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): September 14, 2021

Humanigen, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35798**	**77-0557236**
(State or other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

533 Airport Boulevard, Suite 400
Burlingame, CA 94010
(Address of principal executive offices, including zip code)

(650) 243-3100
(Registrant's telephone number, including area code) (Former Name or Former Address, if Changed Since Last Report)
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 (see General Instruction A.2):

☐ 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	**HGEN**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure

On September 14, 2021, Humanigen, Inc. (the "Company") announced its participation in multiple investor conferences in September 2021. A copy of the presentation management will present in these conferences is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. In addition, this presentation will be made available on the Company's website, www.humanigen.com.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K, including Exhibit 99.1, contains 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 the sufficiency of the data from the ACTIV-5/BET-B study to warrant a future submission of a new EUA request; statements regarding the Company's efforts to request and receive Marketing Authorization or Conditional Marketing Authorization for lenzilumab in COVID-19 in the U.K. and other territories; the Company's expectations for the duration and severity of COVID-19 in the United States and around the world and its projections for COVID-19 hospitalizations in 2021 and future years; the Company's projections regarding the need for lenzilumab as a therapeutic if authorized or approved; the commercial potential of lenzilumab and the Company's ability to maintain a single worldwide price in the multiple jurisdictions in which it is seeking marketing authorizations or approvals or otherwise working to sell product prior to formal approvals; and the Company's other plans to initiate or participate in planned clinical trials and otherwise explore the effectiveness of lenzilumab and other candidates in its development portfolio as therapies for other inflammation and immune-oncology indications. These forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in the Company's lack of profitability and need for additional capital to grow its business; the Company's dependence on partners to further the development of its product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory authorization and approvals 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 and elsewhere in the Humanigen's periodic and other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this filing. The Company undertakes no obligation to revise or update any forward-looking statements made in this filing to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

Certain Information

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, except to the extent expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Humanigen September 2021 Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

HUMANIGEN, INC.

By: /s/ Cameron Durrant
Name: Cameron Durrant
Title: Chairman of the Board and Chief Executive Officer

Dated: September 14, 2021

Humanigen

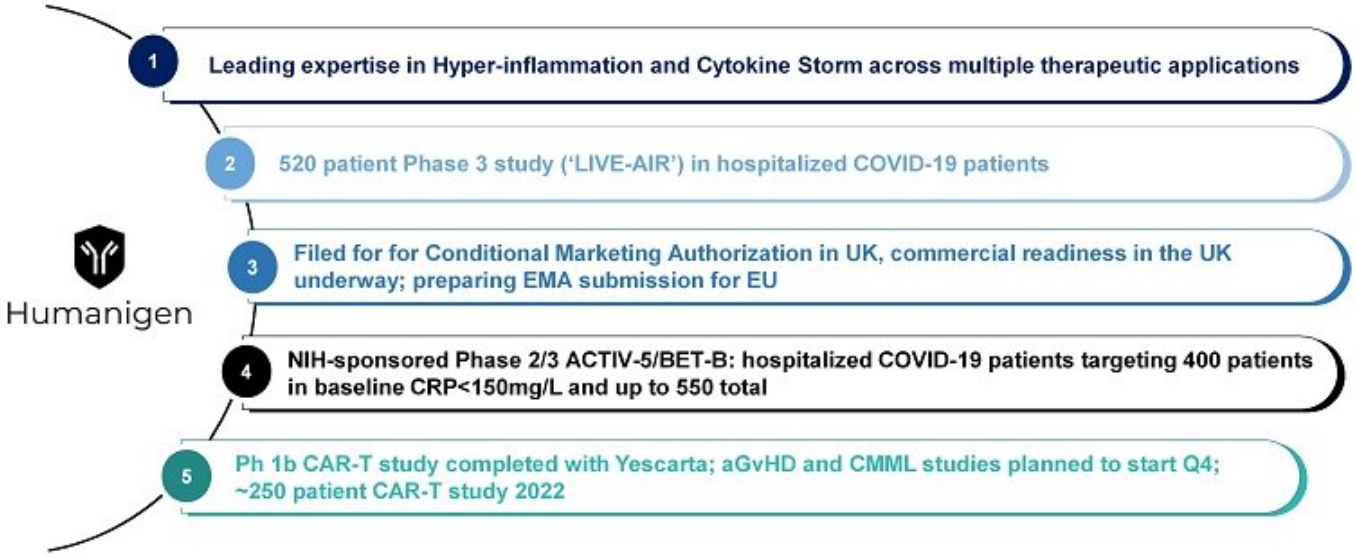
Cautionary Note Regarding Forward-Looking Statements

All statements other than statements of historical facts contained in this presentation 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 the sufficiency of the data from the ACTIV-5/BET-B study to warrant a future submission of a new EUA request; statements regarding our efforts to request and receive Marketing Authorization or Conditional Marketing Authorization for lenzilumab in COVID-19 in the U.K. and other territories; our expectations for the duration and severity of COVID-19 in the United States and around the world and our projections for COVID-19 hospitalizations in 2021 and future years; our projections regarding the need for lenzilumab as a therapeutic if authorized or approved; the commercial potential of lenzilumab and our ability to maintain a single worldwide price in the multiple jurisdictions in which we are seeking marketing authorizations or approvals or otherwise working to sell product prior to formal approvals; and our other plans to initiate or participate in planned clinical trials and otherwise explore the effectiveness of lenzilumab and other candidates in our development portfolio as therapies for other inflammation and immune-oncology indications.

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, attainment of the requisite regulatory authorizations and approvals 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 Overview



Lenzilumab is being developed as a potential treatment for COVID-19, it is not currently approved or authorized for use in any country

Business Update: September 2021

Lenzilumab for COVID-19

- September 8, 2021 FDA response to EUA submission:
  - Declined EUA at this time - invited Humanigen to submit additional data as it becomes available
  - No safety issues identified by FDA, noted relatively limited size of safety database
- Additional data may be be derived both from LIVE-AIR and ACTIV-5/BET-B
- UK Rolling Rapid-19 Review of Marketing Authorization Application (MAA) underway
  - Final module submissions expected before end of September 2021

Other key programs

- CMML and aGvHD studies target FPD Q4, 2021
- CAR-T study protocol to be submitted to FDA for review and approval, target FPD 1H, 2022

Robust Clinical Pipeline

	Indication	Phase	Status	Centers	Partners
Lenzilumab	**LIVE-AIR** Hospitalized COVID-19	3	Completed (520 patients)	24 US 11 Brazil	Company sponsored
	ACTIV-5/BET-B Hospitalized COVID-19 (DSMB recommended continuation following safety and futility interim analysis)	2/3	Enrolling (400 patients CRP<150 mg/L, up to 550 patients total) ~60% enrolled	Up to 70 sites	
	ZUMA-19 Prophylaxis (with Yescarta) in R/R DLBCL	1b	Completed (6 patients) No safety issues or severe CRS/NT at RP2D	10 sites	
	RATinG Prevention/Treatment of Acute GvHD (aGvHD)	2/3	Q4 FPD	Up to 23 sites[1]	
	PREACH-M Chronic myelomonocytic leukemia (CMML)	2/3	Q4 FPD	4 sites[2]	
Ifabotuzumab	**Solid Tumors** (Glioblastoma Multiforme)	1	Completed (12 patients)		

Note: DSMB-Data Safety Monitoring Board; R/R-Relapsed/Refractory; DLBCL-Diffuse Large B-Cell Lymphoma; CRS-Cytokine Release Syndrome; NT-Neurotoxicity; RP2D-Recommended Phase 2 Dose; FPD-first patient dosed

1. UK
2. Australia

Lenzilumab is being developed as a potential treatment for COVID-19, it is not currently approved or authorized for use in any country

LIVE-AIR Demographics and Baseline Characteristics (mITT Population)

Characteristics		Lenzilumab (N=236)	Placebo (N=243)	Overall (N=479)
Age	Mean (SD)	60.5 (13.5)	60.5 (14.3)	60.5 (13.9)
	Median (Min-Max)	62.0 (28-98)	62.0 (22-96)	62.0 (22-98)
	< 65 years old (%)	60.2	58.4	59.3
	≥65 years old (%)	39.8	41.6	40.7
	>80 years old (%)	7.6	5.3	6.5
Gender	Male (%)	64.8	64.6	64.7
Race	American Indian/Alaskan Native, %	1.7	0.0	0.8
	Asian, %	4.2	2.1	3.1
	Black/African American, %	16.1	13.6	14.8
	White, %	69.9	73.3	71.6
	Multiple, %	0.4	0.0	0.2
	Other, %	7.6	11.1	9.4
Ethnicity	Hispanic or Latino, %	35.2	42.0	38.6
	Not Hispanic or Latino, %	64.0	56.8	60.3
Body Mass Index	Mean (SD)	33.1 (8.4)	31.0 (7.9)	32.5 (8.2)
	≥30 Kg/m², %	57.6	52.7	55.1
Clinical Status at Baseline	SpO2 ≤94% or low-flow oxygen	61.9	57.6	59.5
	High-flow oxygen or NIPPV	38.1	42.8	40.5
CRP	Median	77.0	82.0	79.0
	CRP <150 mg/L, %	75.8	79.9	77.9
	CRP >150 mg/L, %	24.2	20.1	22.1

Study Primary Endpoint Met
Kaplan-Meier Estimates For IMV and/or Death

Failure to achieve survival without ventilation was defined as mortality or the requirement for IMV

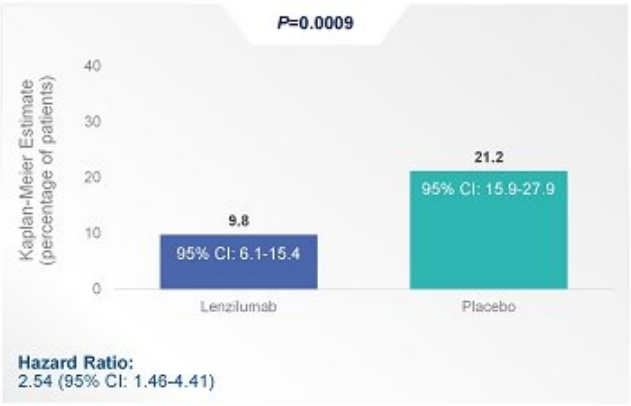
Fewer patients required IMV or died with lenzilumab treatment compared to placebo

Invasive Mechanical Ventilation (IMV) and/or death
mITT population (n=479)

Hazard Ratio:
1.54 (95% CI: 1.02-2.32); P=0.0403

Patients With Baseline CRP<150 mg/L Required IMV Or Died

SWOV CRP<150 mg/L*
mITT population (n=351)



Hazard Ratio:
2.54 (95% CI: 1.46-4.41)

SWOV in Black/African-American Patients: CRP<150 mg/L*
mITT population (n=51)

Hazard Ratio:
8.90 (95% CI: 1.08-73.09)

*Study was not powered to demonstrate a difference in mortality

Safety Balanced Between Treatment Arms

No Suspected Unexpected Serious Adverse Reactions (SUSARS) or SAEs attributed to lenzilumab were reported

No increased risk of infections, cases of PAP, or serious infusion related reactions were reported with lenzilumab

FDA noted relatively limited size of safety database but did not identify any safety issues

System Organ Class Preferred Term n (%)	Lenzilumab (N=255)	Placebo (N=257)	Overall (N=512)
Any AE ≥ Grade 3	68 (26.7)	84 (32.7)	152 (29.7)
Respiratory, thoracic, and mediastinal disorders	64 (25.1)	71 (27.6)	135 (26.4)
Cardiac disorders	15 (5.9)	14 (5.4)	29 (5.7)
Infections and infestations	10 (3.9)	16 (6.2)	26 (5.1)
Vascular disorders	10 (3.9)	15 (5.8)	25 (4.9)
Renal and urinary disorders	5 (2.0)	11 (4.3)	16 (3.1)
General disorders and administration site conditions	4 (1.6)	11 (4.3)	15 (2.9)

Cardiac SAEs from LIVE-AIR

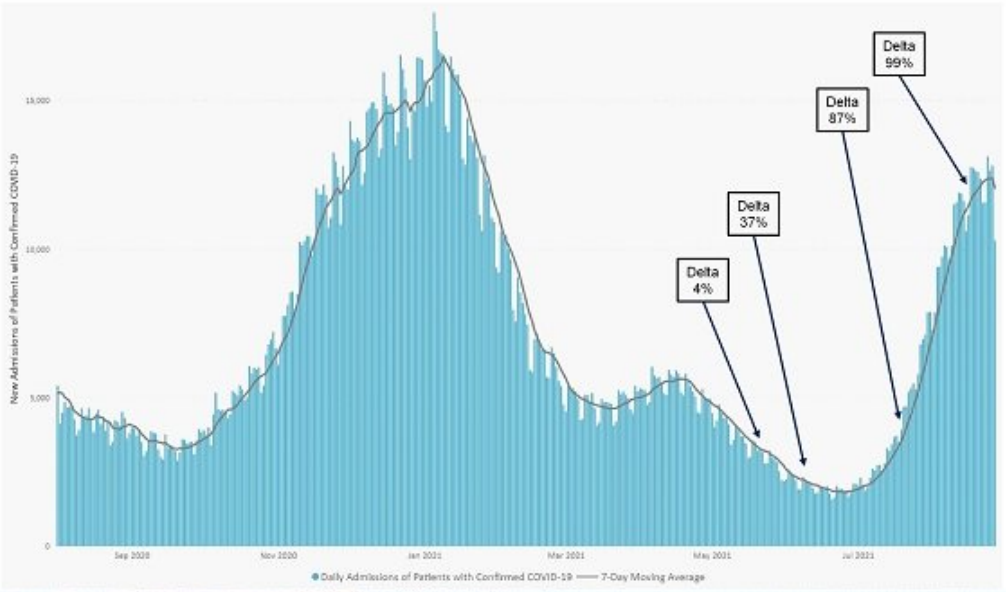
The overall incidence of cardiac SAEs was equivalent between the treatment groups

All subjects had significant underlying conditions

FDA noted relatively limited size of safety database but did not identify any safety issues

Preferred Term n (%)	Lenzilumab (N=255)	Placebo (N=257)	Overall (N=512)
All cardiac SAEs	12 (4.7)	13 (5.1)	25 (4.9)
Cardiac arrest/cardio-respiratory arrest	11 (4.3)	8 (3.1)	19 (3.7)
AMI	0 (0.0)	3 (1.2)	3 (0.6)

US Hospitalization Rates Continue at Accelerating Pace (>100,000*)



*As of September 2021 Sources: https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fvariant-proportions.html#new-hospital-admissions https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed Aug. 30, 2021. https://coronavirus.jhu.edu/data/hospitalization-7-day-trend/inpatient-capacity https://covid.cdc.gov/covid-data-tracker/#county-view|Hospital|admissions_covid_confirmed_last_7_days|all

Lenzilumab in the United Kingdom

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Multiple Agency Interactions

- ✓ Introductory meeting held with Rapid C-19 multi-agencies (MHRA, Therapeutics Task Force (TTF), NICE, NHSE, DHSC)
- ✓ MAA accepted for rolling review July 7, classified as "COVID rolling review"
- ✓ Information request provided to NICE, multiple interactions

- ❑ All modules to expected to be submitted by end of September 2021
- ❑ Additional data from LIVE-AIR being furnished to MHRA, similar to additional data to be furnished to FDA following EUA assessment letter
- ❑ Supply chain and local UK distributor agreements at or close to completion
- ❑ Additional meetings scheduled with DHSC, NHSE and NICE

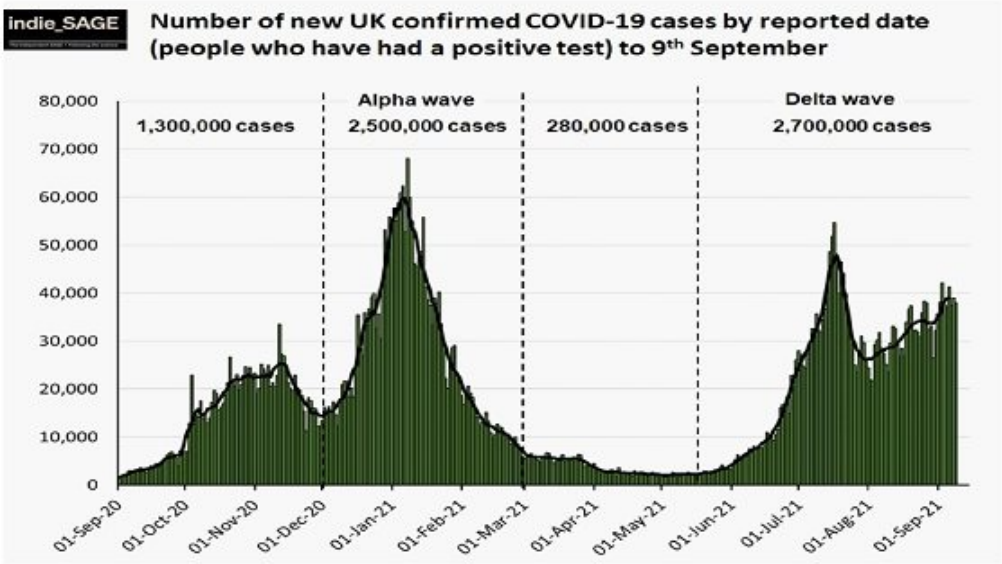
Approved Hospital Therapeutics

***Tocilizumab**
Dexamethasone
Remdesivir
Sarilumab

***Tocilizumab authorized by MHRA prior to FDA**

1. https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19 4. https://www.gov.uk/government/groups/the-covid-19-therapeutics-taskforce 5. https://www.pulsetoday.co.uk/news/clinical-areas/infectious-diseases/antiviral-drug-remdesivir-approved-for-covid-19-treatment-in-the-uk/
2. https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk

Cases Continue to Rise Despite High Vaccination Rate (Currently 65%)



* https://www.pharmaceutical-technology.com/covid-19-vaccination-tracker/
https://coronavirus.data.gov.uk

https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/

Key UK Statistics (as of September 12, 2021)

- >134,000 deaths
- Daily death rate ⬆30% vs. September 5
- 30,000 people tested positive September 11
- 7.2 million cases to date
- > 8,000 people hospitalized (⬆14% from prior 11 days)

Potential Demand based on current:

- Hospitalizations > 8,000
- Concentration of cases in NorthWest England

https://www.msn.com/en-gb/news/uknews/uk-covid-death-toll-exceeds-134000-as-hospitalisation-numbers-rise/ar-AAOta8Q
https://www.independent.co.uk/topic/death-toll

UK Commercial Preparation

UK launch plan developed in parallel with US preparation and leverages multiple tools already created in anticipation of US launch

- Market research shows potentially positive acceptance of lenzilumab value proposition by physicians
- Importation and distribution channels identified and in preparation
- Budget impact model developed, collaborating with NICE to refine
- Local resources in place, key account managers recruitment underway
- US MSLs already hired and trained to be deployed to UK account
- Scientific Advisory Board scheduled this month

Clinical Development Pipeline

Humanigen

ZUMA-19 Phase 1b Results

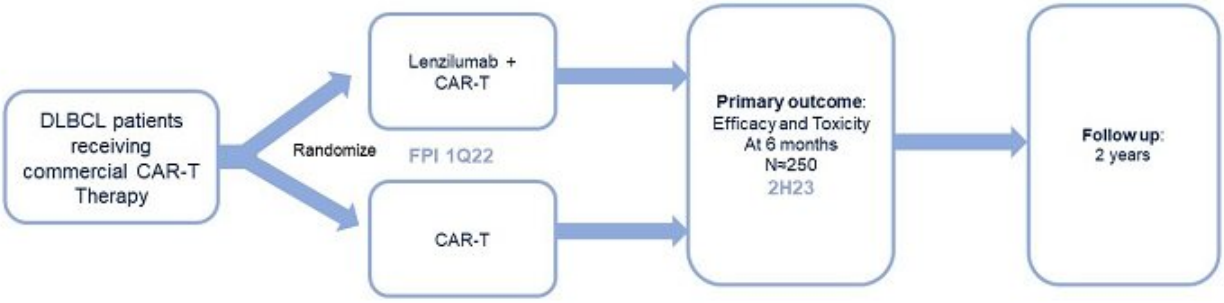
- Lenzilumab in combination with CAR-T in DLBCL demonstrated a 100% objective response rate (ORR) at the recommended Phase 2 dose
- No severe cytokine release syndrome or severe neurotoxicity
- Lenzilumab reduced IL-6, CRP, ferritin, MCP-1, IL-8, and IP-10 (CXCL-10) in a dose- dependent fashion
- Plans to conduct a potentially registrational Phase 2 study with all 3 currently commercially available CAR-T therapies in DLBCL

Note: DLBCL-Diffuse Large B-Cell Lymphoma; CRP-C-Reactive Protein

Significant CAR-T Market Growth Expected

- The CAR-T market is expected reach $6.1 billion by 2030[1]
- Multiple barriers to stronger uptake of CAR-T therapy[2]
- 1/3 of physicians surveyed think toxicity might hinder their use of CAR-T
- Over 60% suggested that patients should be monitored for 1 to 2 weeks after administration

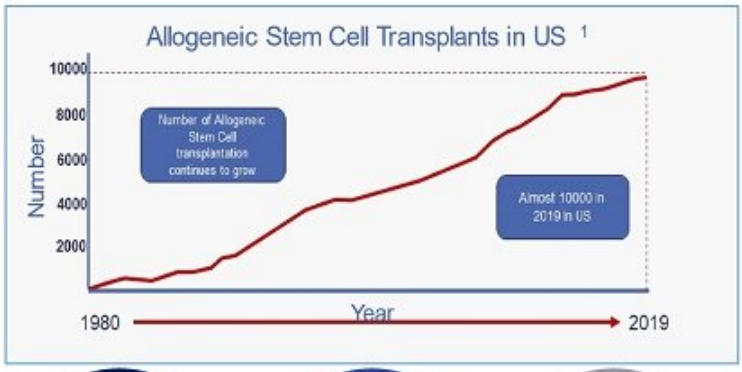
Phase 2 trial intended to address these barriers



1. "Global CAR-T Therapy Market Report 2020" Research And Markets https://www.prnewswire.com/news-releases/global-car-t-therapy-market-report-2020-market-is-expected-to-stabilize-and-reach-3-150-million-in-2025---covid-19-impact-and-recovery-forecast-to-2030--301218802.html Feb. 1, 2021
2. Journal of Clinical Pathways. 2017;3(7):31-35

Lenzilumab is being developed as a potential treatment for COVID-19. It is not currently approved or authorized for use in any country

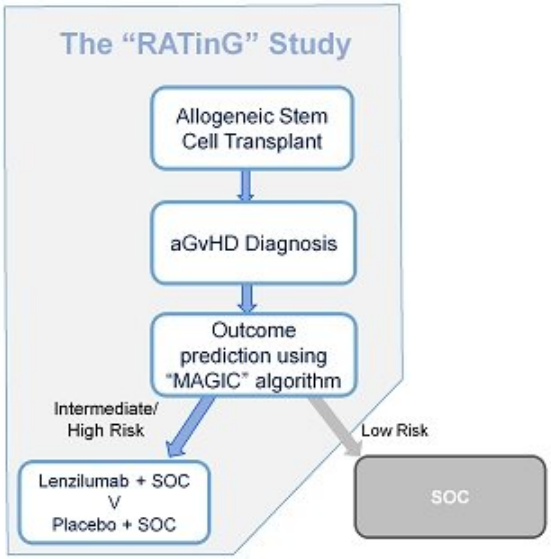
Acute Graft vs. Host Disease (aGvHD): Growing Market, High Unmet Need



Steroids used for initial treatment of aGvHD[2-6]

~50% of patients do not respond adequately to steroids[2-6]

Steroid-resistant aGvHD patients have a very poor prognosis >90% mortality[7]



1. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR US summary slides, 2020. 2. First and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2021;18(8):1150-1163.3. Diagnosis and management of acute graft-versus-host disease. Br J Haematol. 2012;158(1):30-45. 4. Response of 443 patients to steroids as primary therapy for acute graft-versus-host disease: comparison of grading systems. Biol Blood Marrow Transplant. 2002;8(7):387-394. 5. EBMT-NCI-CIBMTR Task Force position statement of standardized terminology & guidance for graft-versus-host disease assessment. Bone Marrow Transplant. 2018;53(11):1401-1415. 6. New and emerging therapies for acute and chronic graft-versus-host disease. Ther Adv Hematol. 2018;9(1):21-45. 7. Steroid-refractory acute GVHD: Predictions and outcomes. Advances in Hematology 2011

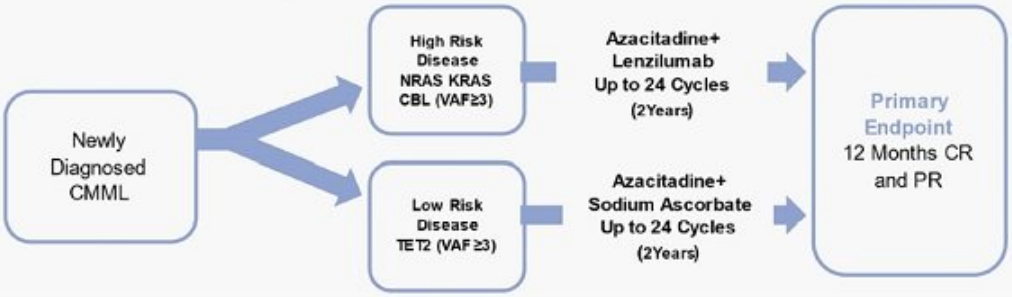
PREACH–M trial (PREcision Approach to CHronic Myelomonocytic Leukemia)

Partners

SAHMRI
South Australian Health & Medical Research Institute

THE UNIVERSITY of ADELAIDE

PREACH–M Trial Design

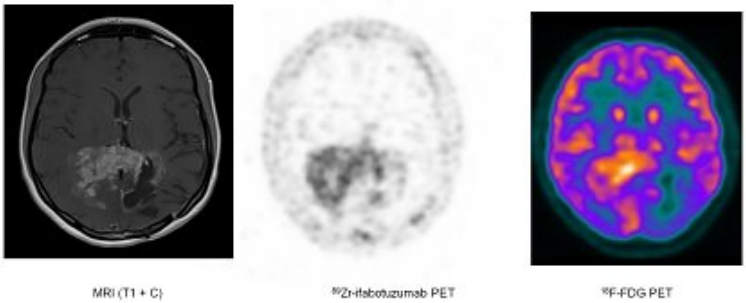


1. Murthy et al, Leukemia Lymphoma, 2017 Jul;58(7):1648-1654
2. SEER Hematopoietic and Lymphoid Neoplasm Database (cancer.gov)

Note: CRS-Cytokine Release Syndrome; NT-Neurotoxicity; RP2D-recommended Phase 2 dose; R/R-Relapsed/Refractory; DLBCL-Diffuse Large B-Cell Lymphoma; NRAS, KRAS, and CBL are gene mutations found in some CMML patients

Phase 1 Ifabotuzumab Data in GBM and Development Plan

Activity in Glioblastoma Multiforme



MRI (T1 + C) | ^{89}Zr-ifabotuzumab PET | ^{18}F-FDG PET

Radio-labelled ifabotuzumab showed rapid, specific targeting of GBM tumor

No normal tissue uptake of ^{89}Zr-ifabotuzumab

Phase 1 study: multiple tumors

Breast	Lung	Colorectal	Pancreas

Financial Overview

Balance (based on 10-Q filing as of June 30, 2021)

- Cash and cash equivalents $120MM
  - Q2 manufacturing scale-up, advance purchasing of raw materials and production slots ~$57MM
  - Future spending expected to be significantly reduced
  - ACTIV-5 paid for by NIH
  - aGvHD, CMML trials majority paid for by partners
  - HGEN infrastructure remains minimal

Hercules Loan Facility

- Total credit available $80MM
- Initial draw (3-29-21) $25MM
- Interest only period for 18 months

12 Month Goals

- ❑ Complete regulatory submission for lenzilumab in hospitalized COVID-19 in the UK in September and commence commercialization if authorized
- ❑ Short-term: Provide additional data from LIVE-AIR to support EUA application in US
- ❑ Medium-term: Provide additional data from ACTIV-5/BET-B to support EUA application in US
- ❑ Initiate Phase 2 potential registrational CAR-T, Phase 2/3 acute GvHD, Phase 2/3 CMML studies
- ❑ Exploring other revenue-generating opportunities
- ❑ Carefully manage cash