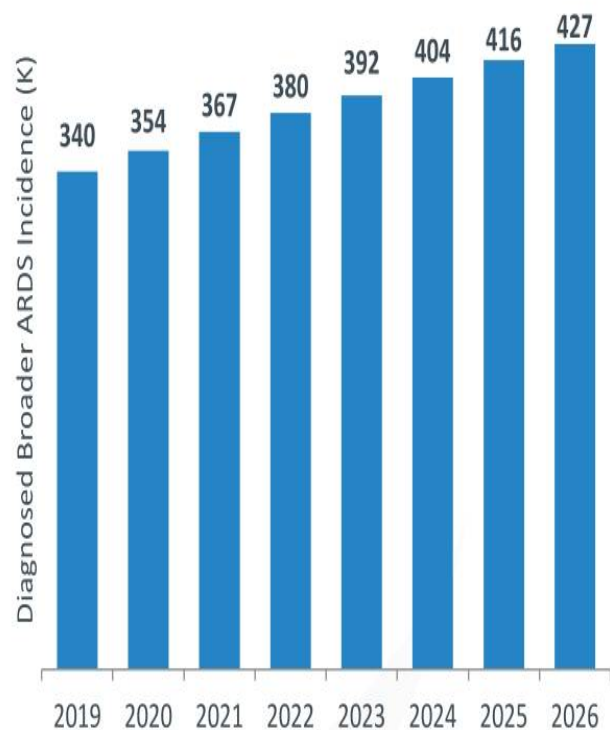
# COVID-19 and Broader ARDS Target Populations

COVID-19 ARDS provides a potential path to treat a larger patient population in broader ARDS

## U.S. COVID-19 Related ARDS Patients



## U.S. Broader ARDS Patients Excluding COVID-19



There is a large market opportunity and high unmet need for effective therapy in cytokine storm induced ARDS beyond COVID-19

# CERC-002: A Novel First-in-Class Anti-LIGHT mAb

The only known clinical stage anti-LIGHT antibody

## Free LIGHT Assay Developed in Collaboration with Myriad RBM

Enables a biomarker / precision medicine development approach

## Positive Toxicology Profile

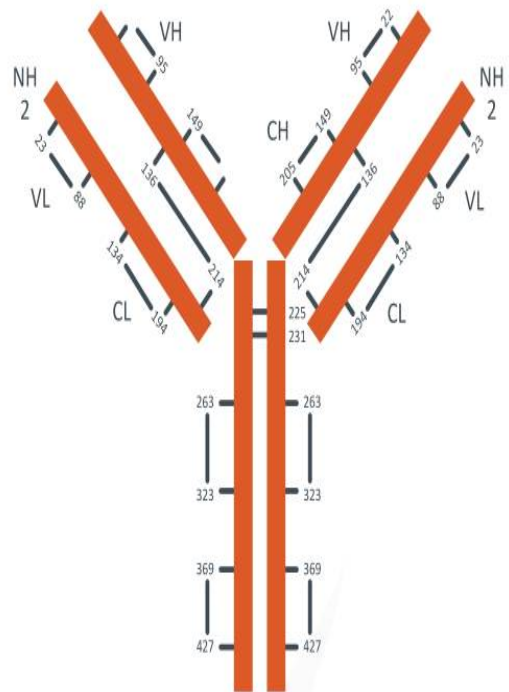
8-week monkey toxicology study was well tolerated up to 100 mg/kg per week with NOAEL at 60 mg/kg

## Phase I Trial Successfully Completed

Up to 1200 mg SQ in healthy volunteers (n=48) without significant toxicity

## Phase I/II open-label signal finding study in Crohn's disease currently ongoing (US IND 113264)

One patient completed study and drug was well-tolerated with a **significant reduction in LIGHT levels at a low dose with a clinically meaningful improvement**



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

17 | SQ: Subcutaneous; NOAEL: No observed adverse effect level.





# Clearance from the FDA to Initiate Clinical Trial in Cytokine Storm-Induced COVID-19 ARDS with CERC-002

Clear path for clinical development in COVID-19 ARDS, creating a path for development in generalized ARDS

## Planned Development Path for CERC-002

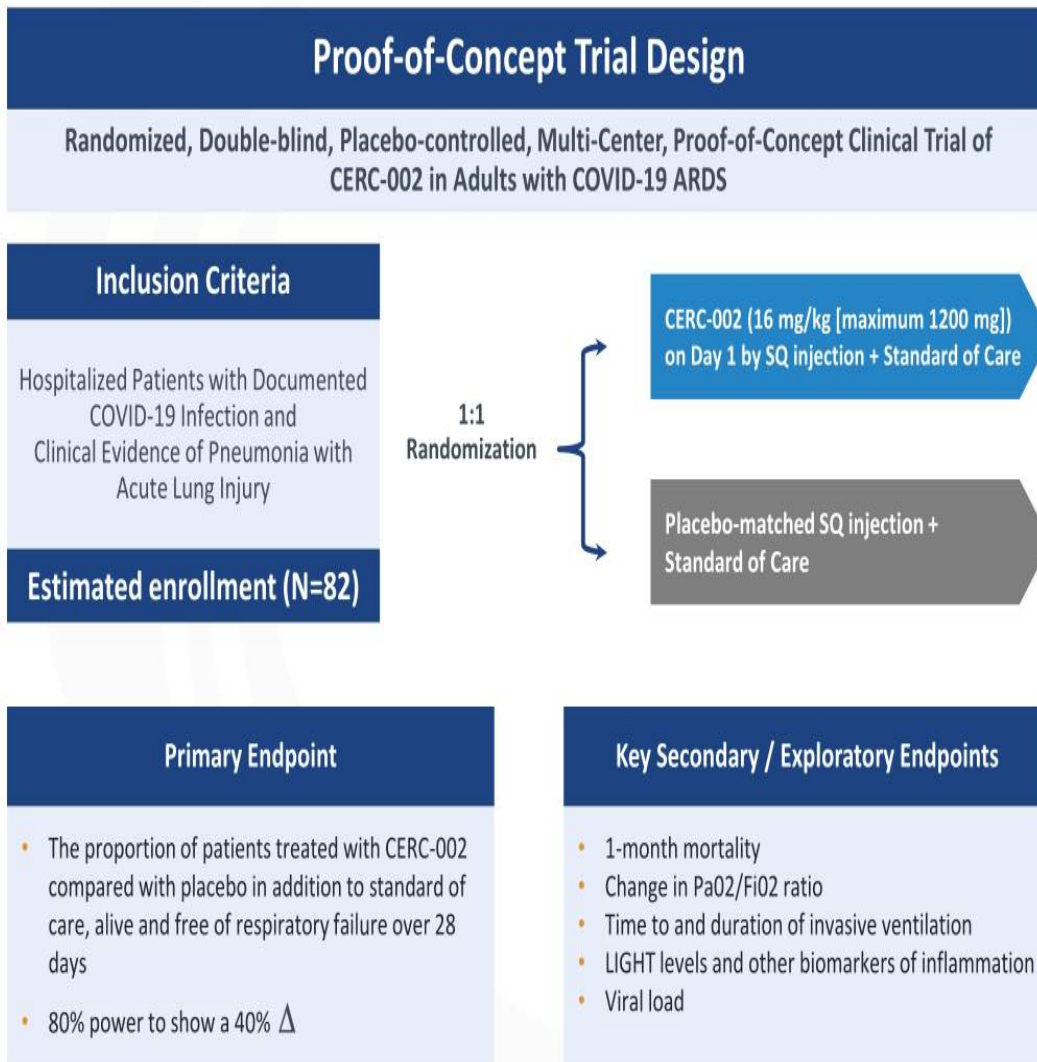
1H 2020			2H 2020			1H 2021		2H 2021		1H 2022		2H 2022		
Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4



Proof of Concept trial to begin in June 2020; Expected top line data Q4

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

## Primary Endpoint: Respiratory Failure and Mortality Over 28 Days



## Physician Perspectives on CERC-002

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Front line physicians<sup>1</sup> (n=14) with significant experience in COVID-19 and ARDS broadly viewed CERC-002's mechanism as novel with potential to fill an urgent unmet need

### Urgent Medical Need

“There are very few options for ARDS patients so I would definitely want to use an agent like this.”

### Novel MOA

“This mechanism has higher potential to address ARDS than other cytokine inhibitors.”

### Broad Anticipated Utilization

“This mechanism makes sense for all types of ARDS, not just COVID-19.”

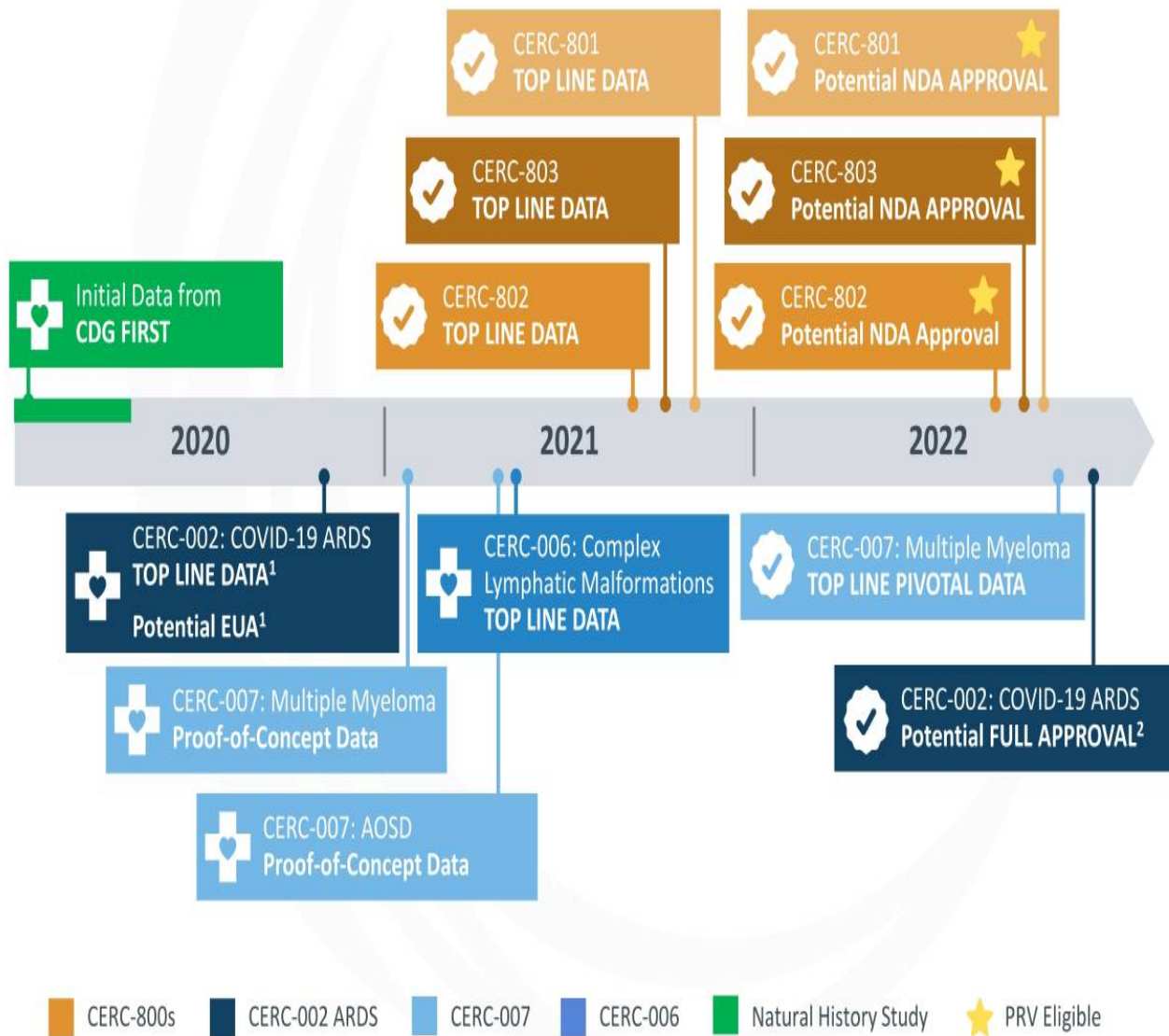
Source: Physician Interviews, ClearView Healthcare Partners.

20 | <sup>1</sup>14 physicians and KOLs were interviewed for an hour each for insights into COVID-19 ARDS, broader ARDS, and CERC-002.



# Highlights through 2022

- Multiple catalysts and 3 potential PRV awards from first-in-class medicines for diseases with no approved treatment options



<sup>1</sup> COVID-19 Related ARDS; additional pivotal study will be run if necessary.  
<sup>2</sup> Broader ARDS. EUA: Emergency Use Authorization.





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**NASDAQ:CERC**

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# Select Board and Management Team Members

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Michael F. Cola  
Chief Executive Officer



Garry A. Neil, MD  
Chief Scientific Officer



Sol J. Barer, PhD  
Chairman



## References

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