

## Cautionary Note Regarding Forward-Looking Statements

All statements other than statements of historical facts contained in this presentation, including information concerning the offering, our possible or assumed future results of operations and expenses, business strategies and plans, competitive position, business and industry environment and potential growth opportunities, are forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements regarding:

- Our expectations for timing and achievement of the key corporate and COVID-19 milestones described in the presentation, including;
  - The target date for completion of patient enrollment in our Phase 3 trial of lenzilumab in COVID-19 patients;
  - The anticipated use of lenzilumab in the ACTIV-5 Trial sponsored by NIAID, and the anticipated scope of that trial and timeline for same;
  - Our potential request for and receipt of an Emergency Use Authorization from FDA for lenzilumab in COVID-19 and our expectations for filing a BLA; and
  - Our plans to launch and commercialize lenzilumab following receipt of the requisite regulatory authorizations or approvals; and
- Our expectations for timing and achievement of milestones for our pipeline outside of COVID-19, including in respect of our ZUMA-19 Phase Ib trial of lenzilumab that is being conducted with Kite, a Gilead company; our ongoing Phase I trial of ifabotuzumab in GBM patients; our plans for a study of lenzilumab in GVHD expected to be conducted with the IMPACT Group in the United Kingdom and a study in the US, and our plans for a study of lenzilumab in CMML in Australia;

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in our lack of profitability and need for additional capital to grow our business; our dependence on partners to further the development of our product candidates; the uncertainties inherent in the development and launch of any new pharmaceutical product; the outcome of pending or future litigation; and the various risks and uncertainties described in the "Risk Factors" sections of our latest annual and quarterly reports and other filings with the SEC.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not rely upon any forward-looking statements, as predictions of future events. We undertake no obligation to revise or update any forward-looking statements made in this presentation to reflect events or circumstances after the date hereof, to reflect new information or the occurrence of unanticipated events, to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, in each case, except as required by law.

## **Company Highlights**

Leading expertise in Hyper-inflammation and Cytokine Storm across multiple therapeutic applications 300 patient Phase 3 registration study in COVID-19; ACTIV-5 200 patient, fully-sponsored COVID-19 BET study; positive case control-study published Strong mid-to-late stage clinical pipeline including potential registration studies in CAR-T (US) and GvHD (UK); collaboration with Kite/Gilead in CAR-T Potential Emergency Use Authorization, commercial readiness and manufacturing scale-up Humanigen underway Backed by blue-chip institutional shareholders, including Venrock, Valiant, Surveyor, Healthcor, as well as management. NASDAQ listing added additional Institutional Healthcare investors. **Experienced and execution-oriented management and Board of Directors** 

## Lenzilumab™: A First-in-Class Humaneered® Monoclonal Antibody Targeting **Human GM-CSF**



 Humanigen has developed a neutralizing, IgG1, monoclonal antibody against human GM-CSF, using proprietary Humaneered technology

- Humaneered technology designed to optimize antibody properties
- Lenzilumab shown to be safe in clinical settings following administration to 125 patients<sup>1</sup> in multiple indications (including severe respiratory conditions and leukemia) with no serious adverse events

### **Engineering Process**



- Murine segments replaced by human sequences from human donor library
- Very high specificity to human-germline
- Reduces immunogenicity
- Higher binding affinity, slow off-rate
- Attractive COGs



#### **Therapeutic Goals**



- Designed to eliminate immunogenicity that may arise from chimeric conventionally humanized antibodies
- Clinically tested in more than 200 subjects (sum of lenzilumab plus chimeric predecessor antibody) with no serious immunogenicity

## Clinical-Stage Pipeline: Lenzilumab in COVID-19

	Indication	Phase	Status	Centers	Partners
Lenzilumab™	Potential Registration Enabling Prevention / treatment of Hyper-inflammation / Cytokine Storm	3	Recruiting 300 patients (>50% enrolled)	18 US Up to 12 Brazil Up to 5 Mexico	MAYO CLINIC Dartmouth GEISEL SCHOOL OF MEDICINE  Company sponsored
	ACTIV-5/BET Prevention / treatment of Hyper-inflammation / Cytokine Storm	2	Recruiting 200 patients	Up to 40 sites	National Institutes of Health

Phase 3 top-line data readout expected Q4 2020

## Clinical-Stage Pipeline: Non COVID-19

	Indication	Phase	Status	Centers	Partners
	ZUMA-19: Break CAR-T Efficacy/Toxicity Linkage Prophylaxis as sequenced therapy with Yescarta in r/r DLBCL	1b/2 <sup>1</sup>	Recruiting	10 sites MD Anderson Cancer Center Including MD Anderson and other ZUMA-1 sites	Kite GILEAD Creating Possible
	Prevention/Treatment of Acute GvHD Allogeneic HSCT	2/3	Advanced planning	Up to 23 sites <sup>2</sup>	PACT  THE UNIVERSITY OF LINEAU TRANSPLATION  THE UNIVERSI
Lenzilumab	CMML  Lenz + azacitidine in NRAS, KRAS or CBL  mutant-positive newly-diagnosed patients	2	Advanced planning		Undisclosed
	CMML  Monotherapy in salvage patients	1	Completed	MAYO CLINIC MOFFITT CANCER CENTER	
	Eosinophilic Asthma (EA) Inadequately controlled asthma	2	Completed	47 sites³	
Ifabotuzumab	Solid Tumors (Glioblastoma Multiforme)	1	Active, almost fully recruited	QIMR Berghofer Medical Research Institute Olivia 4 Newton-John Carcer Research Institute	Olivia Newton-John Cancer Research Institute
HGEN005	EA and other eosinophilic diseases	Preclinical	Initiating IND- enabling studies		National Institutes of Health



<sup>&</sup>lt;sup>1</sup> Phase III may not be necessary for approval in ZUMA-19; precedent is CAR-Ts to date have been approved on Phase II data <sup>2</sup> UK

<sup>&</sup>lt;sup>3</sup> US, EU, Australia

## Key Expected Corporate and Lenzilumab in COVID-19 Milestones

2020

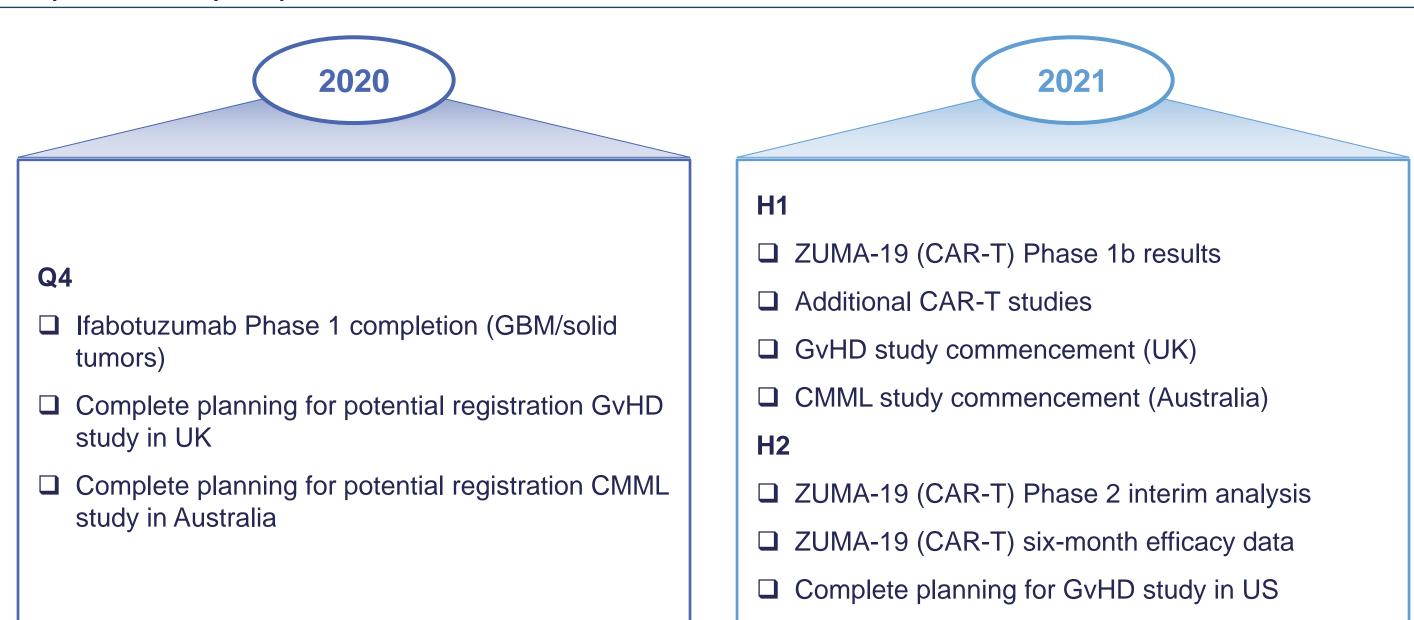
2021

#### **H2**

- Mayo case-controlled publication
- ✓ ACTIV-5/BET NIH fully-sponsored 200 patient study (lenzilumab + rem vs. rem alone)
- ☐ Target completion of Phase 3 enrollment
- ☐ Phase 3 top-line data
- Increased manufacturing capacity
- □ Application for Emergency Use Authorization (EUA)

- ☐ ACTIV-5 top-line data
- BLA submission
- ☐ Large scale manufacturing capacity
- ☐ Life cycle management:
  - New patient segments
  - Label expansion
  - Additional dose formulations
  - Further international studies

## Pipeline Key Expected Non-COVID Milestones



## Experienced and Execution-Oriented Management



#### Cameron Durrant, MD, MBA – Chief Executive Officer

- Serial biotech experience as Exec Chair, CEO, CFO
- Led previous deals with Gilead while at J&J
- Launched 5 blockbusters

Johnson Johnson









#### Tim Morris, CPA - Chief Operating and Financial Officer

- Retired CFO lovance; raised > \$2Bn over 28 years
- Extensive deal experience with >75 transactions, combined value \$4B
- 5 NDA/MAA and associated commercial prep and launch experience











#### Dale Chappell, MD, MBA - Chief Scientific Officer

- Founder, Black Horse Capital Advisors; decades of biotech investment experience
- Head of healthcare portfolio, Chilton Investment Company
- Multiple publications in T-cell therapy, GM-CSF, immunology pathways







## David Tousley, CPA, MBA – Chief Accounting and Administrative Officer, Corp Secretary and Treasurer

- Significant pharmaceutical and biotech experience
- Led many corporate functions, including finance and accounting
- Raised \$400+ million in equity and debt financings







#### Ed Jordan, MBA - Chief Commercial Officer

- Senior commercial roles, across the healthcare industry
- Extensive product launch experience including immunology, oncology, hematology









#### **Bob Atwill, MBA - Head of Asia-Pacific Region**

- 30 years of biopharma experience, including cell therapy
- Extensive network in Asia-Pacific, BD+L, fundraising and clinical development



**SANOFI** 

**meso**blast

#### Omar Ahmed, PharmD - SVP. Clinical, Medical and Scientific Affairs

- 20-year pharmaceutical executive experience
- Led multiple blockbuster launches
- Led development of Janssen's immunology portfolio strategy









## Highly Credentialed and Engaged Board

#### **Bob Savage, MBA**

- Former Worldwide Chairman, J&J Pharmaceuticals
- Former President WW Therapeutics and Inflammation, Pharmacia
- Served on 12 boards, 40+ years of experience







#### Ron Barliant, JD

- Of counsel with Goldberg Kohn
- US bankruptcy judge for N. Illinois for 14 years, extensive legal and bankruptcy experience





#### Cameron Durrant, MD, MBA – Chief Executive Officer

- Serial biotech experience as Exec Chair, CEO, CFO
- Led previous deals with Gilead while at J&J
- Launched 5 blockbusters









#### Rainer Boehm, MD, MBA

- Former interim CEO Novartis Pharma; Chief Commercial and Chief Medical Affairs Officer, Novartis Pharma; EVP, Novartis Oncology
- Board member Cellectis





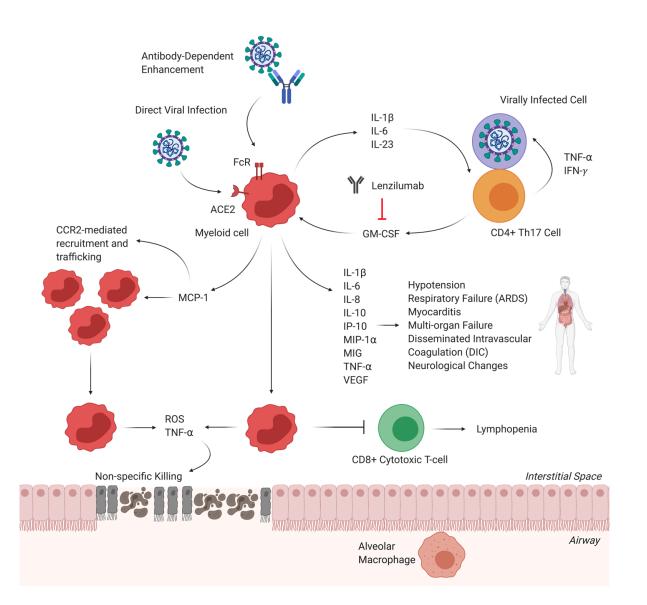
#### **Cheryl Buxton**

- Vice Chair, Global Pharmaceuticals, Korn Ferry
- Former HR Director, J&J Pharmaceuticals



- 1 Therapeutic for COVID-19 Patients
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## Neutralization of GM-CSF to Prevent COVID-19 Cytokine Storm

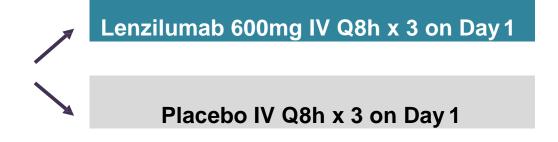


- GM-CSF neutralization prevents CD14+CD16+ inflammatory myeloid cell activation and reduces all downstream monokine production
- IL-6 blockade reduces only IL-6 and does not block inflammatory myeloid cells activation and all downstream monokine production
- IL-6 blockade alone has not shown clinical utility as a preventative measure in CAR-T induced Cytokine Storm
   IL-6 inhibitors have failed in studies in COVID-19
- Monokines such as MCP-1, MIP-1α, MIG, IP-10, IL-1 are important in the inflammatory cascade and only blocked with GM-CSF neutralization

### Lenzilumab Phase 3 in Severe or Critical COVID-19

Multicenter, randomized, double-blind, placebo-controlled pivotal trial NCT 04351152

Adults ≥ 18 yrs
Hospitalized, confirmed SARS-CoV-2
Severe or Critical COVID-19 pneumonia
(N = 300, 1:1)



Daily assessment through Day 28 for 1° and 2° endpoints while hospitalized;

If discharged, follow-up assessments on Days 28 and Day 60

- Severe COVID-19: SpO<sub>2</sub> ≤ 94% on Room Air or Low-flow Supplemental Oxygen
- Critical COVID-19: High-flow Oxygen Device or NPPV or Multi-organ Failure or Shock

All subjects receive institutional standard of care which may include remdesivir or corticosteroids

### Lenzilumab for COVID-19 Clinical Status: Phase 3 Remains on Track

Double-blind, placebo-controlled study of 300 patients, 18 US sites, expanded to Brazil, Mexico approved

- Potential to serve as basis for Emergency Use Authorization (EUA)
- Enrollment now greater than 50%
- Trial designed at 90% power to show improvement of time to recovery from 9 days for placebo to 6 days with lenzilumab (HR=1.5)
- DSMB interim analysis completed (50% of events achieved)
  - Event defined as 'recovery' on the 8-point hospital ordinal scale (discharged or no longer receiving medical care)
  - Reviewed safety
  - Reviewed for futility
  - Reviewed for sizing and powering assumptions

DSMB Recommendation in September 2020 to Proceed as Planned Per Protocol

## Primary Endpoint: Time to Recovery by Day 28 (Ordinal Scale 6, 7 or 8)

Consistent with NIAID-Sponsored ACTT-1 and ACTT-2 Studies of remdesivir and baricitinib

	Clinical Status Ordinal Scale	Clinical Status Description for Assessment
	8	Not hospitalized, no limitations on activities
1° Endpoint	7	Not hospitalized, limitation on activities, and/or requiring home oxygen
	6	Hospitalized, not requiring supplemental oxygen and no longer requires ongoing medical care (if hospitalization extended for infection-control purposes)
Phase 3 Eligible	5	Hospitalized, not requiring supplemental oxygen; requiring ongoing medical care (COVID-19 related or otherwise)
	4	Hospitalized, requiring supplemental oxygen
	3	Hospitalized, on noninvasive ventilation or high-flow oxygen devices
	2	Hospitalized, on invasive mechanical ventilation or ECMO
Endpoints	1	Death

## Mayo Clinic Case-Control Trial Design

- Case-control study (n=39)
  - 12 patients treated with lenzilumab
    - Lenzilumab treated patients dosed with 600 mg intravenously for three doses
  - Contemporaneous standard of care control patients selected from electronic medical records from across Mayo clinic enterprise (n=27)
    - Substantial number of standard of care control patients received other COVID-specific treatments
    - Outcomes of control patients unknown at time of selection.
- Patients matched for age, gender, disease severity

#### Mayo Clinic Proceedings

Lenzilumab for COVID-19

#### GM-CSF Neutralization With Lenzilumab in Severe COVID-19

#### Pneumonia: A Case-Control Study

#### Authors

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## Mayo Clinic Case-Control Trial Baseline Characteristics

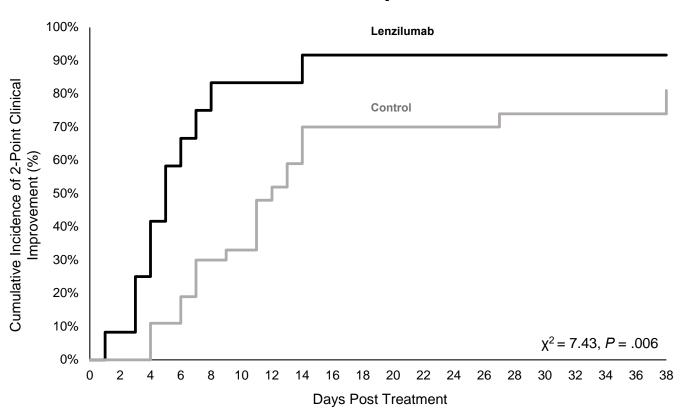
- Patients matched for baseline characteristics
- Lenzilumab group has slightly higher COVID-19 relative risk factors
  - DM2, HTN, BMI
- CRP elevated in lenzilumab group but T cell counts similar
- Oxygen therapy equally matched

Characteristic	Lenzilumab group (n=12)	Control group (n=27)	P-value
Age, y	65 (52-70)	68 (61-76)	.25
Male	8 (67%)	19 (70%)	> .99
Female	4 (33%)	8 (30%)	> .99
Race			
White	9 (75%)	17 (63%)	.79
Asian	2 (17%)	5 (19%)	> .99
American Indian/Native American	1 (8%)	0 (0%)	.36
Comorbidities			
Diabetes mellitus	7 (58%)	14 (52%)	> .99
Hypertension	7 (58%)	na	na
Obesity (BMI > 30)	6 (50%)	9 (33%)	.54
Coronary artery disease	2 (17%)	4 (15%)	> .99
Kidney transplantation	1 (8%)	na	na
Obstructive lung disease	4 (33%)	na	na
Chronic obstructive pulmonary disease	2 (17%)	11 (41%)	.47
Reactive airway disease	1 (8%)	na	na
Temperature (degrees Celcius)	38 (37.25-38.5)	37.5 (37.1-38.4)	.76
nflammatory markers before treatment			
CRP (<= 8.0 mg/L)	103.2 (52.7-159.9)	74.4 (42.2-131.5)	.25
Ferritin (24-336mcg/L)	596.0 (358.3-709.0)	673.0 (406.8-1012.8)	.75
IL-6 (<= 1.8 pg/mL)	30.95 (24.18-34.05)	29.20 (13.55-40.70)	.87
D-dimer (<=500 ng/mL)	829 (513 5-1298 5)	916 (585 0-1299 0)	.84
Lymphocyte count before treatment (0.95-3.07x10^9/L)	0.75 (0.55-1.04)	0.76 (0.59-1.01)	.91
Oxygen therapy before treatment			
Nasal cannula (=4 clinical ordinal endpoint scale)	8 (67%)	20 (74%)	> .99
High-flow oxygen/NIPPV (=3 clinical ordinal endpoint scale)	4 (33%)	7 (26%)	.73
Invasive ventilation (=2 clinical ordinal endpoint scale)	0 (0%)	0 (0%)	> .99
SpO2/FiO2 before treatment	280.9 (252.5-317.9)	289.1 (254.9-342.0)	.98

## Lenzilumab Significantly Improved Clinical Outcomes

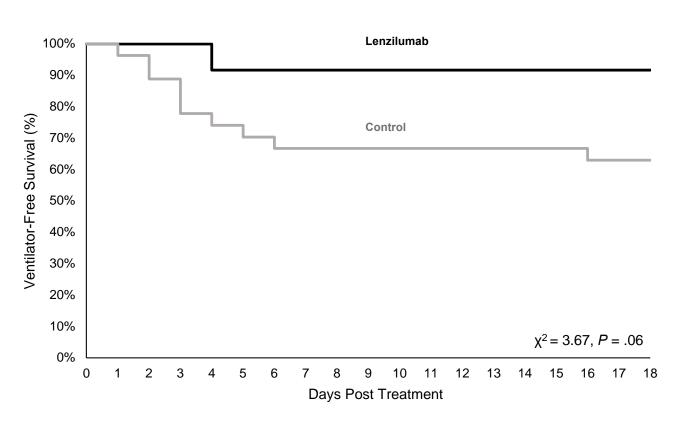
# Time to clinical improvement significantly shorter for lenzilumab (5 days vs 11 days)

#### **Time to Clinical Improvement**



### Ventilator-free survival better for lenzilumab

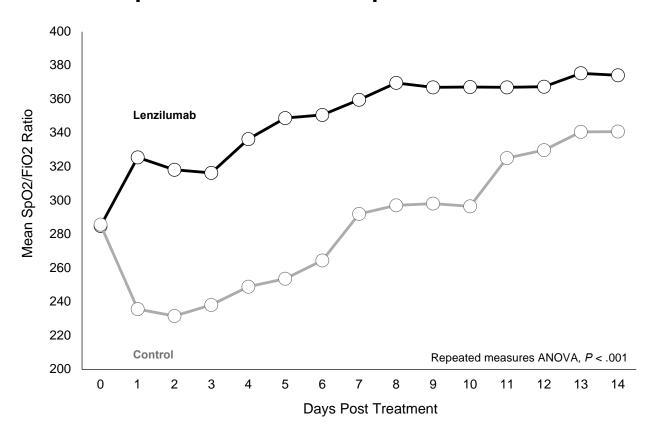
#### **Progression to IMV and/or Death**



## Lenzilumab Rapidly Improves Oxygenation Status

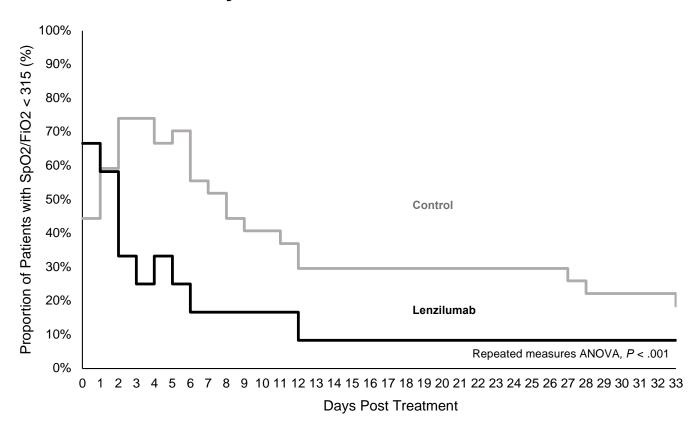
# Significant difference between lenzilumab and untreated groups over time post-treatment

#### Improvement in Mean SpO2/FiO2 Ratio



# Proportion of patients free of ARDS significantly increased with lenzilumab over time

#### Days to resolution of ARDS



## Lenzilumab Reduces Hospital Stays and Risk of Ventilation/Death

Table 2. Clinical Outcomes	Lenzilumab group (n=12)	Control group (n=27)	<i>P</i> -value
Incidence of clinical improvement	11 (92%)	22 (81%)	.43
Days to clinical improvement	5 (1 - 14)	11 (4 - 42)	.006
Days to discharge from hospital	5 (3-19)	11 (4 - 42)	.008
Mean temperature reduction	1.075	0.459	.02
Days to resolution of fever	2 (1-6)	1 (1-3)	.22
Incidence of IMV	1 (8%)	10 (37%)	.10
Incidence of death	1 (8%)	5 (19%)	.43
Incidence of IMV and/or death	1 (8%)	11 (41%)	.07

Table 3. Laboratory Markers	Lenzilumab group (n=12)	Control group (n=27)	<i>P</i> -value
CRP reduction	135.8	-0.95	.01
IL-6 reduction	20.1	na	na
ALC increase	0.46 x 10^9/L	0.03 x 10^9/L	.04
PLT increase	52.5	63.2	.61

## ACTIV-5/BET Big Effect Trial (BET-B) for the Treatment of COVID-19

Double-blind, placebo-controlled study of 200 patients, NIH-sponsored, up to 40 US sites NCT 04583969

- Lenzilumab is the third of six agents selected by NIH, the only GM-CSF molecule selected
- Over 400 compounds reviewed by NIH for inclusion in ACTIV protocols
- Humanigen is the only small company in NIH-sponsored studies
- NIH has awarded contracts totaling ~\$26M to support the study, HGEN providing lenz
- NIH will conduct the study, HGEN and NIH collaborated on protocol
- First subject expected to be dosed in October
- Planned interim analysis for efficacy at 50% enrollment
- Study expands number of patients for BLA submission and potential label to include use with remdesivir

## COVID-19 Associated ARDS Successfully Treated with Lenzilumab-Case Study

- COVID-19 subject treated at Baptist Medical Center, Jacksonville, FL
  - 77-year-old male
  - Medical history of severe chronic obstructive pulmonary disease (COPD) with emphysema, coronary artery disease, type II diabetes, and obstructive sleep apnea
- Admitted to ICU with fever, shortness of breath and confirmed SARS-CoV-2 infection
- Patient developed ARDS that did not resolve with standard therapies
- Patient treated with lenzilumab on week 13 under emergency single use IND
- One-week post-therapy: oxygen demands decreased and lymphopenia appeared to improve
- Discharged from ICU after 16 days
  - Lenzilumab appeared to accelerate recovery and discharge time

#### COVID-19 associated chronic ARDS successfully treated with lenzilumab

**Authors:** Juan D. Pulido, M.D.<sup>1</sup>, Rida Rasool, D.O.<sup>1</sup>, Gabrielle Chappell<sup>2</sup>, Omar Ahmed,

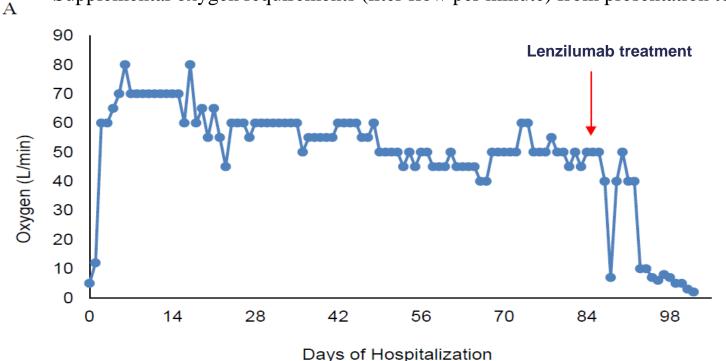
Pharm.D.<sup>2</sup>, Cameron Durrant, M.D. M.B.A.<sup>2</sup>, Dale Chappell, M.D. M.B.A.<sup>2</sup>

#### **Affiliations:**

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<sup>2</sup>Humanigen, Inc, Burlingame, CA

Supplemental oxygen requirements (liter flow per minute) from presentation to discharge

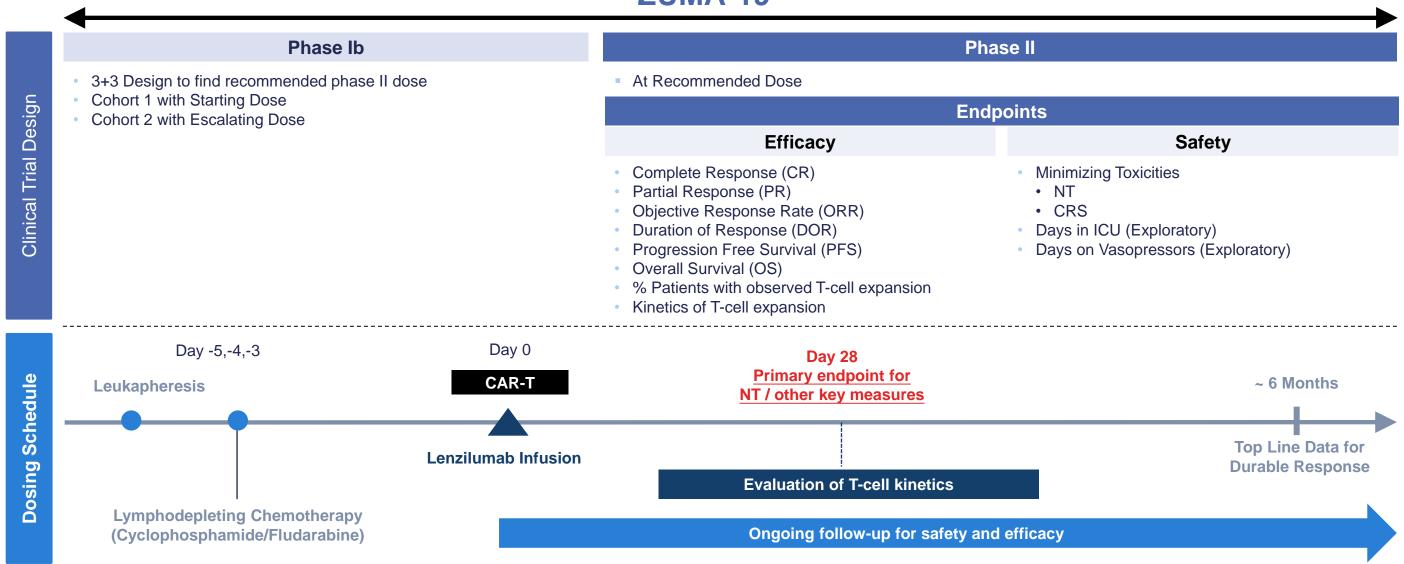


- 1 Therapeutic for COVID-19 Patients
- 2 Improving efficacy / safety of CAR-T
- 3 Prevention / Treatment of Acute GvHD
- 4 Market Potential/Financial overview

## **ZUMA-19 Potential Registration Study**



### **ZUMA-19**



ClinicalTrials.gov Identifier: NCT04314843

## Benefits Of Deal Structure To Humanigen





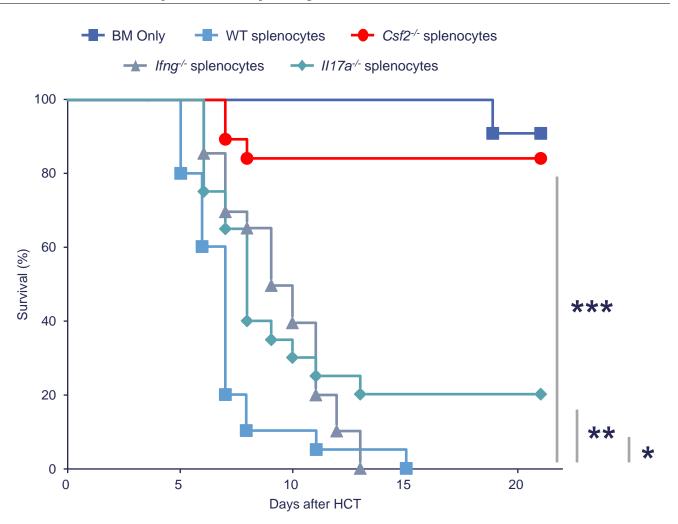
Non-exclusive deal
Humanigen retains 100% of lenzilumab economics
Multicenter trial with CAR-T world leader
Significant costs funded by external party
Leverages Kite development infrastructure

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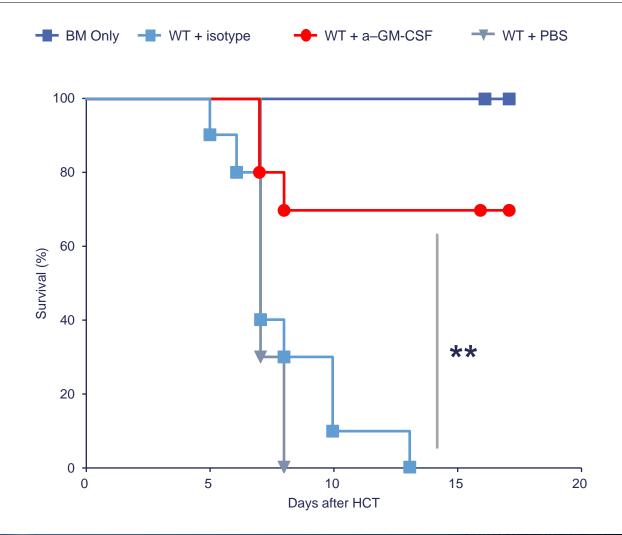
## **GM-CSF Blockade Reduces GvHD Mortality**

Proof of concept study demonstrates role of GM-CSF in GvHD

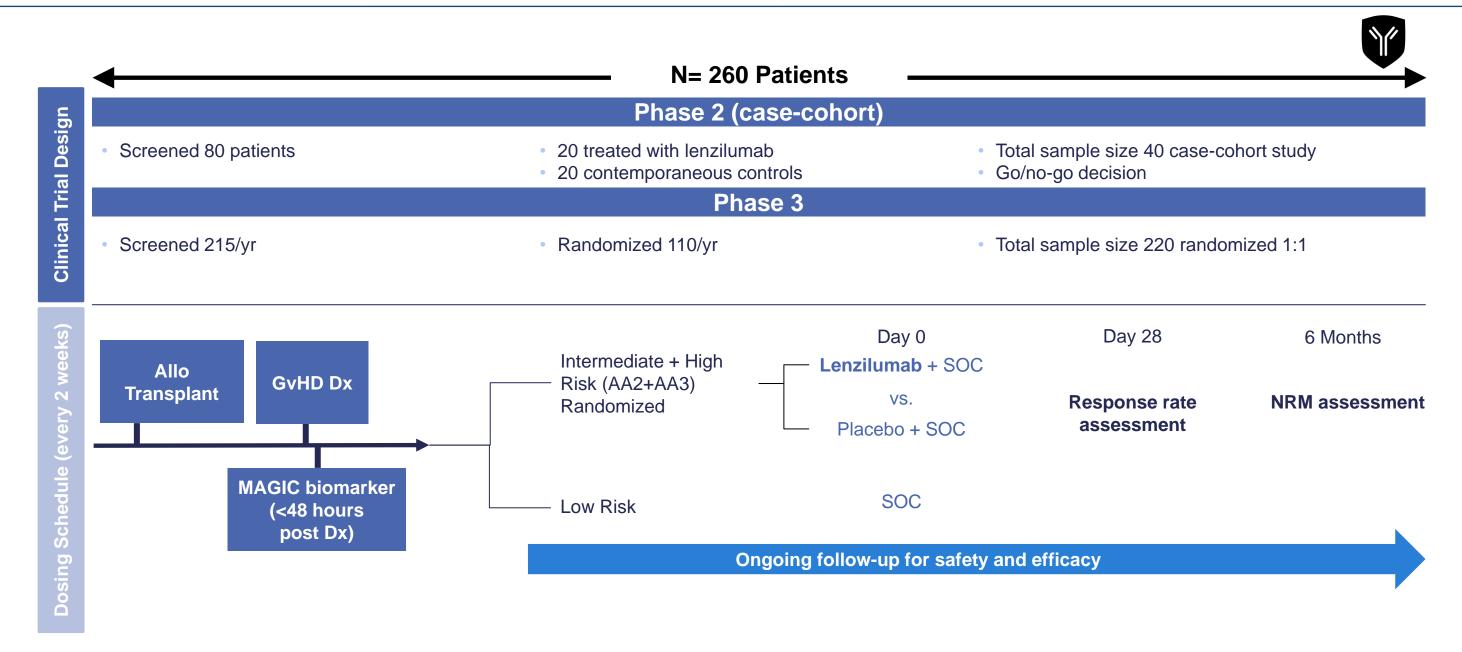
### **GM-CSF k/o (CSF2-/-) improves GvHD survival**



#### Anti-GM-CSF antibody improves GvHD survival



## IMPACT Partnership/HGEN GvHD Trial Design



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## Significant Market Potential for Lenzilumab for COVID-19



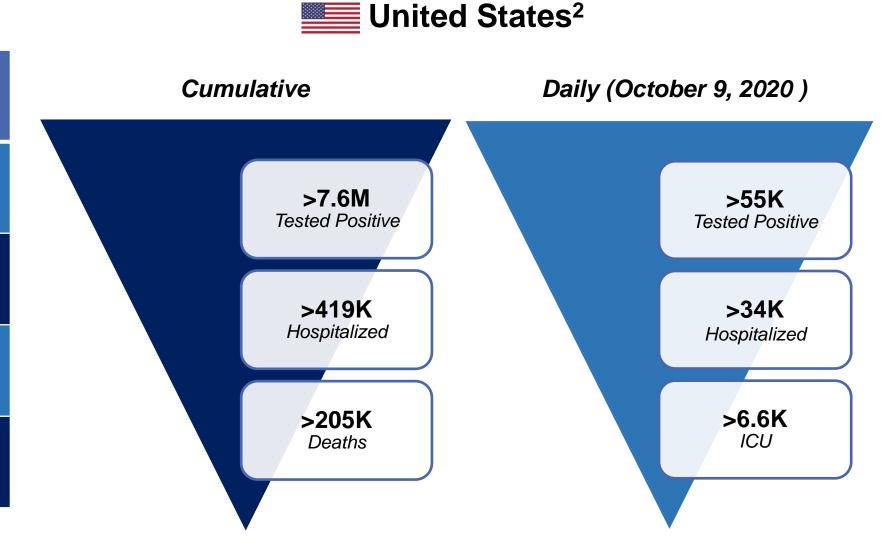
37M cases worldwide<sup>1</sup>
1 million deaths

Lung injury is most frequent cause of death related to COVID-19

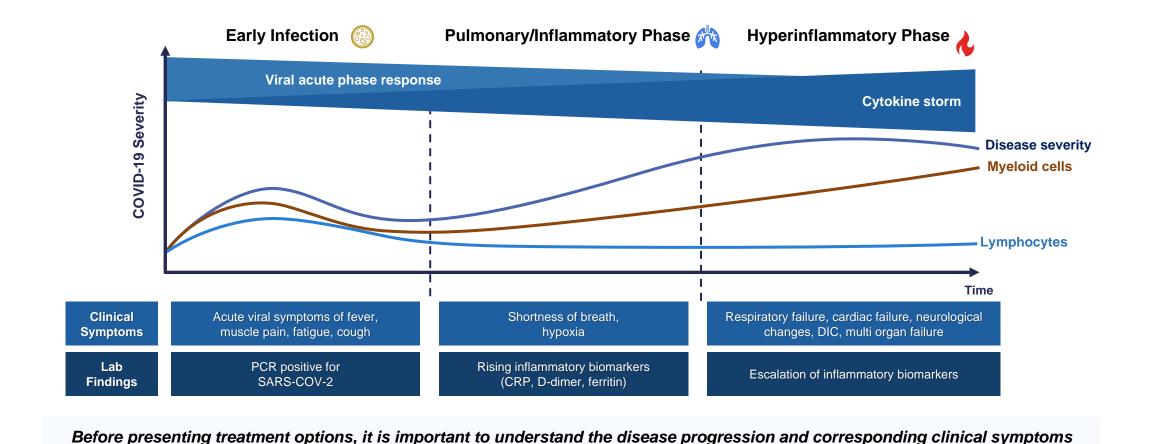
**Mortality rate for ventilator patients is >23%** 

Limited treatments with benefit available

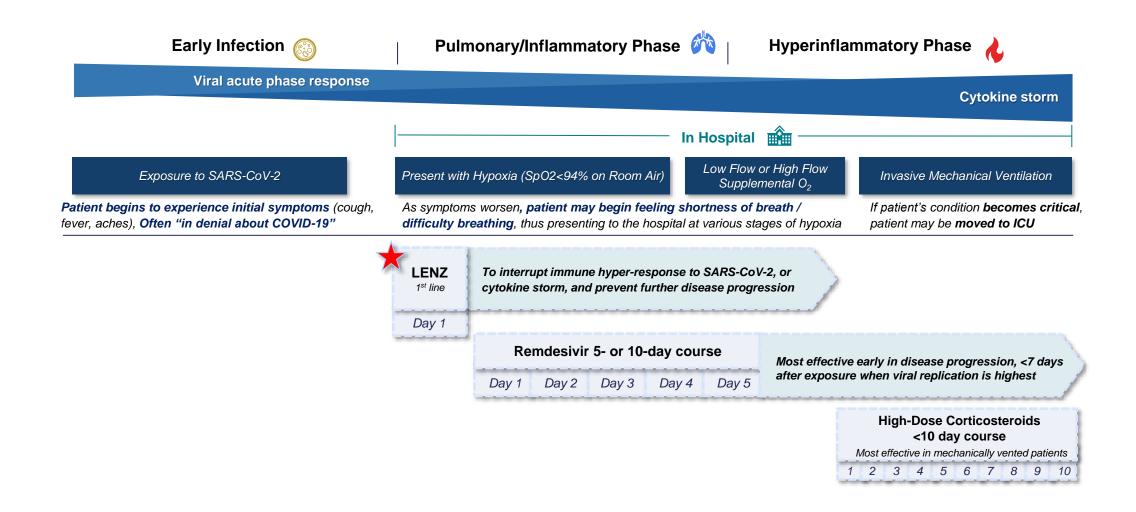
Vaccine timelines and effectiveness unclear



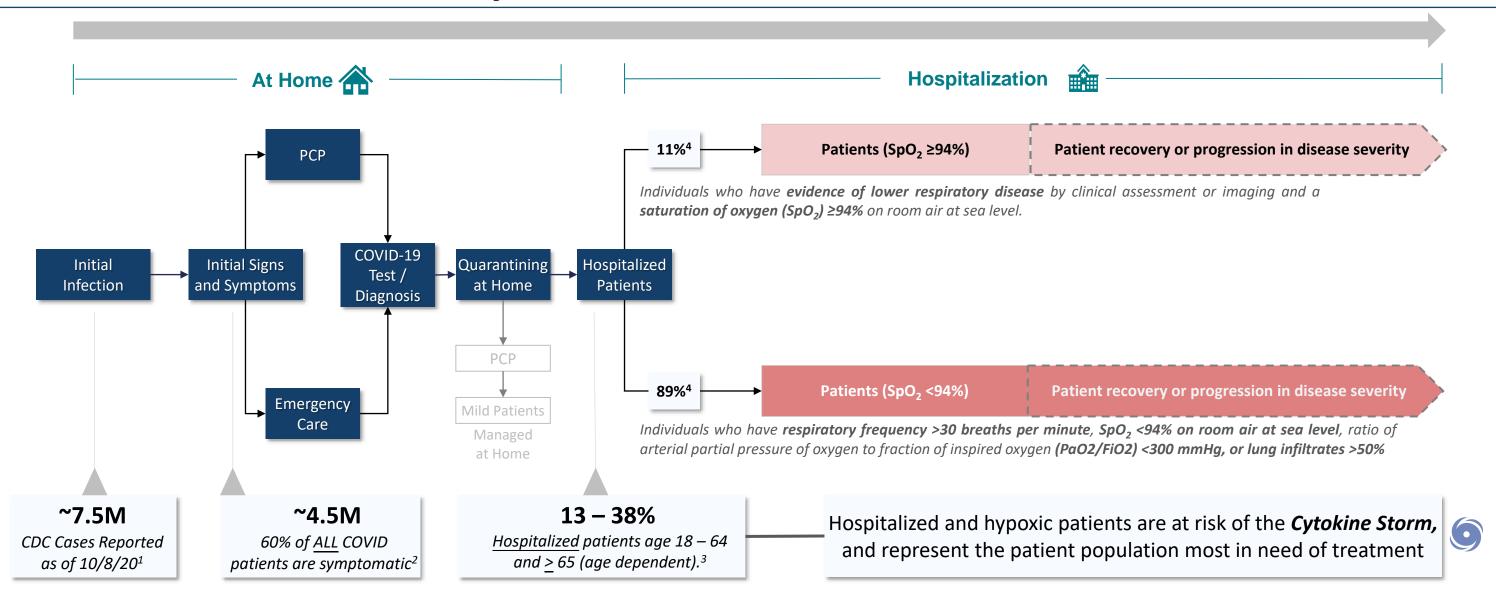
## Disease Progression Through 3 Key Phases



## Patient Journey | COVID-19 Treatment Options

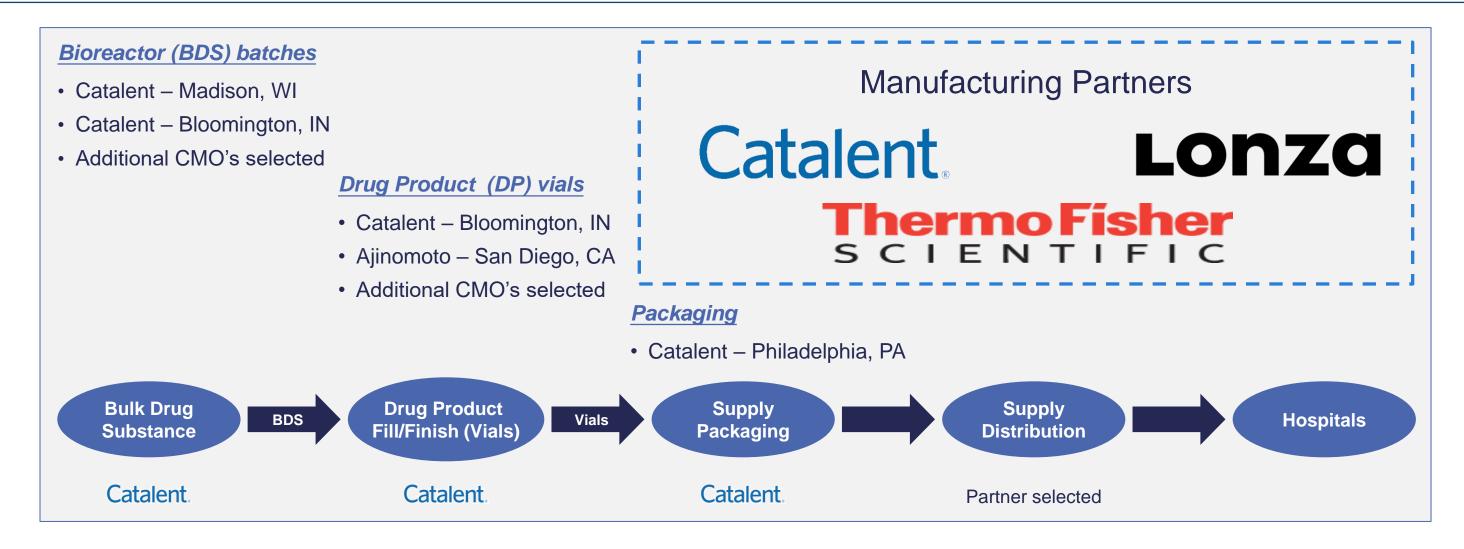


## **Covid-19 Patient Journey**





## Established Manufacturing Agreements for Lenzilumab



Engaged multiple contract manufacturing organizations (CMOs) to scale-up and optimize the manufacturing process to meet a target of supplying ~100,000 treatment courses

## Nasdaq Listing Effective 9.17.20 Trading Under "HGEN"



### Proceeds from IPO of \$78 Million, JP Morgan and Jefferies Lead Underwriters

Humanigen, Inc. is offering 8,000,000 shares of its common stock.

Our common stock is currently listed for quotation on the OTCQB Venture Market operated by OTC Markets Group, Inc. We completed a 1-for-5 reverse stock split on September 11, 2020. Unless we indicate otherwise, all share and per share information presented as of June 30, 2020 in this prospectus supplement reflects the completion of the reverse stock split. Our historical financial statements incorporated by reference into this prospectus supplement do not reflect the reverse stock split. Our common stock currently is quoted on the OTCQB Venture Market under the symbol "HGEND". On September 17, 2020, the last reported sale price per share of our common stock on the OTCQB Venture Market was \$10.40.

We have received approval from The Nasdaq Stock Market, LLC to list our common stock on the Nasdaq Capital Market under the symbol "HGEN" subject to confirmation of the issuance of the shares in this offering.

	Per Share		<u>Total</u>
Public offering price	\$ 8.	50	\$ 68,000,000
Underwriting discounts <sup>(1)</sup>	\$ 0.	51	\$ 4,080,000
Proceeds to Humanigen, before expenses	\$ 7.	99	\$ 63,920,000

The Company has agreed to reimburse the underwriters for certain expenses. See "Underwriting" beginning on page S-32 of this prospectus supplement.

The underwriters expect to deliver the shares of common stock to purchasers on or about September 22, 2020.

J.P. Morgan

**Jefferies** 

National Securities Corporation Bryan, Garnier & Co.

H.C. Wainwright & Co. Roth Capital Partners

September 17, 2020

#### Proforma Cap Table

	As of June 30, 2020		
	Actual	As	Adjusted
	(in thousar	ıds, e	except
	share	data	
Cash and cash equivalents	\$ 41,729	\$	104,979
Long-term debt	\$ 	\$	
Common stock, par value \$0.001 per share: 225,000,000 shares authorized, actual and as adjusted; 41,974,915 shares issued and outstanding, actual; 49,974,915 shares			
issued and outstanding, as adjusted	42		50
Additional paid-in capital	342,943		406,185
Accumulated deficit	(311,384)		(311,384)
Total stockholders' equity	31,601		94,851
Total capitalization	\$ 342,985	\$	406,235

#### **Use of Proceeds**

- Completion of Phase 3 clinical trial
- Submission of EUA
- Expand manufacturing capacity for lenz
- Prepare for EUA commercialization and revenues



## **Upcoming Catalysts and Goals**

Complete recruitment in Phase 3 COVID-19 study and ACTIV-5 **Top-line data from Phase 3 study EUA Submission and subsequent approval** Prepare for EUA distribution and scale-up manufacturing Continue CAR-T recruitment, and complete planning for GvHD study