
**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): **March 17, 2021**

CERECOR INC.

(Exact name of registrant as specified in its charter)

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**

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 March 17, 2021, the Company released an updated investor presentation (the “Investor Presentation”). The Investor Presentation will be used from time to time in meetings with investors. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements related to the Company’s estimated cash and cash equivalents as of February 28, 2021. The words “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. While the Company believes its plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. The Company’s actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements. For information about the factors that could cause such differences, please refer to the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, including the information discussed under the captions “Part I, Item 1A - Risk Factors” and “Part II, Item 7 - Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as the Company’s various other filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Company assumes no obligation to update any forward-looking statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor 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: March 17, 2021

By: /s/ Schond L. Greenway
Schond L. Greenway
Chief Financial Officer



Patient Inspired Science

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



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.

Pipeline Highlights

- Cerecor has created a rich pipeline of six novel, first-in-class assets in eight clinical development programs across immunology, oncology, and rare diseases
- All assets have proven mechanistic rationale, biomarkers or established proof-of-concept to de-risk the pipeline and increase probability of success
- CERC-002 (anti-LIGHT mAb) demonstrated statistically significant improvement in the primary endpoint in Phase 2 COVID-19 ARDS clinical trial
- Near term catalysts anticipated over next 12 months
 - CERC-002: initial data for severe pediatric onset Crohn's Q2 2021
 - CERC-007: top line POC data for multiple myeloma (2H 2021) and initial data for AOSD (Q2 2021)
 - CERC-006: initial data for complex lymphatic malformations Q2 2021
 - CERC-800s: congenital disorders of glycosylation pivotal data 2H 2021
- Currently, four assets have been designated ODD* and RPDD* enabling Priority Review Vouchers (would provide non-dilutive financing of the pipeline)



³| *Orphan Drug Designation, Rare Pediatric Disease Designation; Eligibility for Priority Review Voucher Upon Approval

Clinical-Stage Pipeline

Core Research & Development Areas	Therapeutic Area	Program	Mechanism of Action	Lead Indication	Development Stage				Anticipated Milestone
					Preclin	Phase 1	Phase 2	Pivotal Trial	
Immunology	Inflammation	CERC-002	Anti-LIGHT mAb	COVID-19 ARDS					FDA EOP-2 Meeting 1Q 2021
		CERC-002	Anti-LIGHT mAb	Severe Pediatric Onset Crohn's					Initial Data 2Q 2021
		CERC-007	Anti-IL-18 mAb	AOSD					Initial Data 2Q 2021
Oncology	Blood Cancers	CERC-007	Anti-IL-18 mAb	Multiple Myeloma					Top Line Data 2H 2021
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					Pivotal Trial Data 2H 2021
		CERC-802 ⁺ ‡	D-Mannose replacement	MPI-CDG					Pivotal Trial Data 2H 2021
		CERC-803 ⁺ ‡	L-Fucose replacement	LAD-II (SLC35C1-CDG)					Pivotal Trial Data 2H 2021

⁺ Orphan Drug Designation, Rare Pediatric Disease Designation; Eligibility for Priority Review Voucher upon approval

⁴⁾ ‡ Fast Track Designation



CERC-002

Anti-LIGHT monoclonal antibody in clinical studies for
COVID-19 ARDS and Severe Pediatric-onset Crohn's Disease



Executive Summary – Final Data Analysis

Phase 2 Clinical Trial Met Primary Endpoint in Patients Hospitalized with COVID-19 ARDS

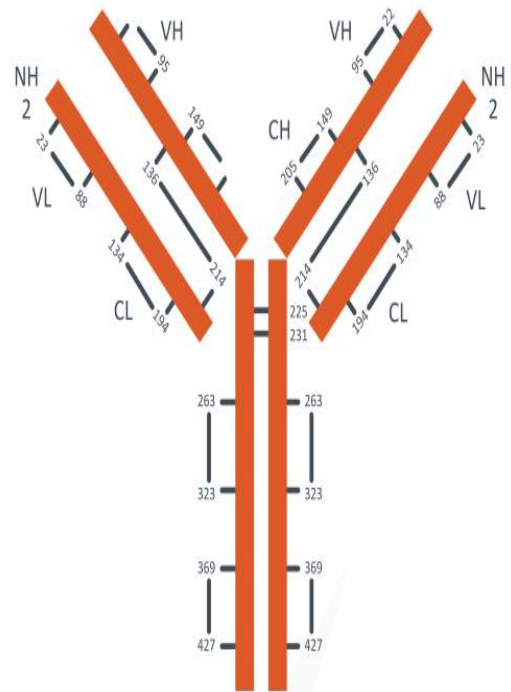
- CERC-002 significantly reduced respiratory failure and mortality in Phase 2 clinical trial in patients hospitalized with COVID-19 ARDS
 - This analysis updates the preliminary topline data reported on January 5, 2021, and is inclusive of 60-day safety data
 - Hospitalized COVID-19 patients treated with a single dose of CERC-002 demonstrated statistically significant 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, p=0.044)
 - Efficacy was highest in a prespecified subpopulation of patients over the age of 60 (n=34, p=0.042), the population most vulnerable to severe complications and death with COVID-19 infection
 - At both the 28-day and the 60-day final timepoints, an approximately 50% trend in mortality reduction (22.5% vs 10.8%) was observed
 - CERC-002 showed statistically significant efficacy on top of corticosteroids and standard of care in COVID-19 ARDS (>90% of patients in the trial received corticosteroids and >65% 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
- Cerecor has applied for Breakthrough Therapy and Fast Track Designations, and plans to meet with FDA to discuss potential path to Emergency Use Authorization
- Additionally, the company is exploring the applicability of CERC-002 in non-COVID-19 ARDS



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

The Only Known Clinical Stage Anti-LIGHT Antibody

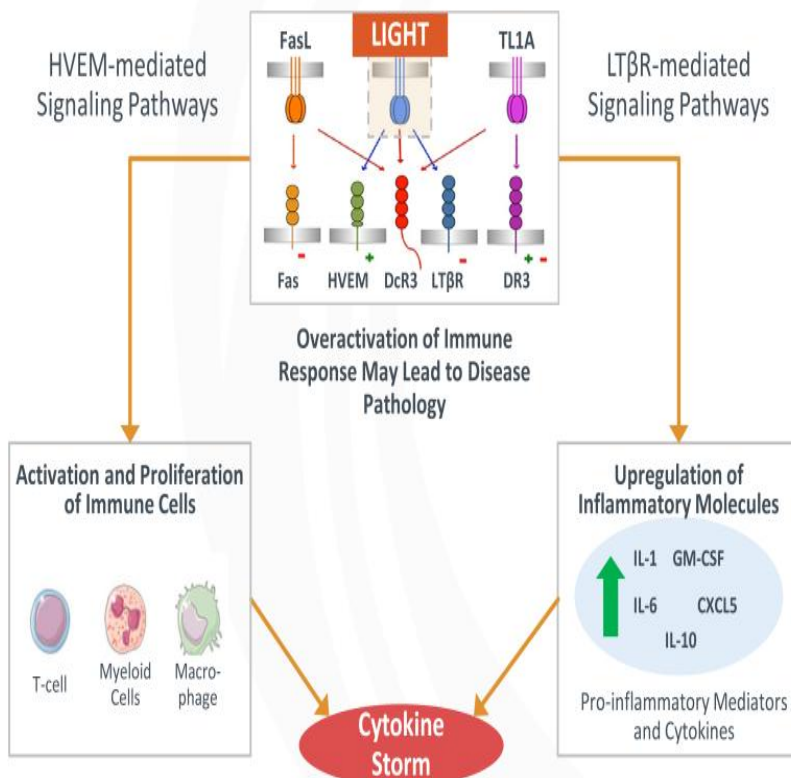
- In-licensed from Kyowa Kirin Co.
- Positive toxicology profile
 - 8-week monkey toxicology study was well tolerated up to 100 mg/kg per week with NOAEL at 60 mg/kg
- Phase I trial previously completed
 - Up to 1200 mg SQ in healthy volunteers (n=48) without significant toxicity
- Proprietary free LIGHT 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

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 ARDS¹

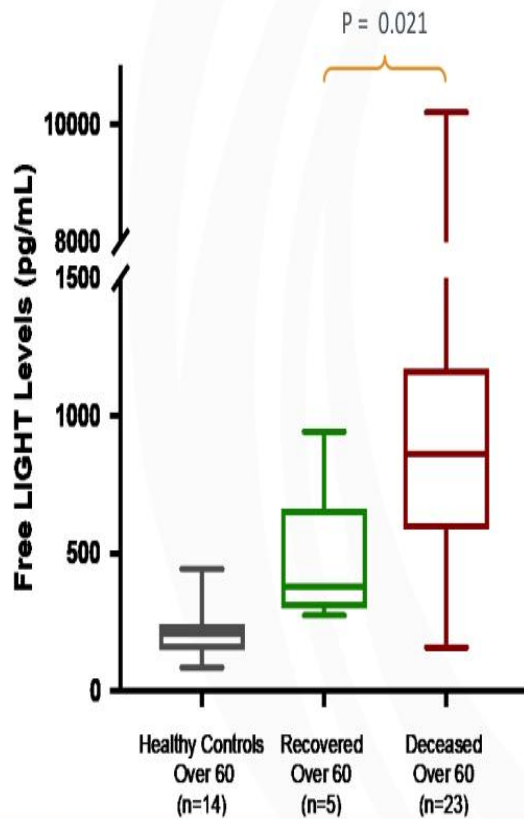
8| 1. Perlin et al. (2020) *mSphere*. 5(4):e00699-20.

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 was higher for patients over 60 of age (82%) compared to patients <60 years (32%)

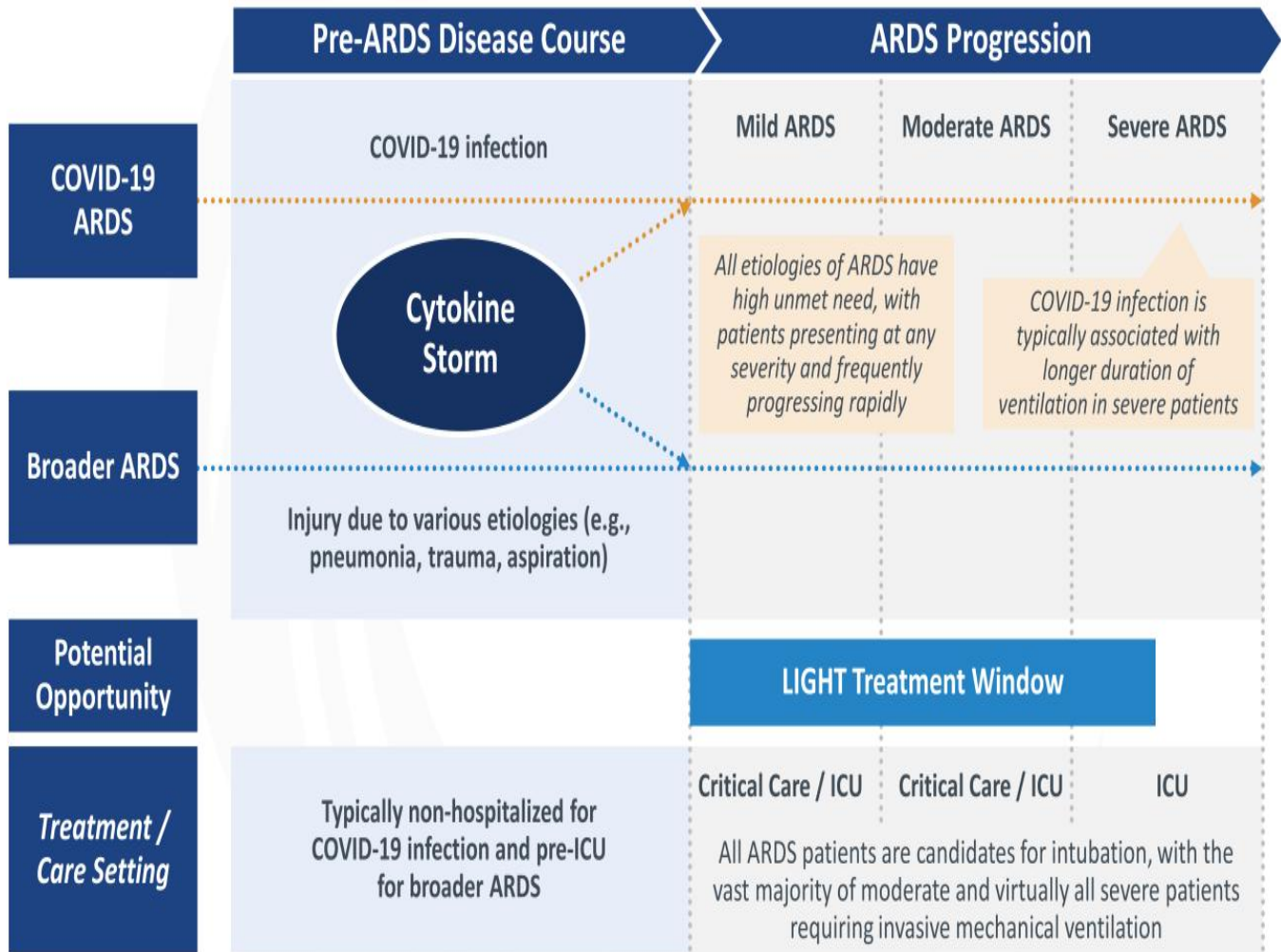
Elevated LIGHT levels in hospitalized COVID-19 patients were most strongly associated with mortality in patients over 60

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



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

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



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

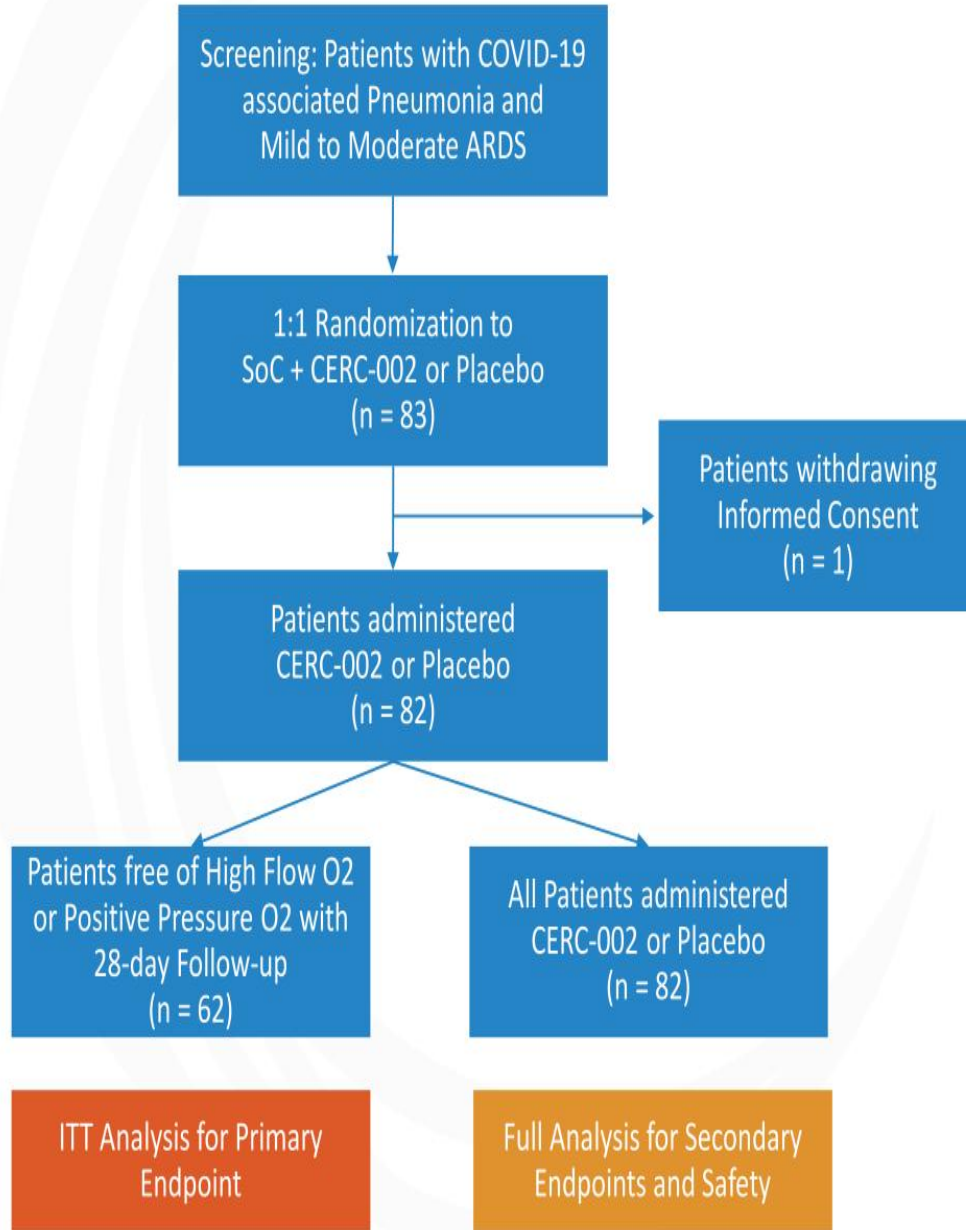
Key Secondary / Exploratory Endpoints

- 1-month mortality
- Change in PaO₂/FiO₂ ratio
- Time to and duration of invasive ventilation
- LIGHT levels and other biomarkers of inflammation
- Viral load

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



Patient Disposition Chart



Patient Demographics

Characteristic	CERC-002 (n=41)	Placebo (n=42)
Age, years Mean (SD)	59.2 (14.5)	58.1 (14.2)
Age Group		
<60 years (n, %)	20 (48.8%)	21 (50.0%)
≥60 years (n, %)	21 (51.2%)	21 (50.0%)
Gender		
Male	25 (61%)	32 (76.2%)
Female	16 (39%)	10 (23.8%)
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%)
Free LIGHT Level at Baseline Mean (range) pg/mL	348 (63 - 1050)	273 (37 - 843)
Concomitant Medication Use at Baseline*		
Systemic corticosteroids	38 (95.0%)	37 (88.1%)
Remdesivir	26 (65.0%)	28 (66.7%)

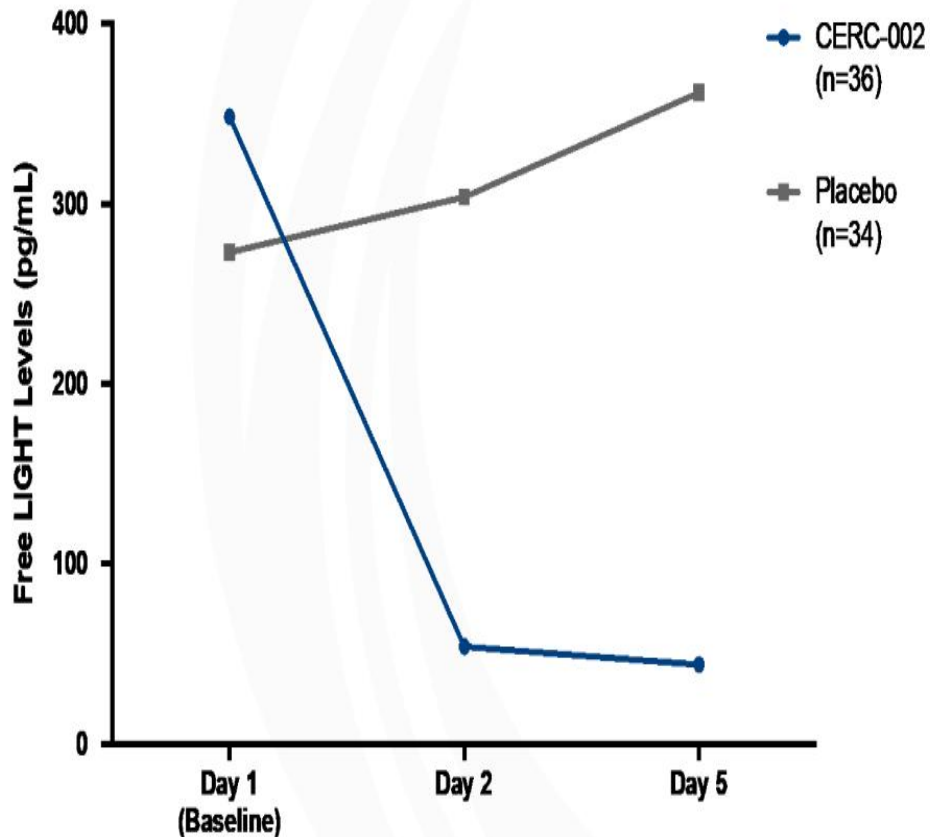
Data on file

13| * Calculated from patients dosed (n=40 for CERC-002, n=42 for placebo)



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

Free LIGHT Levels (pg/mL) Over Treatment Period

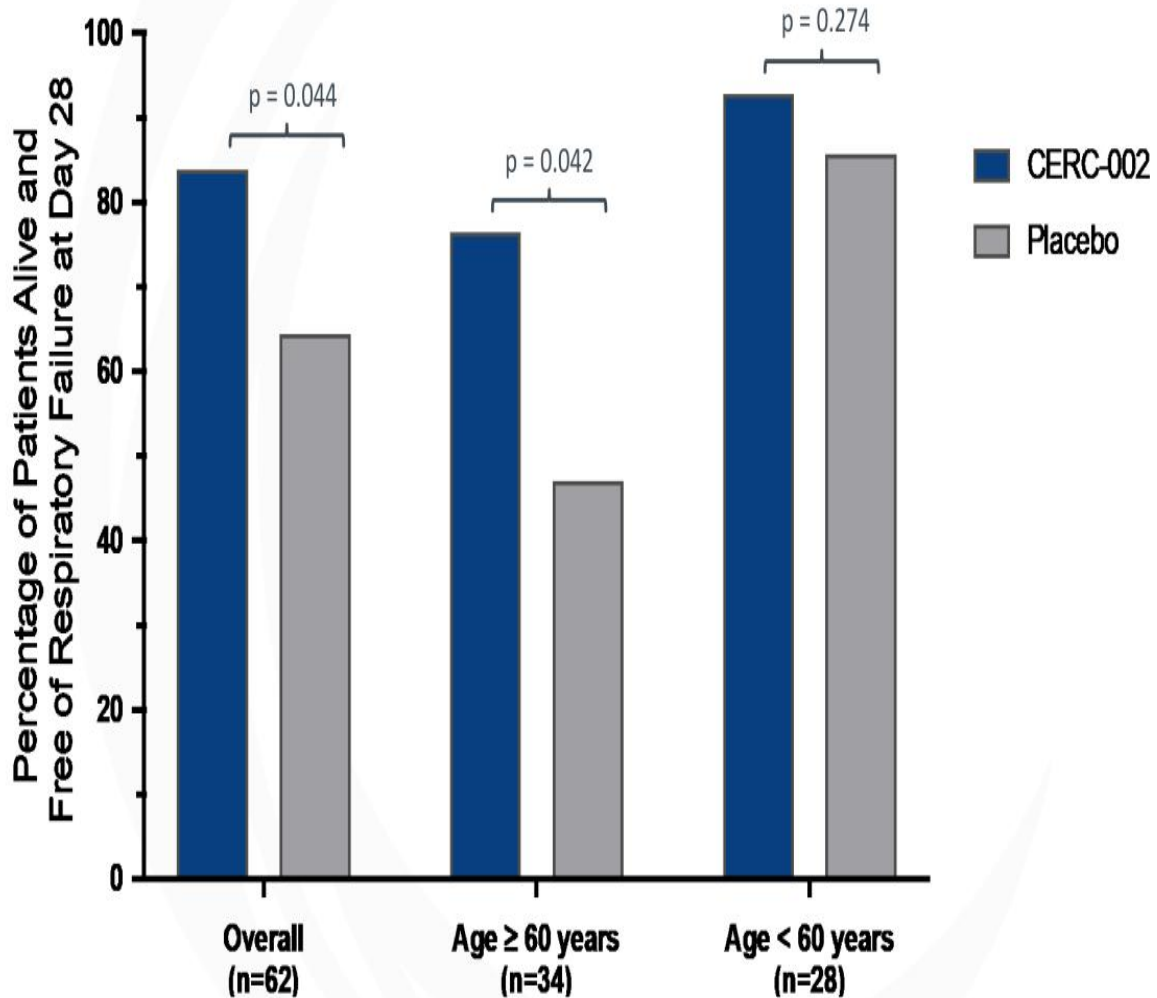


- Mean free LIGHT levels were comparable at baseline across cohorts
- Mean free LIGHT levels were about 100 pg/mL higher in the patients ≥ 60 years-old
- Free LIGHT levels reduced quickly in the active cohort and increased in the placebo cohort
- The pharmacodynamic effect was on top of standard of care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

Free LIGHT is inhibited by Day 1 and remains low

CERC-002 Significantly Reduced Respiratory Failure and Mortality in Phase 2 Clinical Trial in Patients Hospitalized with COVID-19 ARDS

Primary Endpoint: Percentage of Patients Alive and Free of Respiratory Failure at Day 28



Efficacy was highest in patients over the age of 60* (n=34, p=0.042), the population most vulnerable to severe complications and death with COVID-19 infection

Data on file

15|

* Prespecified analysis



A Single Dose of CERC-002 Reduced Mortality by ~50% in this Study

	CERC-002	Placebo
28-day Mortality	7.7%	14.3%
60-day Mortality	10.8%	22.5%

- A trend in ~50% reduction in mortality was observed at both the 28-day and the 60-day timepoints
- Efficacy observed is on top of corticosteroids and standard of care
 - (>90% of patients in the trial received corticosteroids and >65% received remdesivir)

Safety and Tolerability

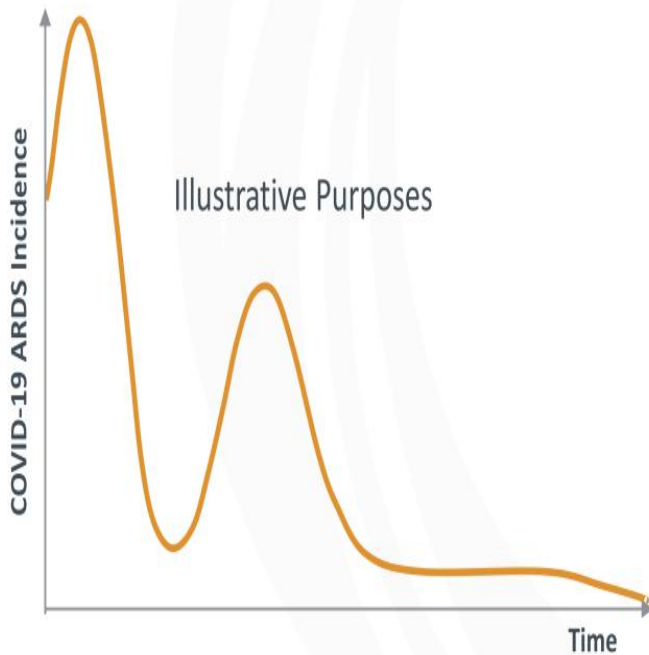
- CERC-002 was well-tolerated at a single dose of 16 mg/kg
- No serious adverse events attributable to CERC-002
- Majority of AEs judged to be mild or moderate
- No evidence of increased infections or adverse events related to immunosuppression

	CERC-002 (n=40)	Placebo (n=42)
Subjects with ≥1 AE (%)	16 (40%)	21 (50%)
Subjects with ≥1 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%)

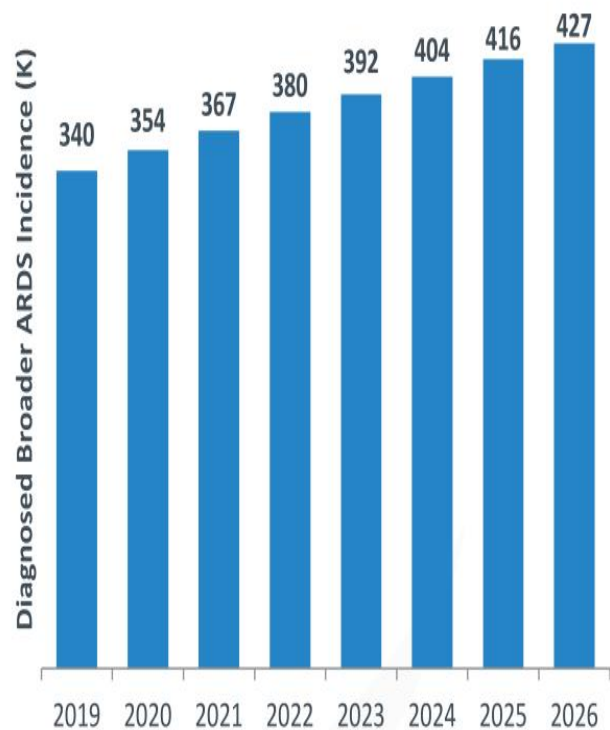
COVID-19 and Broader ARDS Target Populations

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

U.S. COVID-19 Related ARDS Patients



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



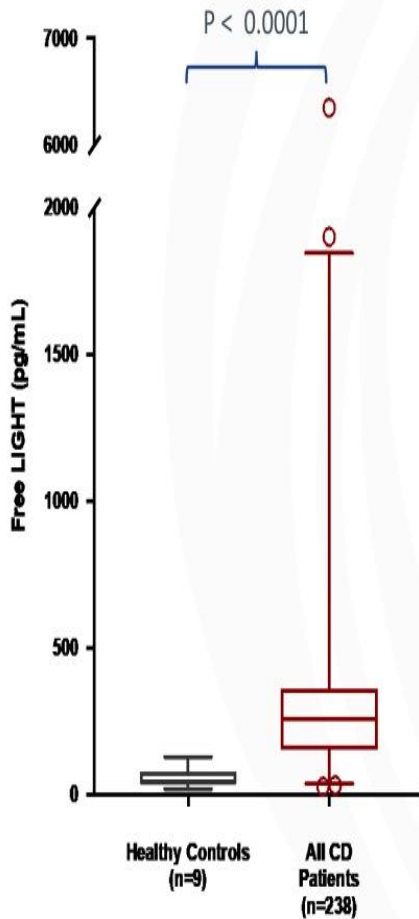
There is a large market opportunity and high unmet need for effective therapy in cytokine storm induced ARDS beyond COVID-19

Next Steps

- Applied for FDA Breakthrough Therapy and Fast Track Designations
- Plan to meet with FDA to discuss potential path to Emergency Use Authorization
- Manuscript in preparation with plan to present full data at a future scientific meeting
- Currently exploring the applicability of CERC-002 in non-COVID-19 ARDS

Elevated Free LIGHT Levels Detected in Pediatric Crohn's Disease Patients Using Cerecor's Proprietary Free LIGHT Assay

Plasma LIGHT levels are significantly elevated in Crohn's Disease patients (n=238) over healthy individuals (n=9)



- Using the proprietary free LIGHT assay, we demonstrated that free LIGHT levels are significantly elevated in Crohn's Disease patients

Data displayed as box-and-whiskers graph (1 - 99% percentile)

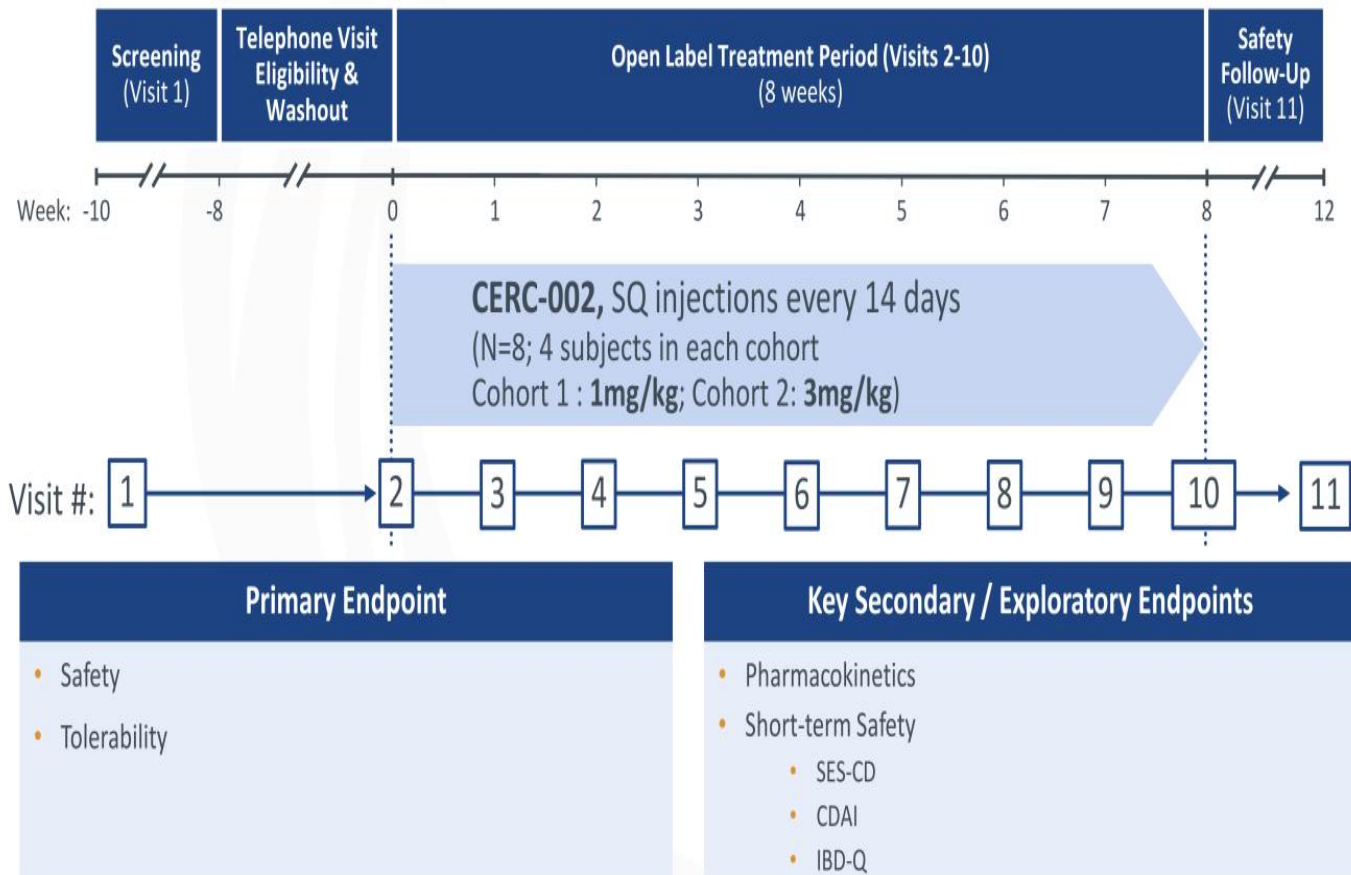
* Determined by Kruskal-Wallis test followed by Dunn's multiple comparisons

Plasma samples from CHOP Biobank; controls are matched for age and gender

CERC-002 Pediatric onset Crohn's Disease Phase 1b Study Design

Proof-of-Concept Trial Design

Open-label Proof-of-Concept Clinical Trial of CERC-002 in Adults moderate-to-severe, active Crohn's disease who have previously failed anti-tumor necrosis factor alpha (anti-TNF α) treatment.



Pediatric onset Crohn's disease initial data anticipated Q2 2021

CERC-007

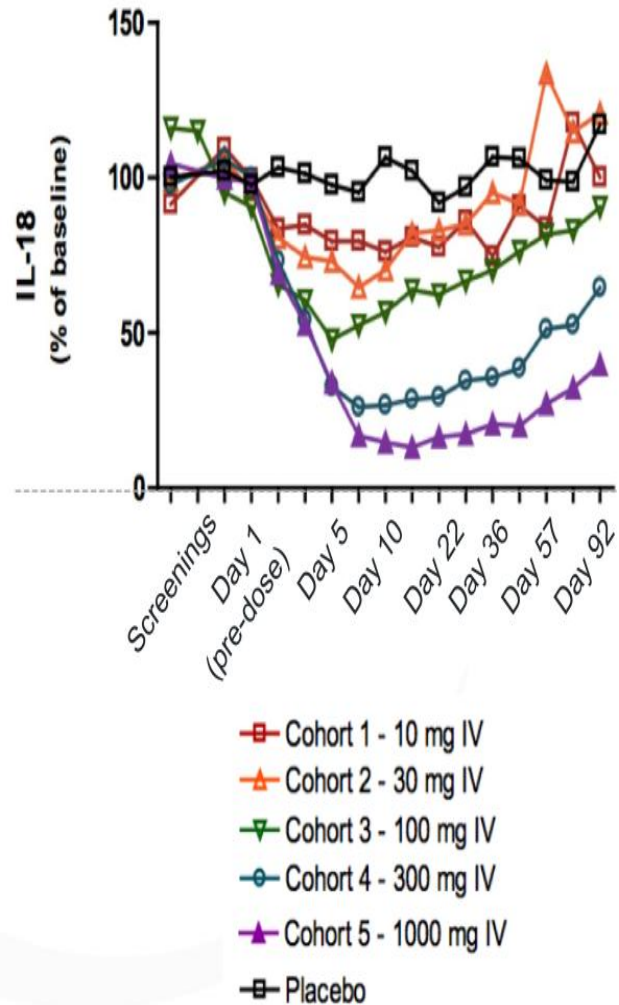
Phase 1b anti-IL-18 monoclonal antibody for
Multiple Myeloma and Still's Disease (AOSD and sJIA)



First-in-Class Anti-IL-18 High Affinity Monoclonal Antibody

Data from phase 1 study demonstrated favorable PK and safety profile

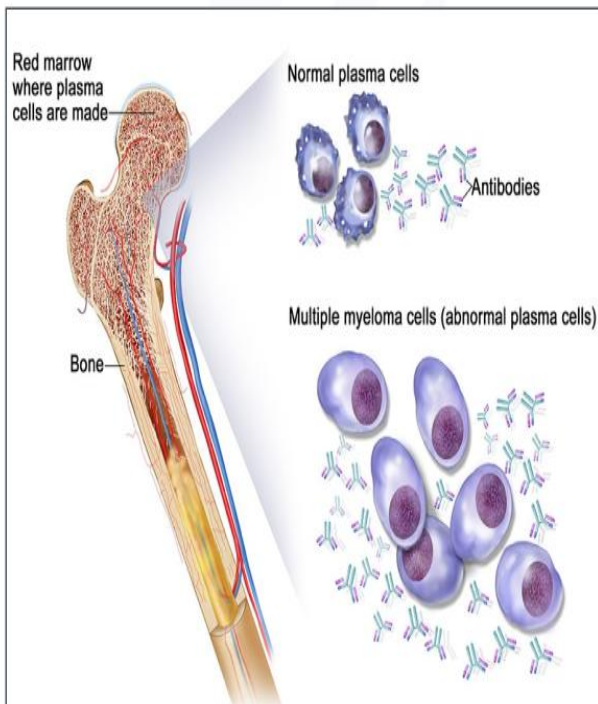
- In-licensed from Medimmune / AZ
- Potent and durable IL-18 inhibition
 - Evaluated in phase 1 SAD for COPD (n = 31)
 - IV doses of 10, 30, 100, 300 or 1000 mg
 - Well-tolerated
- Phase 1b asset
 - 13-week monkey tox completed
 - Frozen, unformulated bulk material available to support clinical proof-of-concept in patients and nonclinical 6-month chronic tox studies



Multiple Myeloma Is The Second Most Common Blood Cancer Globally

MM is characterized by the neoplastic proliferation of plasma cells with the overproduction of monoclonal proteins or M-proteins

Multiple Myeloma (MM) Pathophysiology



A progressive disease with both cell-autonomous genetic abnormalities, and microenvironmental changes contributing to the growth of the malignant neoplasm²

Disease Overview

Patient Population

- Prevalence in U.S. ~140,000¹
- Occurs in older people (median age at diagnosis is 69)¹
- 35% of patients are younger than 65¹

Signs and Symptoms

- Majority may present with anemia, bone pain or elevated creatinine while fatigue, hypercalcemia, and weight loss observed in a minority of patients²

Treatment Approach

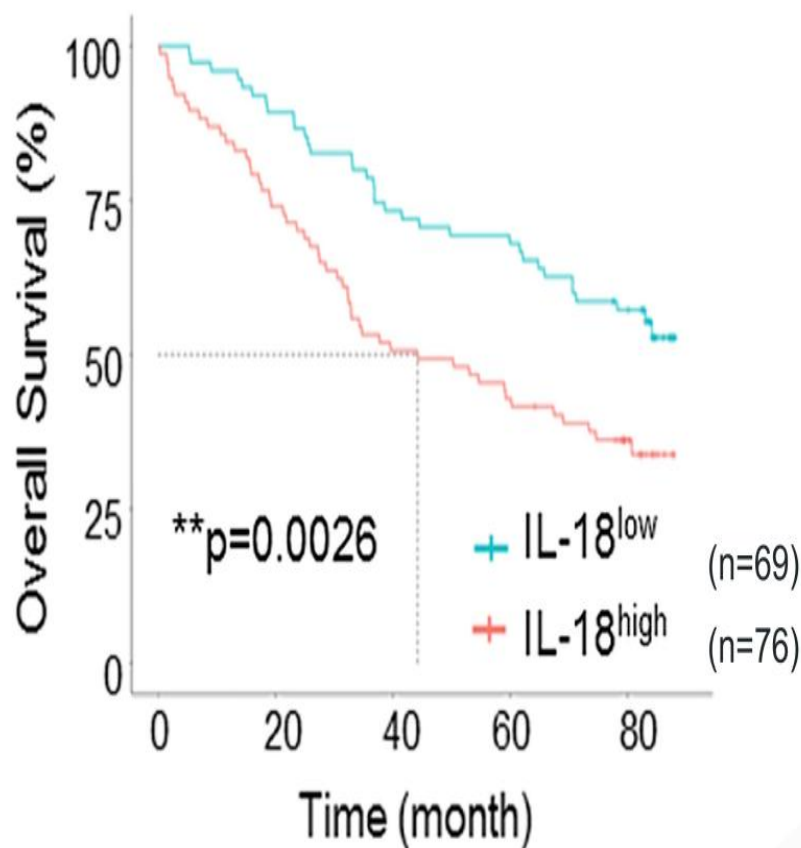
- MM is treated with at least one of three main classes of agents, utilized in combination across all lines of therapy³:
- Immunomodulators - Revlimid®, Pomalyst®
- Protease inhibitors - Velcade®, Kyprolis®
- Anti-CD38 - Darzalex®, Sarclisa®

Prognosis

- Estimated 5-year survival is ~50% in the U.S., though specific genetic deletions such as 17p may be associated with shorter survival¹

Strong Potential in Multiple Myeloma

IL-18 Levels Are Elevated in Many MM Patients and Correlate with Poor Survival



- Patients with high IL-18 have significantly worse median survival (42 months vs. >84 months, p value= 0.0026, HR = 1.84)
- Reducing IL-18 levels prolongs survival in rodent models of multiple myeloma

CERC-007 Treatment of Patients with Resistant and Refractory Multiple Myeloma

Initiating Trial in Multiple Myeloma as a Single Agent with Plans for Combination

Proposed Dose Escalation and Expansion Trial Design

A Multicenter, Open-Label, Dose-Escalation Phase 1b Study of CERC-007 in Subjects with Relapsed or Refractory Multiple Myeloma

Inclusion Criteria

Patients with treatment resistant and refractory multiple myeloma had exposures to IMiDs, Proteasome inhibitors and anti-CD38 mAb
No more than 4–6 lines of therapy

Estimated Enrollment:
Dose Escalation ~ 14
Expansion Phase = 14

CERC-007: Dose Escalation Phase
3 + 3 Design

CERC-007
Expansion Phase at RP2D
N = 14

Primary Endpoint

- Establishment of RP2D in Dose Escalation Phase
- Response rate by International Myeloma Working Group criteria at 8 weeks in Expansion Phase

Key Secondary / Exploratory Endpoints

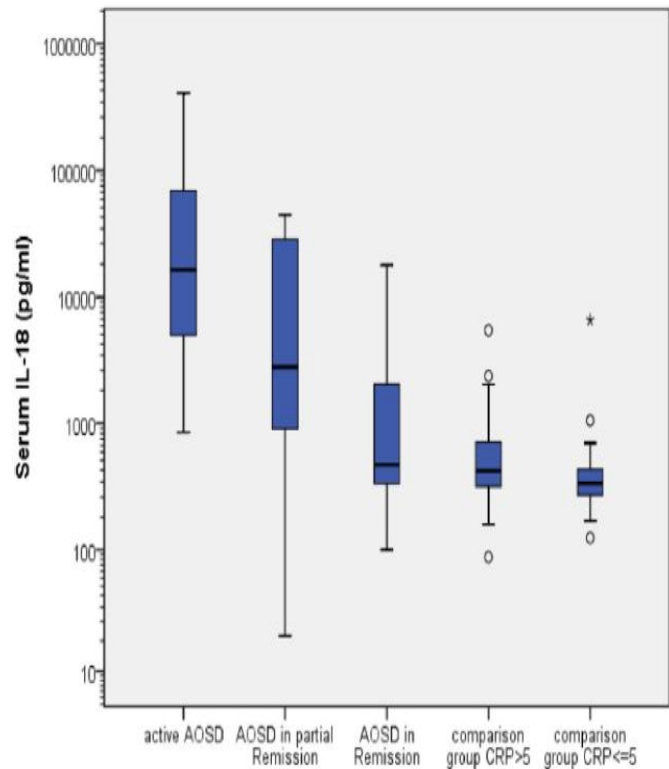
- Change in SPEP from baseline
- Safety and tolerability
- Change in IL-18 levels in blood and bone marrow
- Change in Myeloid derived suppressor cells in bone marrow from baseline to 8 weeks

MM initial cohort successfully completed 1Q 2021
Proof of concept top line data anticipated 2H 2021

Adult-Onset Still's Disease (AOSD) Overview

- Rare disease with estimated U.S diagnosed prevalence of 3,500 to 7,000¹
- Symptoms include fever, rash, pharyngitis, arthritis, liver disease, increased ferritin
- No definitive genetic or infectious cause
- ~40% have severe chronic disease²
- Treatment: NSAID, steroids, immunosuppressants and anti-IL-1

Serum IL-18 Levels Significantly Elevated in AOSD Patients

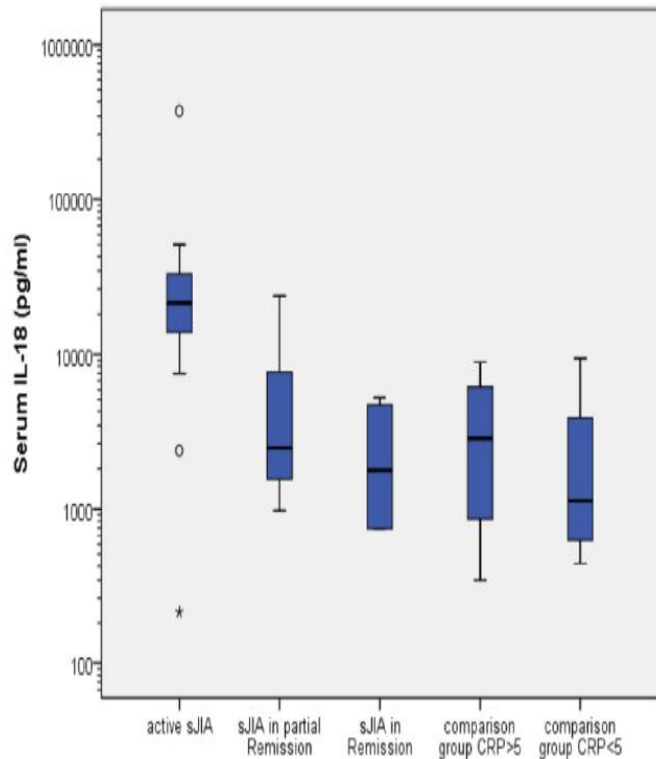


1. ClearView Healthcare Partners Analysis, May 2017
2. Gerfaud-Valentin et al. (2014) *Autoimmun Rev.* 13(7):708-22.
3. Figure from Kudela et al. (2019) *BMC Rheumatol.* 3:4.

Systemic Juvenile Idiopathic Arthritis (sJIA) Overview

- Rare childhood onset disease with estimated U.S. diagnosed prevalence of 4,500 to 6,500¹
- Intermittent fever, rash and arthritis; often splenomegaly, lymph nodes
- Autoinflammatory disease – not autoimmune
 - IL-1, 6, 18 other cytokines important in the pathogenesis
- Treatment: NSAID, DMARDS and Targeted Therapies (anti-IL-1 and anti-IL-6)
 - Significant number of refractory patients

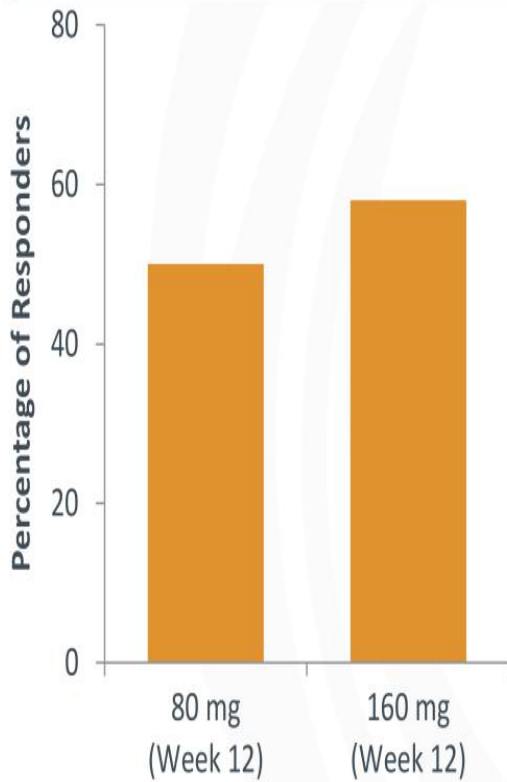
Serum IL-18 Levels Significantly Elevated in sJIA Patients



1. ClearView Healthcare Partners Analysis, May 2017
28 | 2. Figure from Kudela et al. (2019) *BMC Rheumatol.* 3:4.

Proof-of-Concept Clinical Data: IL-18 Binding Protein Demonstrates Efficacy Response in Patients with AOSD

IL-18 Binding Protein Response Rates



Patients Received Subcutaneous Administration of 80 or 160 Mg Three Times per Week

- AB2 Bio clinical proof-of-concept in AOSD (n = 23) using IL-18 binding protein ($T_{1/2} = 40$ h)
 - >50% of AOSD patients treated with IL-18bp achieved response
- Serum IL-18 correlates with disease severity
 - 4/4 patients with undetectable serum IL-18 had a clinical response

Gabay et al. *Ann Rheum Dis*. 2018. 77(6):840-847

Response defined as an improvement of joint count (both Swollen Joint Count (SJC) and Tender Joint Count (TJC) according to a 44-joint assessment) by $\geq 20\%$ from baseline values, and a 70% decrease of CRP levels compared with baseline values (or reduction to normal

29 | levels) or normalization of ferritin



CERC-007 Treatment of Patients with Adult Onset Still Disease

Potential best-in-class and first-in-class anti-IL-18 mAb

Proposed Proof-of-Concept Trial Design

A Multicenter, Phase 1b Study of CERC-007 in Subjects with Active Adult Onset Stills Disease

Inclusion Criteria

- Patients with active AOSD as measured by high fever, elevated CRP and ferritin
- Failed on NSAIDs and Corticosteroids

Estimated Enrollment: N = 12

12 weeks

CERC-007 7 mg/kg (max 500 mg) q 4 weeks
(n=6)

12 weeks

CERC-007 14 mg/kg (max 500 mg) q 4 weeks
(n=6)

Primary Endpoint

- Reduction of CRP by at least 50% and elimination of fever for > 48 hours

Key Secondary / Exploratory Endpoints

- Change from Baseline DAS score, modified Pouchet score, and DAS-CRP
- Change in CRP, Ferritin, and ESR
- Change in IL-18 levels
- Safety and tolerability

AOSD initial data anticipated 2Q 2021

CERC-006

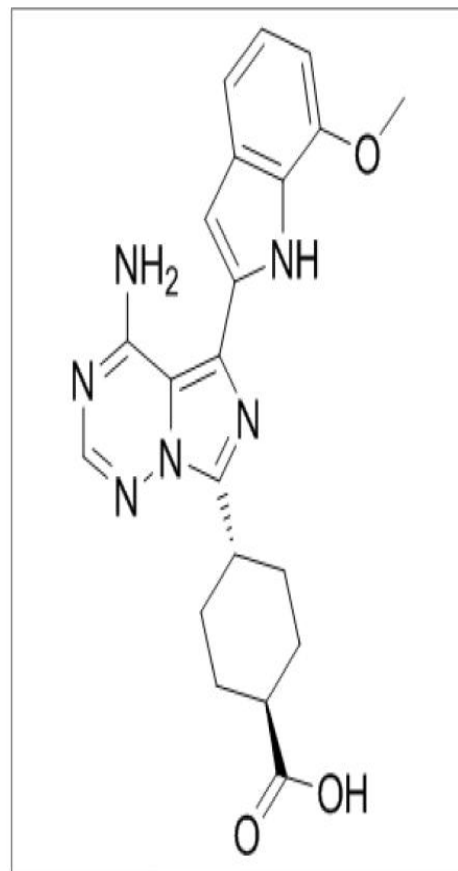
Phase 2-ready, Dual mTORC 1/2 small molecule inhibitor for Complex Lymphatic Malformations



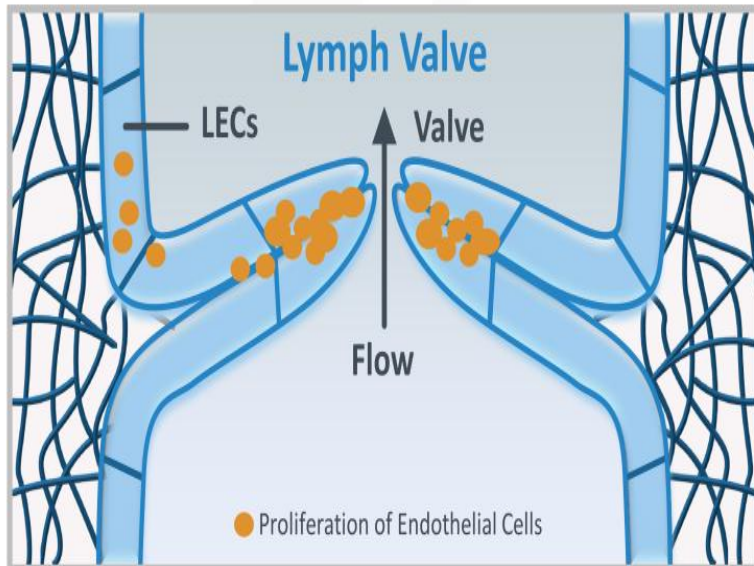
High Potency, Second Generation, Dual Inhibitor of mTORC1/2

Potential for improved efficacy and tolerability

- In-licensed from Astellas
- Phase 2-ready asset
 - 4-week nonclinical tox studies completed
 - Previously studied in Phase 1 MAD (n = 128)
 - Development discontinued upon determination that target efficacious doses were above MTD (30mg QD)¹
 - Significantly lower doses than MTD likely required to treat complex lymphatic malformations
- Dual mTOR inhibitor maximizes impact of mTOR blockade, as mTORC2 is insensitive to rapalogs
 - Orally available, ATP-competitive kinase inhibitor; IC₅₀ = 22 nM and 65 nM for mTORC1 and mTORC2, respectively²



Complex Lymphatic Malformations Are a Family of Potentially Life-threatening Congenital Diseases



- Neoplastic lesions caused by mutations in PI3K/AKT/mTOR pathway
- Leads to local proliferation of lymphatic endothelial cells and perturbation of lymph flow



- Fluid accumulation in limbs, abdomen, and chest which can lead to major disability and death
- Complex lymphatic malformations are not readily treatable by sclerosing agents or surgery many times due to their complexity and location

Off-label Use of mTOR Inhibitor Sirolimus in LM

Open-label clinical studies support efficacy, however use is limited by tolerability issues and lack of FDA approval

- Phase II trial enrolled patients with complicated vascular anomalies¹
 - Study enrolled patients with different subtypes of LM not controlled by previous medication, sclerotherapy and/or surgery
 - Sirolimus was administered orally for 12 courses of 28 days each
 - 57 patients were evaluable for efficacy at the end of course 6, and 53 were evaluable at the end of course 12
- Safety and tolerability profile leads to low compliance, requires frequent monitoring
 - Physicians reported that sirolimus causes high rates of stomatitis (~60%)
 - Sirolimus bears black box warning for immunosuppression and malignancies

Overall Response	6-month (n=57)	12-month (n=53)	Grade 2 or > AEs
Complete Response	0	0	• Blood/bone marrow (50%)
Partial Response	47 (83%)	45 (85%)	• Gastrointestinal (55%)
Progressive Disease	7 (12%)	8 (15%)	• Metabolic/laboratory (20%)
Stable Disease	3 (5%)	0	• Infection (15%)

34 | ¹ Adams et al. *Pediatrics*. 2016, 137(2):e20153257.

CERC-800s

Monosaccharide therapy for Congenital Disorders of Glycosylation (CDGs)



Congenital Disorders of Glycosylation (CDG): Life-Threatening, Ultra-Rare, Inborn Errors of Metabolism (IEMs)

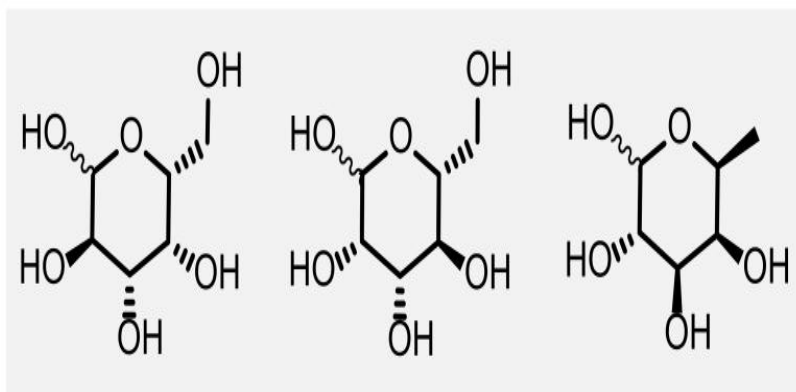
Impaired glycoprotein production and function can simply be restored with substrate supplementation therapy

- Glycosylation is essential for protein structure & function, particularly for circulating proteins and enzymes such as hormones and coagulation factors
- Currently approximately 150 CDGs identified
- Due to a genetic mutation, CDG patients lack the ability to synthesize functioning glycoproteins
- Life-threatening multi-system diseases: failure to thrive, developmental delay, hypotonia, neurologic abnormalities, hepatic disease, and coagulopathy
- Administration of therapeutic doses of specific monosaccharides targeted to specific CDGs can partially restore impaired glycoprotein production resulting in a meaningful clinical benefit
 - PGM1-CDG: D-galactose supplementation¹
 - MPI-CDG: D-mannose supplementation²
 - LAD-II (SLC35C1-CDG): L-fucose supplementation³

Pharmaceutical Grade Treatments for CDGs

Opportunity to be the first FDA approved drugs for CDGs

- Established therapeutic POC
- GMP manufacturing and FDA approval will ensure quality and consistency
- Potential for reimbursement



● D-Galactose

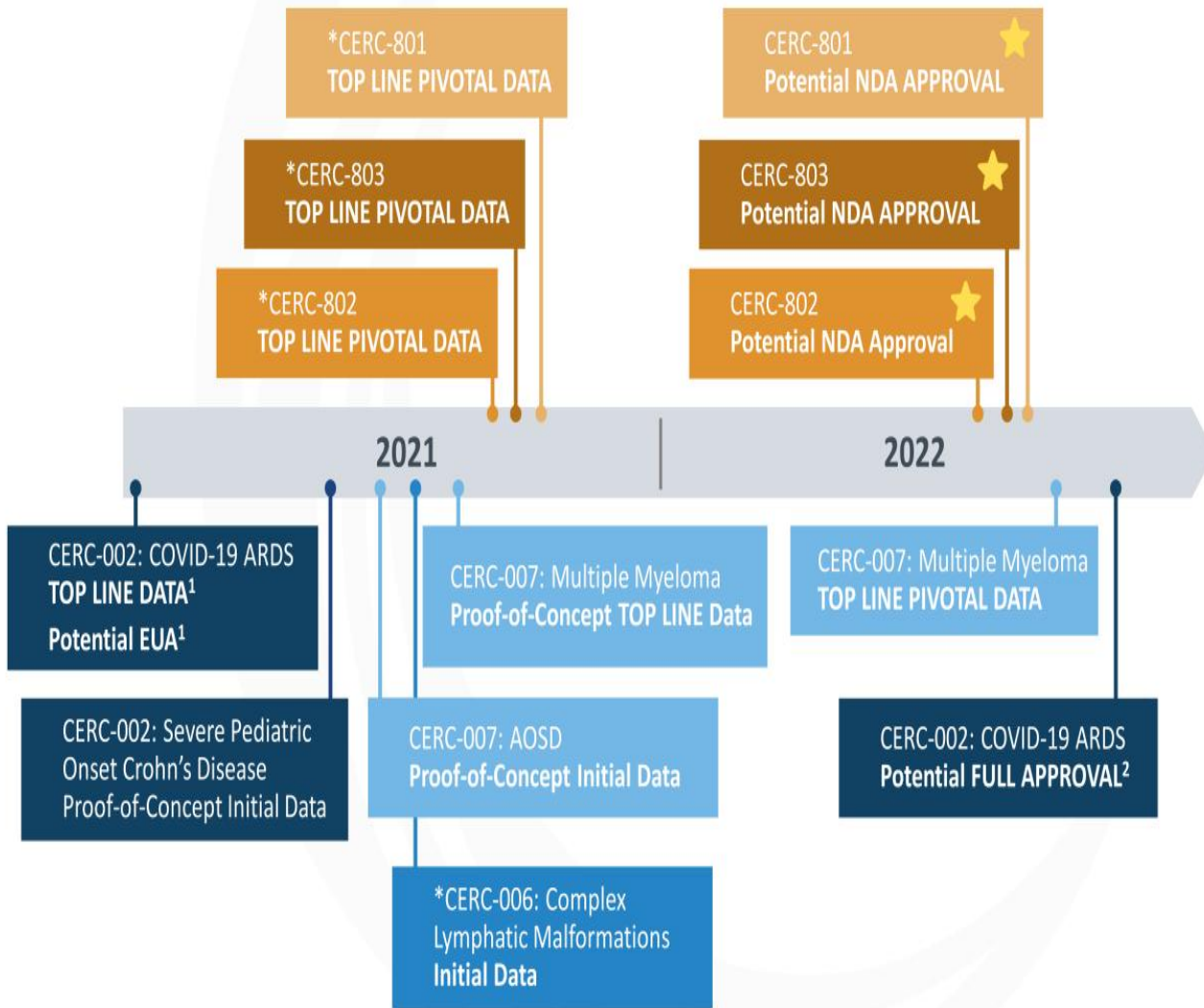
● D-Mannose

◄ L-Fucose

	CERC-801	CERC-802	CERC-803
Accelerated Pathway	✓	✓	✓
FDA ODD 7-yrs Exclusivity	✓	✓	✓
Priority Review Voucher*	✓	✓	✓
Pivotal Data Anticipated	2H 2021	2H 2021	2H 2021

Highlights Through 2022

Multiple catalysts and 4 potential PRV awards from first-in-class medicines for diseases with no approved treatment options



■ CERC-800s
 ■ CERC-002
 ■ CERC-007
 ■ CERC-006
 ★ PRV Award



Key Financial Information



Financial & Investor Information

Key financial highlights

NASDAQ: CERC

Information as of December 31, 2020:

- Outstanding common shares – 75M*
- Fully diluted shares – 95.3M*
- Cash – \$18.9M

Information as of February 28, 2021:

- Unaudited cash balance – \$44M
- Average daily trading volume – 952K⁺

Footnotes

* Issued approximately 14M shares of common stock and 1.7M pre-funded warrants in January 2021 as a part of an underwritten public offering

⁺ Represents trailing 90-day data as of February 28, 2021

Select Board and Management Team Members

Proven track record in drug development & commercialization



Michael Cola

Chief Executive Officer

- Former President of Specialty Pharmaceuticals, Shire plc
- Former President of the Life Sciences Group, Safeguard Scientifics, Inc.



Garry Neil, MD

Chief Scientific Officer

- Former Corporate VP of Science & Technology, Johnson & Johnson
- Former Group President, Johnson & Johnson Pharmaceutical Research and Development



Sol J. Barer, PhD

Chairman of the Board of Directors

- Chairman of the Board of Directors, Teva Pharmaceutical Industries
- Former Chairman and CEO, Celgene Corp.





NASDAQ:CERC

www.cerecor.com



References: CERC-002

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References: CERC-006, CERC-007, CERC-800s

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