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**Genscript Biotech Corporation**

**金斯瑞生物科技股份有限公司\***

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 1548)**

## **VOLUNTARY ANNOUNCEMENT RESEARCH AND DEVELOPMENT UPDATE**

Reference is made to the announcements of GenScript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) dated 14 December 2020.

### **START OF THE PHASE 1 CLINICAL TRIAL FOR LB1901**

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, on 13 September 2021 (New York time), Legend Biotech Corporation (“**Legend Biotech**”), a non-wholly owned subsidiary of the Company, announced the start of a Phase 1 clinical trial in the United States for LB1901, an investigational autologous CD4-targeted chimeric antigen receptor T-cell (“**CAR-T**”) therapy for the treatment of adults with relapsed or refractory peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL). LB1901 targets CD4, a surface membrane glycoprotein uniformly expressed in most TCL subtypes. The trial follows the U.S. Food and Drug Administration (the “**FDA**”) clearance of the Investigational New Drug (the “**IND**”) application submitted by Legend Biotech.

The Phase 1 trial (LB1901-TCL-001), which is being led by Dr. Swaminathan P. Iyer, Professor of Lymphoma & Myeloma at The University of Texas MD Anderson Cancer Center, is an open label, multi-center and multicohort clinical study of LB1901 in patients with relapsed or refractory (RR) PTCL or CTCL (NCT04712864) — patients with histologically confirmed CD4+ RR PTCL (PTCL not otherwise specified, or PTCL-NOS, and angioimmunoblastic T cell lymphoma, or AITL) or RR CTCL (mycosis fungoides and Sézary syndrome). Recruitment in the trial has begun in the U.S. The primary objectives are to characterize the safety and tolerability of LB1901 and determine the optimal dose.

T-cell lymphoma is a heterogeneous group of lymphoid malignancies that account for less than 15 percent of non-Hodgkin’s lymphoma cases in the US. PTCL comprises subtypes that are uncommon and often aggressive, with a 5-year overall survival of only 39%. CTCL are a group of T-cell malignancies that occur primarily in the skin. Despite current treatment options, a substantial proportion of patients with PTCL or CTCL experiences relapse. A high unmet medical need remains for patients with relapsed or refractory PTCL and CTCL.

## UPDATES TO CORPORATE PRESENTATION OF LEGEND

The Board of Directors is pleased announce that, on 13 September 2021 (New York time) Legend Biotech posted an updated version of its corporate presentation (the “**Presentation**”) to its website. The Presentation includes, among other things, updates to certain near term target dates.

For details, please refer to the attached Presentation. The attached Presentation is published on the Legend Biotech’s website available at <https://investors.legendbiotech.com/static-files/5c1f2394-0676-49c3-8530-38436caf485b>.

This announcement has been issued in the English language with a separate Chinese language translation. If there is any inconsistency or ambiguity between the English version and the Chinese version, the English version shall prevail.

**Shareholders and potential investors of the Company are advised to pay attention to investment risks and exercise caution when they deal or contemplate dealing in the securities of the Company.**

By order of the Board  
**Genscript Biotech Corporation**  
**MENG Jiange**  
*Chairman and Executive Director*

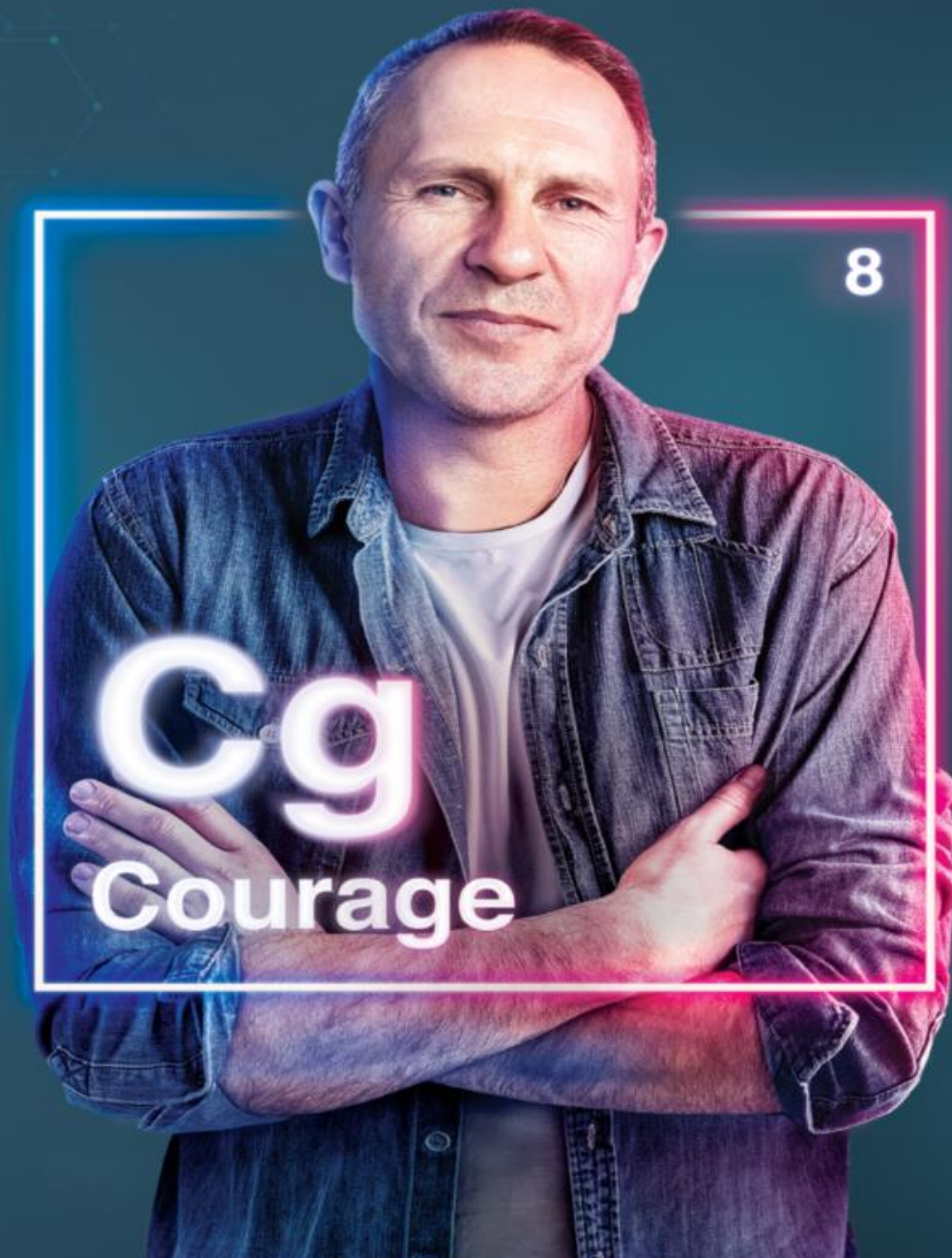
Hong Kong, 13 September 2021

*As at the date of this announcement, the executive Directors are Mr. Meng Jiange, Ms. Wang Ye and Dr. Zhu Li; the non-executive Directors are Dr. Wang Luquan, Mr. Pan Yuexin and Ms. Wang Jiafen; and the independent non-executive Directors are Mr. Guo Hongxin, Mr. Dai Zumian, Mr. Pan Jiuan and Dr. Wang Xuehai.*

\* *For identification purposes only*

Inspired by the  
***human element***  
to advance cell therapy

*September 2021*



**Cg**  
**Courage**

# Disclaimer

This presentation has been prepared by Legend Biotech Corporation (“Legend Biotech” or the “Company”) solely for information purpose and does not contain all relevant information relating to the Company.

The safety and efficacy of the agents and/or uses under investigation discussed in this presentation have not been established. There is no guarantee that the agents will receive health authority approval or become commercially available in any country for the uses being investigated.

Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and Legend Biotech's own internal estimates and research. While Legend Biotech believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. While Legend Biotech believes its internal research is reliable, such research has not been verified by any independent source.

## Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, but are not limited to, statements relating to the Company’s strategies and objectives; the anticipated timing of, and ability to progress, clinical trials; the ability to make, and the timing of, regulatory submissions in the United States, Europe and Asia, including Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for ciltacabtagene autoleucel (cilta-cel) for relapsed or refractory multiple myeloma (RRMM), the submission of a marketing authorisation application (MAA) for cilta-cel to the European Medicines Agency (EMA), and the submission of an Investigational New Drug (IND) for LB1901 in relapsed or refractory T-Cell Lymphoma (TCL); the ability to generate, analyze and present data from clinical trials; patient enrollment; anticipated timing regarding regulatory approvals by the FDA, EMA or Center for Drug Evaluation (CDE); and the potential benefits of Legend Biotech’s product candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech’s expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech’s patent or other proprietary intellectual property protection, including the uncertainties involved in the US litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the “Risk Factors” section of the Company’s Annual Report filed with the Securities and Exchange Commission on April 2, 2021.

Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this presentation as anticipated, believed, estimated or expected.

Any forward-looking statements contained in this presentation speak only as of the date of this presentation. None of the Company nor any of its affiliates, advisers, or representatives has any obligation and does not undertake to update any forward-looking statements to reflect future events or circumstances.

# Legend Highlights



**7**

Years  
Since Inception

**>900**



Employees

**10+**



Pipeline Programs Covering:

- Hematologic malignancies
- Solid tumors
- Infectious diseases

**4**



R&D Platforms:

- Autologous CAR-T
- Allogeneic CAR-T
- TCR
- NK

**3**

Global

Manufacturing Sites:

- United States
- EU\*
- China



**\$663**



Million

in Cash and Cash Equivalents and Time  
Deposits as of June 30, 2021

\*EU manufacturing site: Construction in progress



# **Cell Therapy Platform Overview**

# We Are A Fully Integrated Global Cellular Therapy Company



## COMPELLING DATA WITH INNOVATIVE PIPELINE

- Lead product candidate ciltacabtagene autoleucel (cilta-cel) may have the potential to deliver deep and durable anti-tumor responses in RRMM
- Broad portfolio of earlier-stage autologous product candidates targeting both hematologic and solid cancers, as well as allogeneic CAR-T approaches

### FUTURE PIPELINE

AML

LYMPHOMA

GASTRIC  
CANCER

OVARIAN  
CANCER

INFECTIOUS  
DISEASE

## GLOBAL COLLABORATION WITH JANSSEN\*

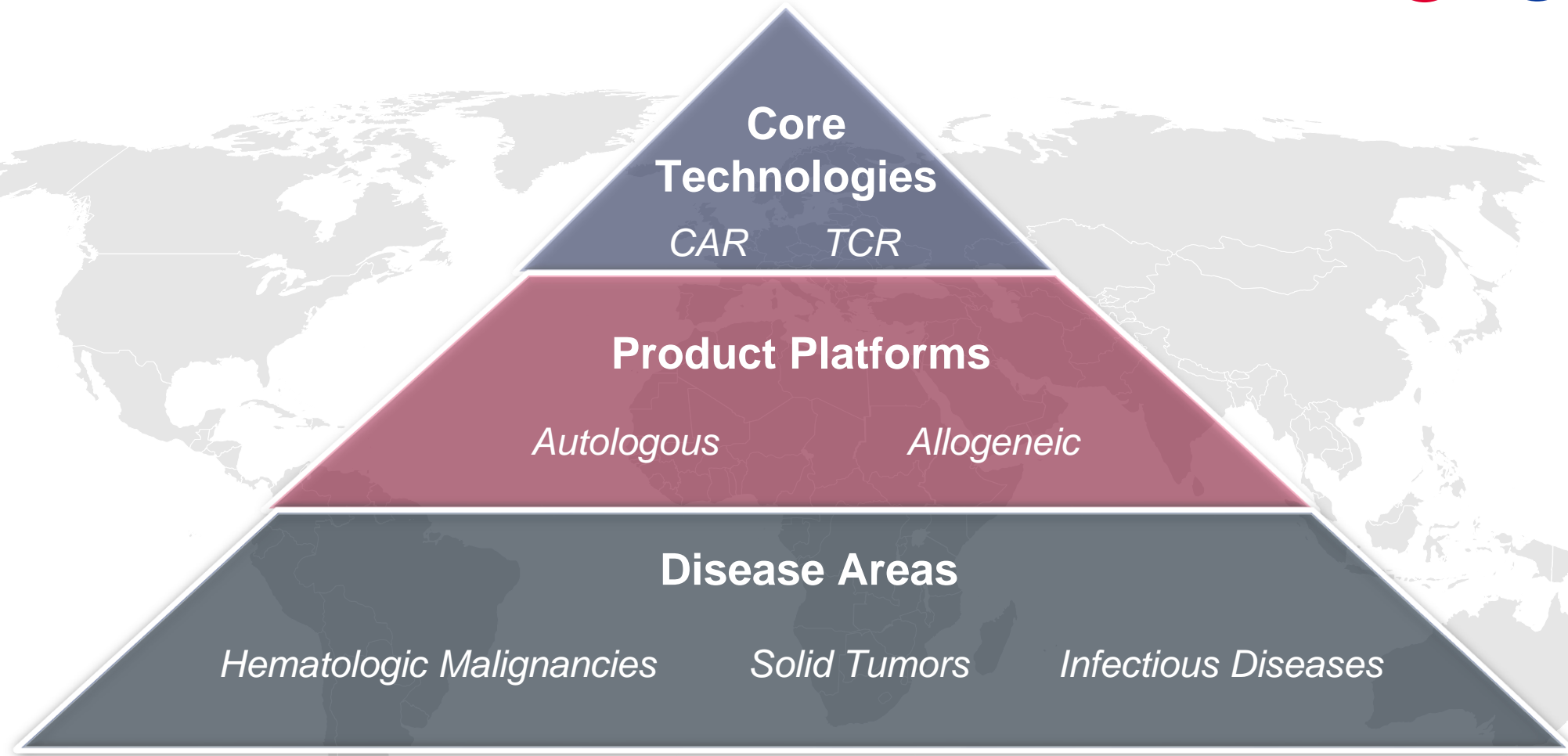
- Global collaboration with Janssen for the development of cilta-cel established December 2017
  - Received an upfront payment of \$350 million and a total of \$200 million in milestone payments to date
  - Up to an additional \$1,150 million in potential future milestone payments



## INTEGRATED CELL THERAPY PLATFORM

- In-house antibody generation and CAR-T specific functional screening technologies
- Early clinical proof-of-concept, leveraging KOL relationships in China, the US and globally
- Building large-scale manufacturing facilities in the United States, Europe and China
- >900 employees worldwide in US, China and Europe

# Legend Biotech's Global R&D Strategy



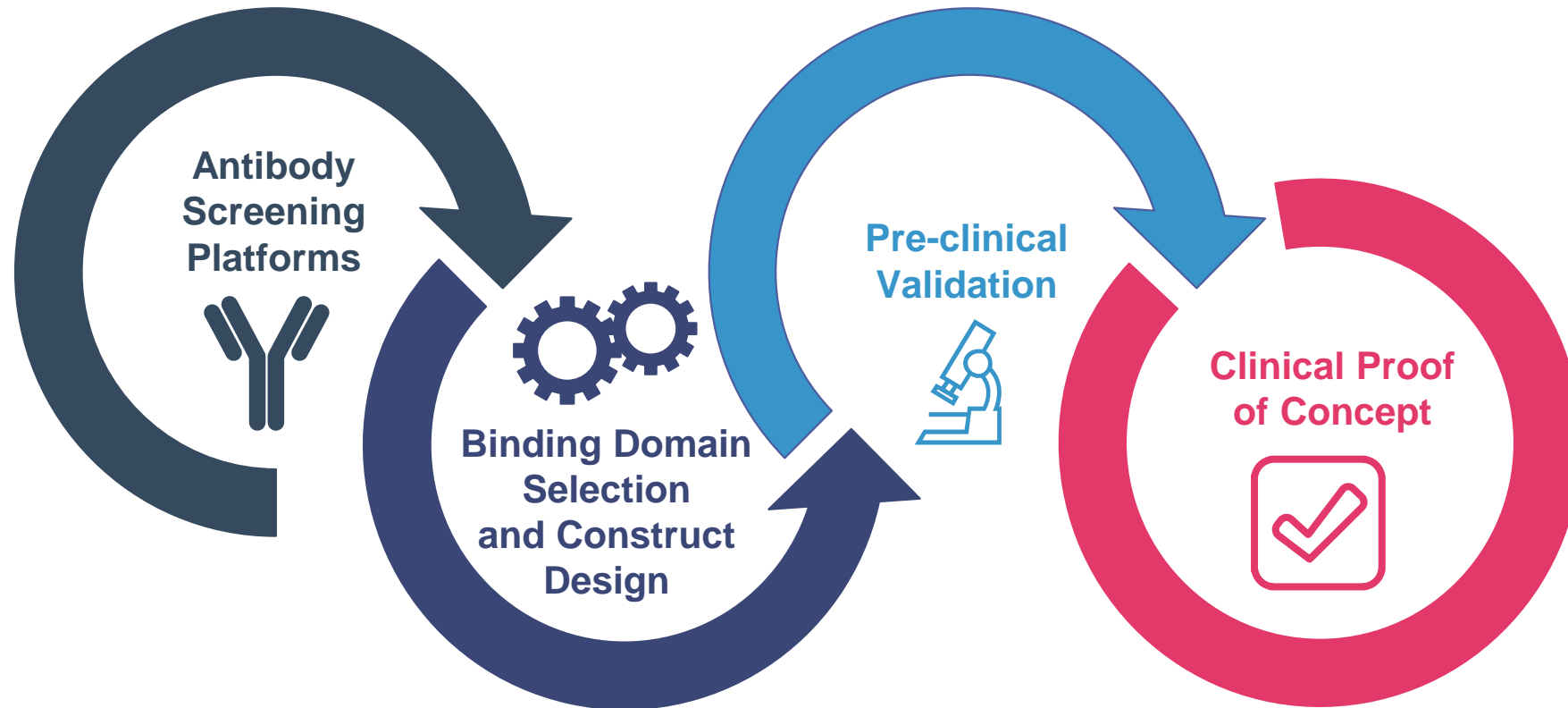
***With a Presence in Major Geographies,  
our Mission is to Improve the Lives of Patients Worldwide***



# End-to-End R&D Capability

High-throughput antibody screening and engineering capability including single-domain antibodies generated from Llama and conventional antibodies

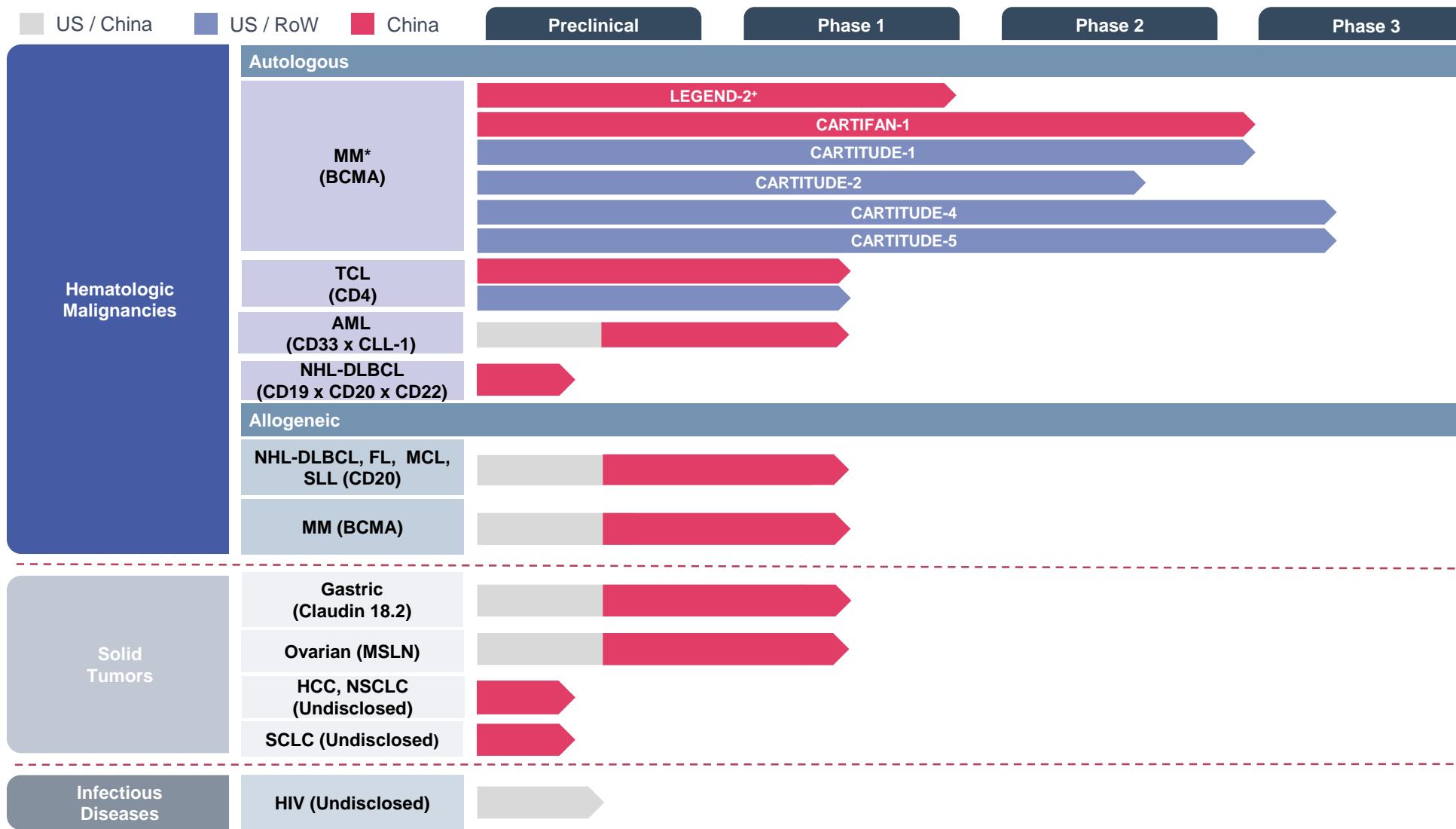
Robust *in vitro* and *in vivo* screening platforms to prioritize pipeline assets



Proprietary methodology to optimize the selection of binding domains and design CAR-T constructs with two or more antigen-binding domains

Efficient clinical translation, leveraging deep relationships with KOLs in US and China

# Robust Pipeline of the Next Generation Cell Therapies



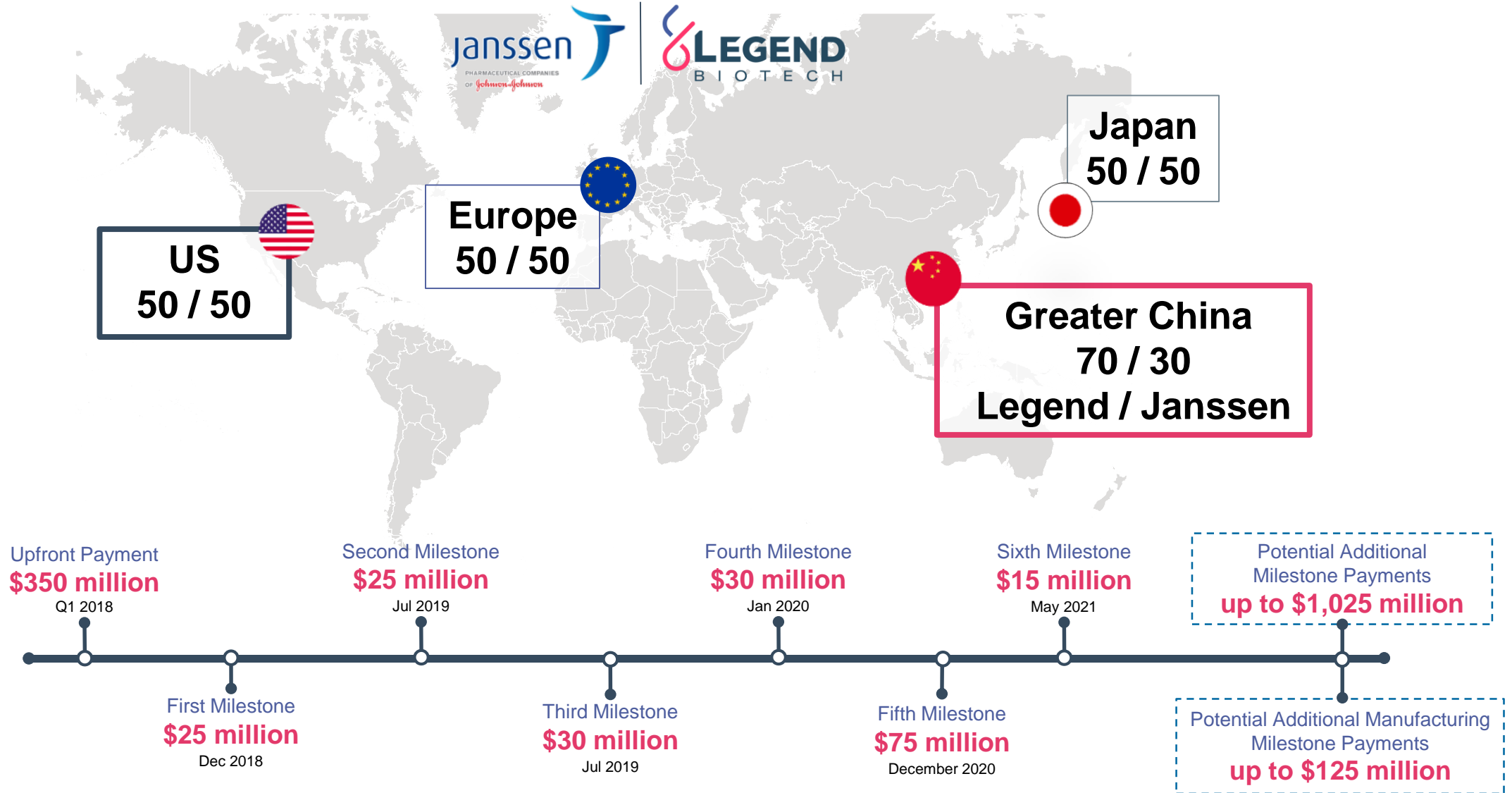
AML, acute myeloid leukemia; BCMA, B-cell maturation antigen; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HCC, hepatocellular carcinoma; HIV, human immunodeficiency virus; MCL, mantle cell lymphoma; NHL, non-Hodgkin lymphomas; MM, multiple myeloma; MSLN, mesothelin; NSCLC, non small cell lung cancer; RoW, Rest of World; SCLC, small cell lung cancer; SLL, small lymphocytic lymphoma; TCL, T-cell lymphoma

\*In collaboration with Janssen, Pharmaceutical Companies of Johnson & Johnson

\*LEGEND-2 trial is completed with ongoing follow-up

# Legend and Janssen Global Collaboration

Worldwide collaboration and license agreement to develop and commercialize cilta-cel



# Highly Experienced Management Team



**YING HUANG**  
Chief Executive Officer/ Chief Financial Officer



US



**Lida Pacaud**  
Clinical Development



**DONG GENG**  
Early-stage Drug Development



**STEVE GAVEL**  
Commercial Development



**ALAN KICK**  
Global Quality



**ELIZABETH GOSEN**  
Global Manufacturing



**YUHONG QIU**  
Global Regulatory



**MEETA CHATTERJEE**  
Global Business Development



**Lori Macomber**  
Finance



CHINA



**FRANK FAN**  
Chief Scientific Officer & Co-Founder



**SIMON WU**  
Research & Development



**TRACY LUO**  
Clinical Development



**CHONG YANG**  
Commercial Development





**Cilta-cel  
Clinical  
Development**

# Multiple Myeloma: Blood Cancer with a High Unmet Need



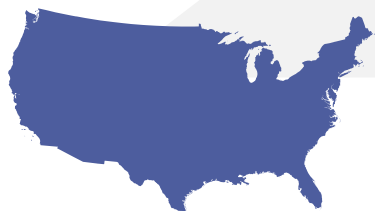
**3<sup>RD</sup> MOST COMMON BLOOD CANCER**

accounting for **18%** of all hematologic cancer<sup>1-3</sup>



**176,404**

**NEW CASES WORLDWIDE IN 2020,**  
accounting for 1% of worldwide  
new cancer cases<sup>3,4</sup>



**US:** Incidence is  
**32,119**, with  
mortality of 13,426<sup>5</sup>



**EUROPE:** Incidence is  
**50,918**, with  
mortality of 32,495<sup>6</sup>

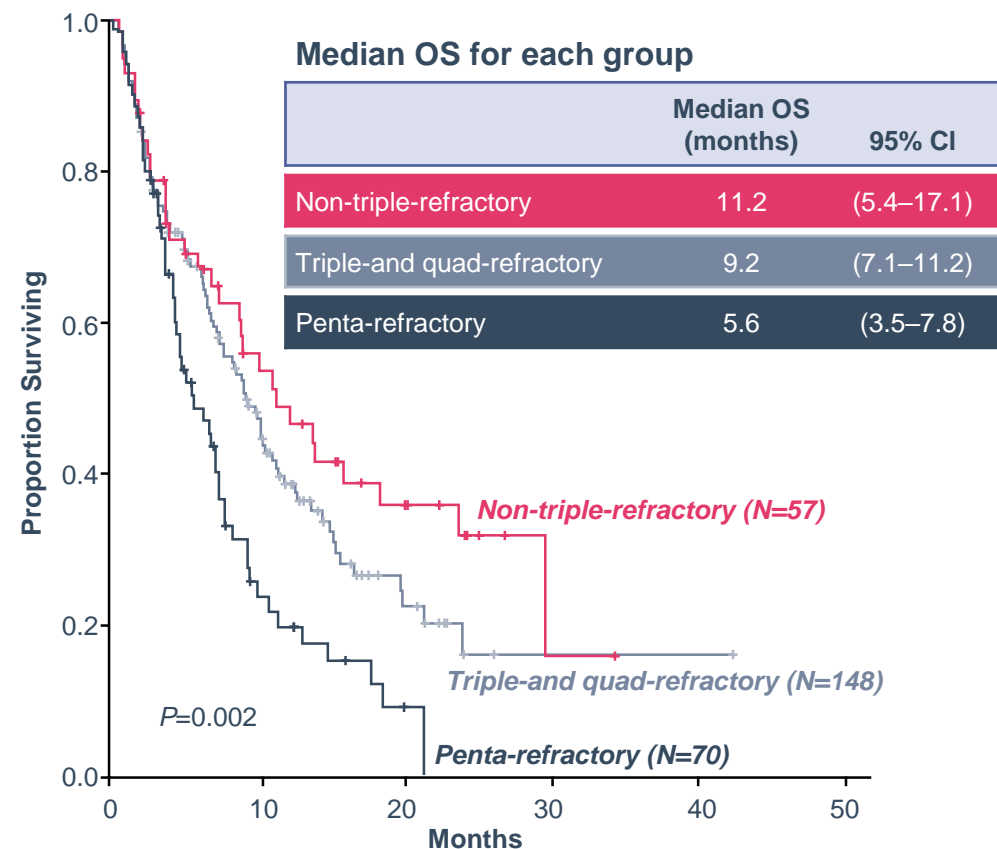


**CHINA:** Incidence is  
**21,116**, with  
mortality of 16,182<sup>7</sup>

**POOR SURVIVAL OUTCOMES IN MULTIPLE  
REFRACTORY MM**

**Median OS < 12 months**

in patients refractory to anti-CD38,  $\geq 1$  PI(s) and / or  $\geq 1$  IMiD(s)<sup>8</sup>



CI, confidence interval; PI, Proteasome Inhibitor; IMiD, immunomodulatory drug; MM, multiple myeloma; OS, overall survival

1. Cancer Stat Facts: Myeloma. <https://seer.cancer.gov/statfacts/html/mulmy.html>. Accessed June 2021. 2. Facts and Statistics. <https://www.ils.org/facts-and-statistics/facts-and-statistics-overview>. Accessed June 2021. 3. Globocan 2020 World Fact Sheet:

<https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf>. Accessed June 2021. 4. Globocan 2020 World Fact Sheet: World. <https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>. Accessed June 2021. 5.

Globocan 2020 World Fact Sheet: United States of America. <http://gco.iarc.fr/today/data/factsheets/populations/840-united-states-of-america-fact-sheets.pdf>. Accessed June 2021. 6. Globocan 2020 World Fact Sheet: Europe.

<https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf>. Accessed June 2021. 7. Globocan 2020 World Fact Sheet: China. <https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf>. Accessed June 2021. 8. Gandhi UH,

et al. Leukemia. 2019;33:2266-75.

# First-in-Human, Phase 1, Dose Finding Study in RRMM LEGEND-2: LCAR-B38M CAR-T cells



## Key Inclusion Criteria<sup>1,2</sup>

- Active MM defined by IMWG criteria with documented disease progression during or within 12 months of most recent anti-MM drugs or auto-HSCT
- Relapsed on prior regimens

## Enrollment

- Total: 74 patients (4 sites in China)
- Xi'an: N=57, Wang, et al. ASH 2019
- JS/RJ/CZ sites: N=17, Chen, et al. ASH 2019

## Preconditioning

- Cyclophosphamide only (Xi'an, Jiangsu)<sup>1,2</sup>
- Cyclophosphamide + fludarabine (Changzheng, Ruijin)<sup>2</sup>

## Administered dose (CAR+ viable T cells/kg)

- Xi'an<sup>1</sup> (median)= $0.5 \times 10^6$  ( $0.07-2.1 \times 10^6$ )
- RJ/CZ/JS<sup>2</sup> (mean)= $0.70 \times 10^6$  ( $0.2-1.5 \times 10^6$ )

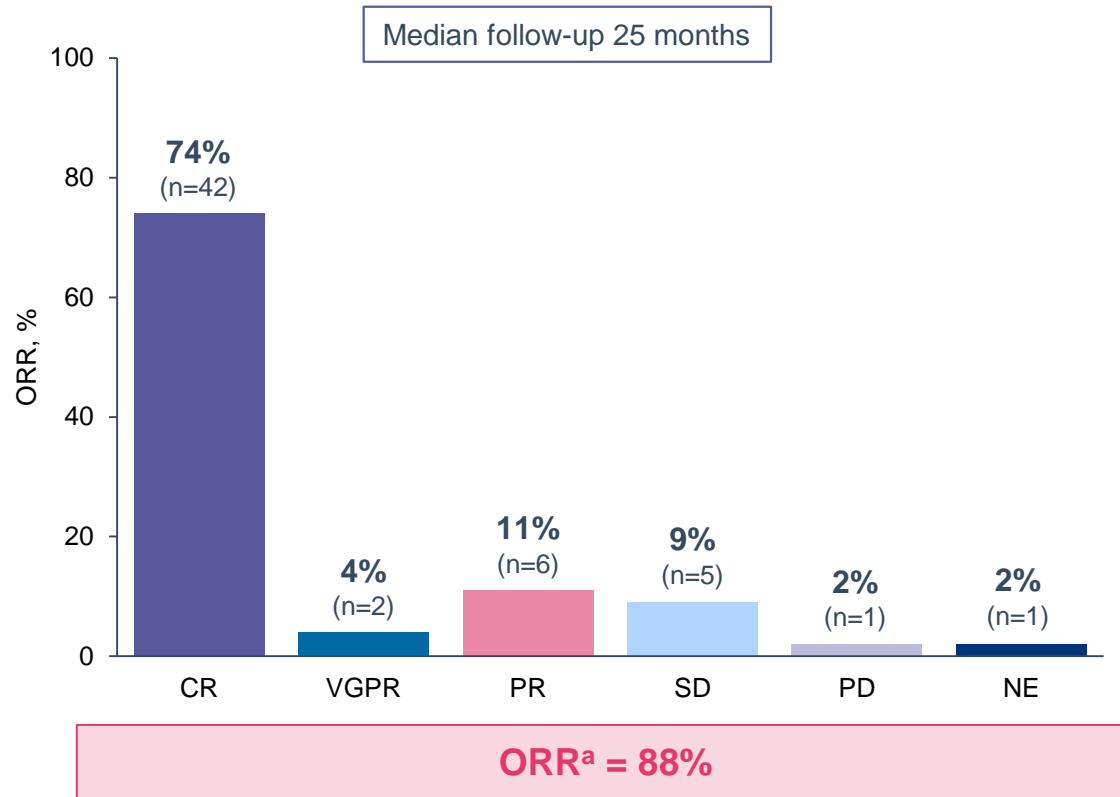
## Safety & Tolerability

- Cilta-cel CAR-T cells displayed a safety profile consistent with other safety reports of BCMA-targeting CAR-T cell therapy<sup>1,2</sup>

# LEGEND-2: Long-Term Deep Responses and High Response Rate

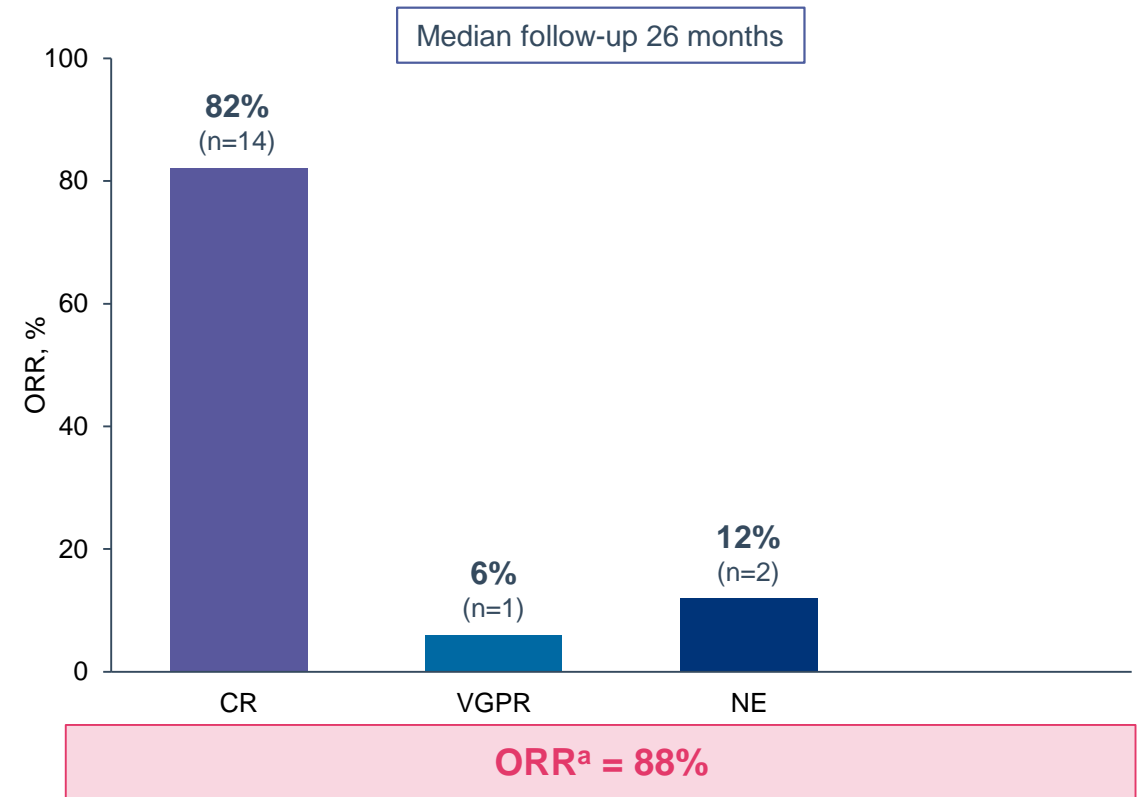
## Xi'an: Best overall response (N=57)<sup>1</sup>

- mDOR= 27.0 months (mDOR for CR= 29.1 months)<sup>1</sup>
- Median time to initial response= 1 month<sup>1</sup>
- mPFS= 19.9 months (mPFS for CR= 28.2 months)<sup>1</sup>
- mOS = 36.1 months (mOS for CR not reached)<sup>1</sup>



## Ruijin (RJ), Jiangsu (JS), Changzheng (CZ): Best overall response (N=17)<sup>2</sup>

- Median time to initial response= 1 month<sup>2</sup>
- mPFS = 18 months; mOS= not reached<sup>2</sup>



Data cut-off: 31 July 2019 (N=57) and 31 October 2019 (N=17); Xi'an: NE patient died of PE/ACS prior to first evaluation. RJ,JS, CZ: For NE patients, 1 patient died on Day 13 due to CRS and tumor lysis syndrome; 1 patient received chemotherapy prior to first assessment and was censored. <sup>a</sup>ORR=PR or better; response assessed per International Myeloma Working Group criteria  
 CR, complete response; VGPR, very good partial response; PR, partial response; SD, stable disease; PD, progressive disease; NE, not evaluable; mDOR, median duration of response; MRD, minimal residual disease; ORR, overall response rate; mPFS, median progression free survival; mOS, median overall survival.

1. Wang B-Y et al. ASH Annual Meeting; December 7-10, 2019; Orlando, FL, Abstract 579; 2. Chen L, et al. ASH Annual Meeting; December 7-10, 2019; Orlando, FL, Abstract 1858.



# CARTITUDE-1: Phase 1b/2 Study Design

## Primary Objectives

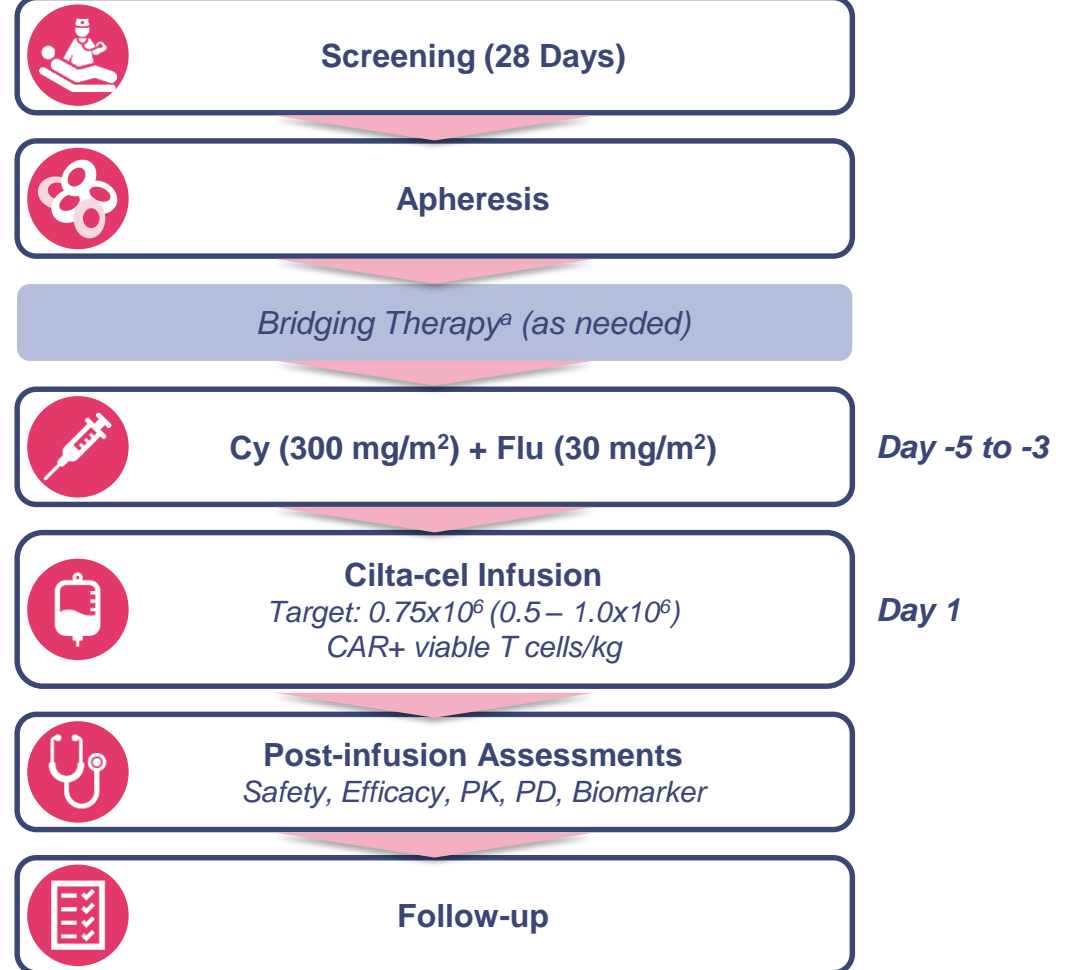
- Phase 1b: Characterize the safety of ciltacabtagene autoleucel (cilta-cel) and confirm the recommended phase 2 dose
- Phase 2: Evaluate the efficacy of cilta-cel by ORR

## Key Inclusion Criteria

- Progressive MM per IMWG criteria
- ECOG PS  $\leq 1$
- Measurable disease
- Received  $\geq 3$  prior therapies or double refractory
- Prior PI, IMiD, anti-CD38 therapy

## Administered dose

- Median administered dose:  
0.71x10<sup>6</sup> (0.51– 0.95x10<sup>6</sup>) CAR+ viable T cells/kg



Cy, cyclophosphamide; ECOG PS, Eastern Cooperative Oncology Group performance status; Flu, fludarabine; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; PI, proteasome inhibitor; PD, pharmacodynamic; PK, pharmacokinetic; MM, multiple myeloma

Data cut-off: Feb 11, 2021; <sup>a</sup> Treatment that was received previously and resulted in at least stable disease.

1. Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005; 2. Clinicaltrials.gov website (NCT03548207). <https://clinicaltrials.gov/ct2/show/NCT03548207>. Accessed June 2021

# CARTITUDE-1: Baseline Characteristics

## Characteristic (N=97)

Age, median (range) years	61.0 (43–78)
Male, n (%)	57 (58.8)
Black/African American, n (%)	17 (17.5)
All plasmacytomas, <sup>a</sup> n (%)	19 (19.6)
Extramedullary plasmacytomas, n (%)	13 (13.4)
Bone-based plasmacytomas, n (%)	6 (6.2)
Bone-marrow plasma cells ≥60%, n (%)	21 (21.9)
Years since diagnosis, median (range)	5.9 (1.6–18.2)
High-risk cytogenetic profile, n (%)	23 (23.7)
del17p	19 (19.6)
t(14;16)	2 (2.1)
t(4;14)	3 (3.1)
Tumor BCMA expression ≥50%, n (%)	57 (91.9) <sup>b</sup>

## Characteristic

Prior lines of therapy, median (range)	6.0 (3–18)
Prior lines of therapy, n (%)	
3	17 (17.5)
4	16 (16.5)
≥5	64 (66.0)
Previous stem-cell transplantation, n (%)	
Autologous	87 (89.7)
Allogeneic	8 (8.2)
Triple-class exposed, <sup>c</sup> n (%)	97 (100)
Penta-drug exposed, <sup>d</sup> n (%)	81 (83.5)
Triple-class refractory <sup>c</sup>	85 (87.6)
Penta-drug refractory <sup>d</sup>	41 (42.3)
Refractory status, n (%)	
Carfilzomib	63 (64.9)
Pomalidomide	81 (83.5)
Anti-CD38 antibody	96 (99.0)
Refractory to last line of therapy, n (%)	96 (99.0)

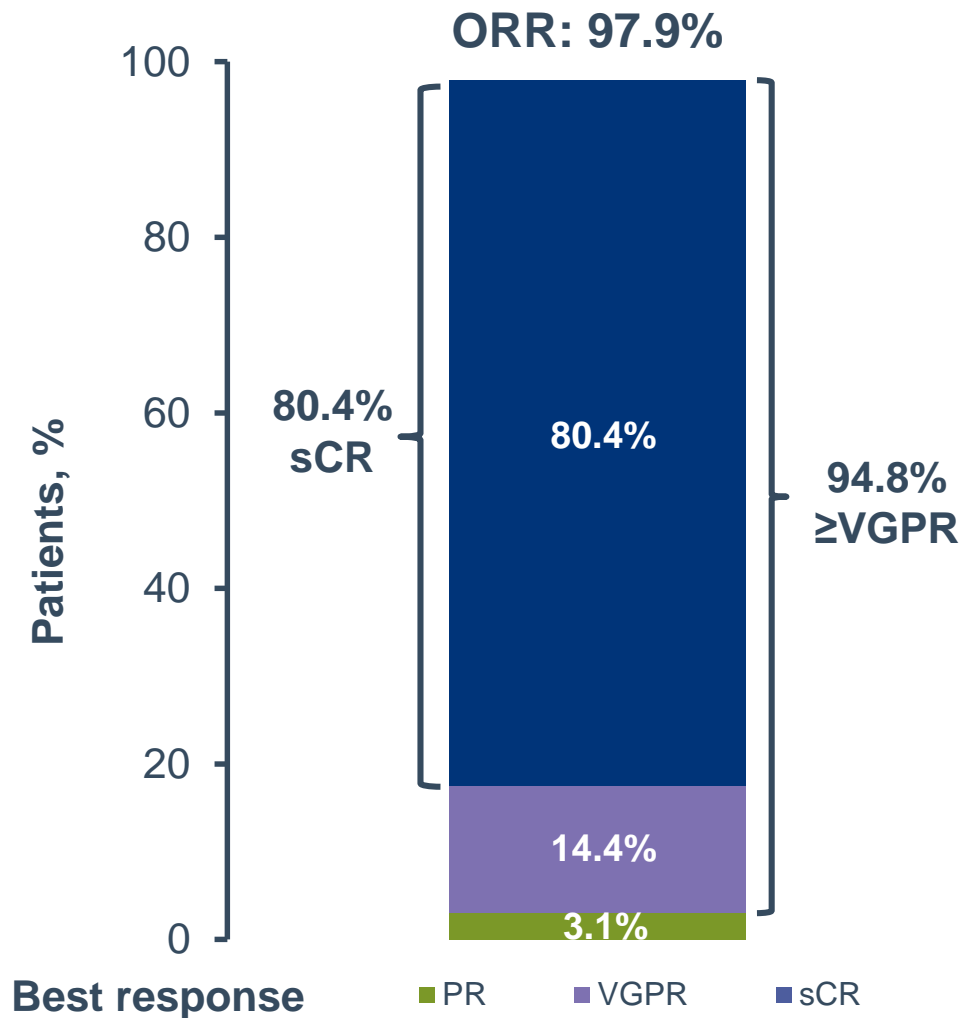
Data cut-off: Feb 11, 2021; BCMA, B-cell maturation antigen; IMiD, immunomodulatory drug; PI, proteasome inhibitor.

<sup>a</sup>All plasmacytomas include extramedullary and bone-based plasmacytomas. <sup>b</sup>Denominator n=62, the number of evaluable samples; BCMA expression detected in all evaluable samples. <sup>c</sup>At least 1 PI, at least 1 IMiD, and 1 anti-CD38 antibody. <sup>d</sup>At least 2 PIs, at least 2 IMiDs, and 1 anti-CD38 antibody.

Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005

# CARTITUDE-1: Overall Response Rate

N=97

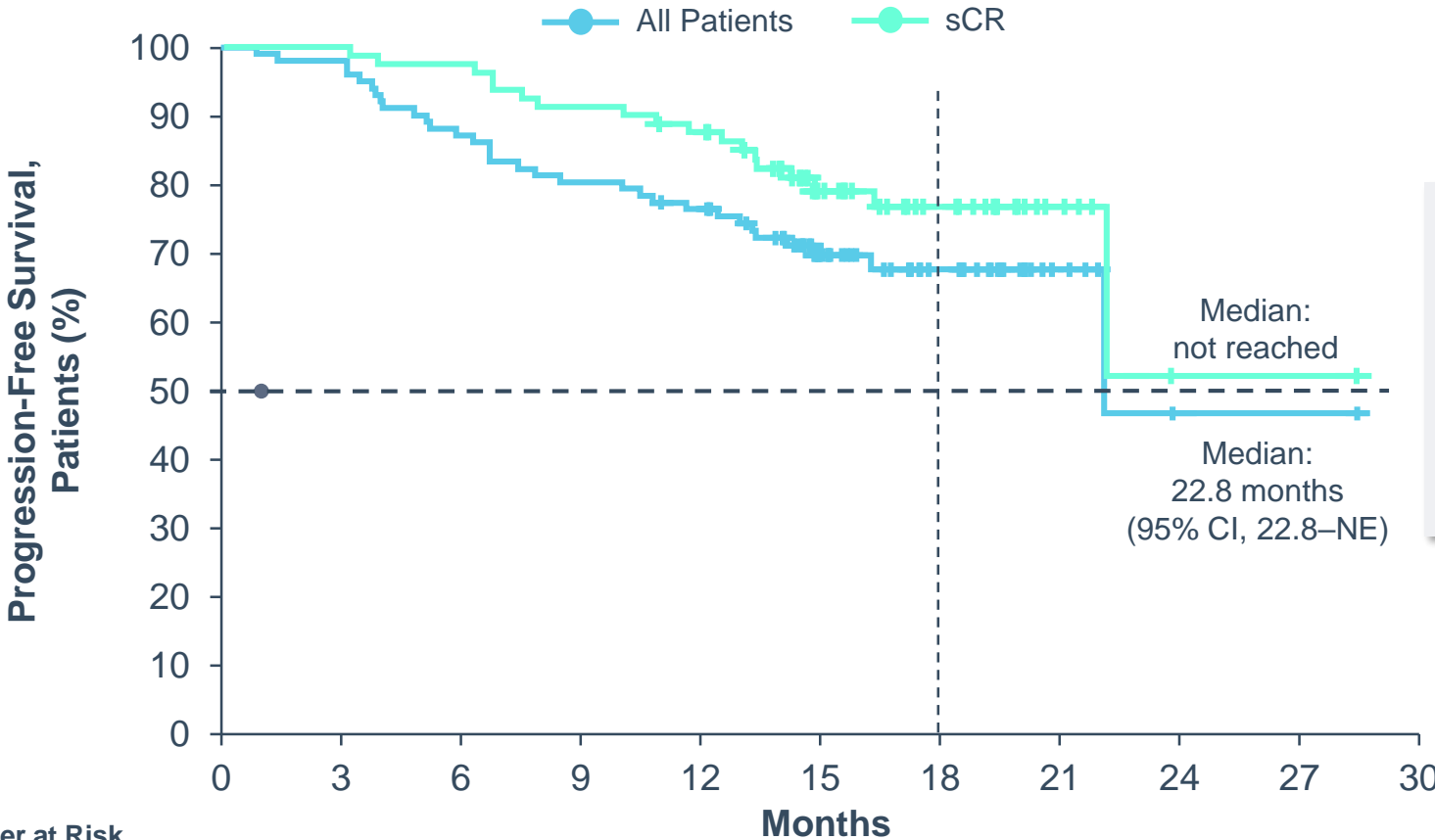


**With longer follow-up, responses deepened with increasing rate of sCR**

- Median time to first response: 1 month (range, 0.9–10.7)
- Median duration of response: 21.8 months (95% CI, 21.8–NE); not reached in patients with sCR
- Response rates were comparable (range, 95–100%) across different subgroups (eg, number of prior lines of therapy, refractoriness, extramedullary plasmacytomas, and cytogenetic risk)<sup>a</sup>
- 91.8% of 61 evaluable patients were MRD negative<sup>b</sup>
  - Median time to MRD 10<sup>-5</sup> negativity: 1 month (range, 0.8–7.7)

Data cut-off: Feb 11, 2021; CR, complete response; MRD, minimal residual disease; ORR, overall response rate; sCR, stringent complete response; VGPR, very good partial response. ORR assessed by independent review committee. <sup>a</sup>Subgroups by number of prior lines of therapy (≤4, >4), refractoriness (triple-class, penta-drug), cytogenetic risk (high risk, standard risk), baseline bone marrow plasma cells (≤30%, >30 to <60%, ≥60%), baseline tumor BCMA expression (≥median, <median), and baseline plasmacytomas (including extramedullary and bone-based). <sup>b</sup>MRD was assessed in evaluable samples (ie, patients with identifiable clone at baseline and sufficient cells for testing at 10<sup>-5</sup> threshold in post treatment samples) by next-generation sequencing (clonoSEQ, Adaptive Biotechnologies) in all treated patients at Day 28, and at 6, 12, 18, and 24 months regardless of the status of disease measured in blood or urine. Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005

# CARTITUDE-1: Progression Free Survival



- **18-month PFS:**  
All Patients: 66.0% (95% CI, 54.9–75.0)  
sCR: 75.9% (95% CI, 63.6–84.5)
- **18-month OS:**  
All patients: 80.9% (95% CI, 71.4–87.6)

Number at Risk		Months										
	0	3	6	9	12	15	18	21	24	27	30	
All Patients	97	95	85	77	73	55	26	9	1	1	0	
Responders With sCR	78	78	76	71	68	51	26	9	1	1	0	

Median duration of follow-up: 18 months (range, 1.5–30.5)

Data cut-off: Feb 11, 2021; NE, not estimable; PFS, progression-free survival; OS, overall survival; sCR, stringent complete response. Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005

# CARTITUDE-1: Safety

N = 97

Any Grade      Grade 3/4

## Hematologic AEs, (≥30%), n (%)

Neutropenia	93 (95.9)	92 (94.8)
Anemia	79 (81.4)	66 (68.0)
Thrombocytopenia	77 (79.4)	58 (59.8)
Leukopenia	60 (61.9)	59 (60.8)
Lymphopenia	51 (52.6)	48 (49.5)

## Non-hematologic AEs (≥30%), n (%)

Hypocalcemia	31 (32.0)	3 (3.1)
Hypophosphatemia	30 (30.9)	7 (7.2)
Fatigue	36 (37.1)	5 (5.2)
Cough	34 (35.1)	0

## CAR-T associated AEs, n (%)

CRS <sup>a</sup>	92 (94.8)	4 (4.1)
Neurotoxicity	20 (20.6)	9 (9.3)

- **No new safety signals with longer follow-up**
- **CRS**
  - 94.6% of patients experienced low-grade CRS (n=92)
  - Median time to onset of 7 days (range, 1-12)
  - Median duration of 4 days (range, 1-97)<sup>b</sup> and resolved in 91 (98.9%) patients within 14 days of onset
- **Neurotoxicity**
  - 20.6% of patients experienced neurotoxicity in total with overlap between ICANS and Other Neurotoxicities (Grade ≥3: 10.3%)
    - ICANS observed in 16.5% (Grade ≥3: 2.1%)
    - Other Neurotoxicities<sup>c</sup> observed in 12.4% (Grade ≥3: 9.3%)
- **6 treatment-related deaths as assessed by the investigator<sup>d</sup>**

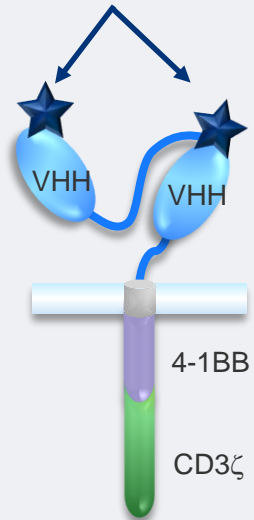
Data cut-off: Feb 11, 2021; AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; HLH, hemophagocytic lymphohistiocytosis. <sup>a</sup>CRS was graded using Lee et al. (*Blood* 2014) in the phase 1b portion of the study and ASTCT in phase 2; in this combined analysis, Lee et al. criteria were mapped to ASTCT criteria for patients in the phase 1b portion. <sup>b</sup>The patient with 97-day duration died due to CRS/HLH. <sup>c</sup>Events not reported as ICANS (ie, onset after a period of recovery from CRS and/or ICANS). <sup>d</sup>There were 21 study deaths: 6 were treatment-related as assessed by the investigator, the remaining were due to AEs unrelated to treatment (n=5) and disease progression (n=10) Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005

# CARTITUDE-2: Multicohort Study

## Cohort A: 1 – 3 prior lines, lenalidomide refractory RRMM

- CARTITUDE-2 is a phase 2, multicohort, open-label study assessing the efficacy and safety of cilta-cel in patients with multiple myeloma in various clinical settings

### BCMA-binding domains



**Cilta-cel  
(CAR-T)**

### Cohort A:

- Cohort A patients had progressive MM after 1–3 prior lines of therapy, and were refractory to lenalidomide
- Despite advances continued unmet need with mPFS of 9.9 months (DPd)<sup>1</sup>

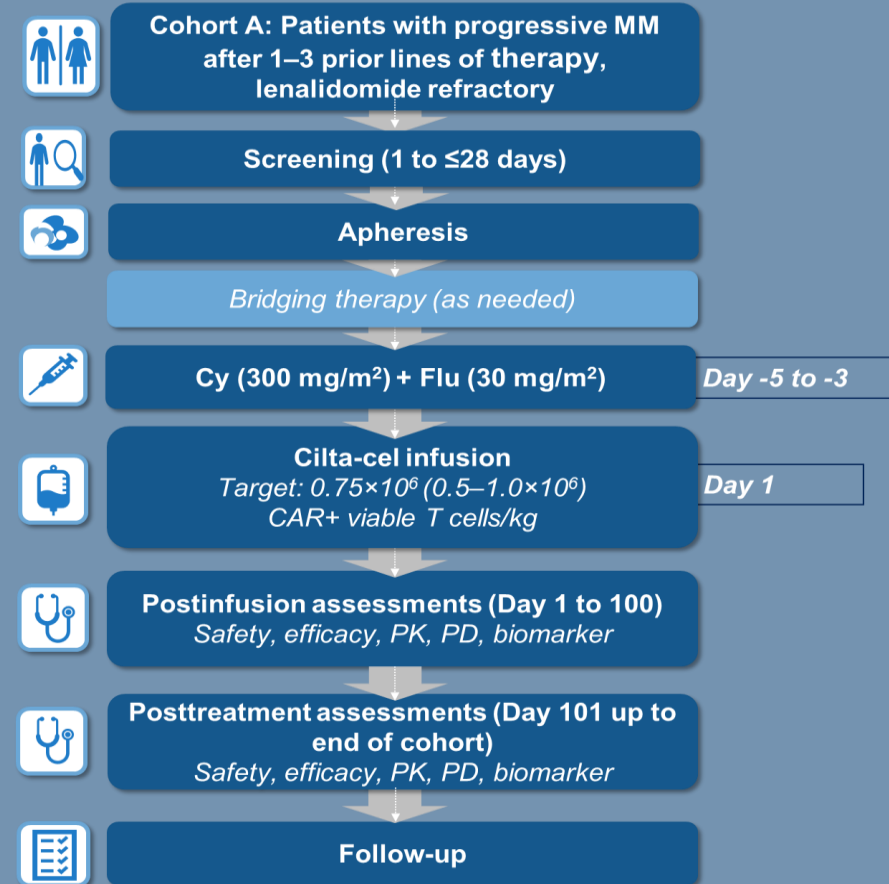
### Primary objectives

- Minimal residual disease (MRD)  $10^{-5}$  negativity

### Secondary objectives

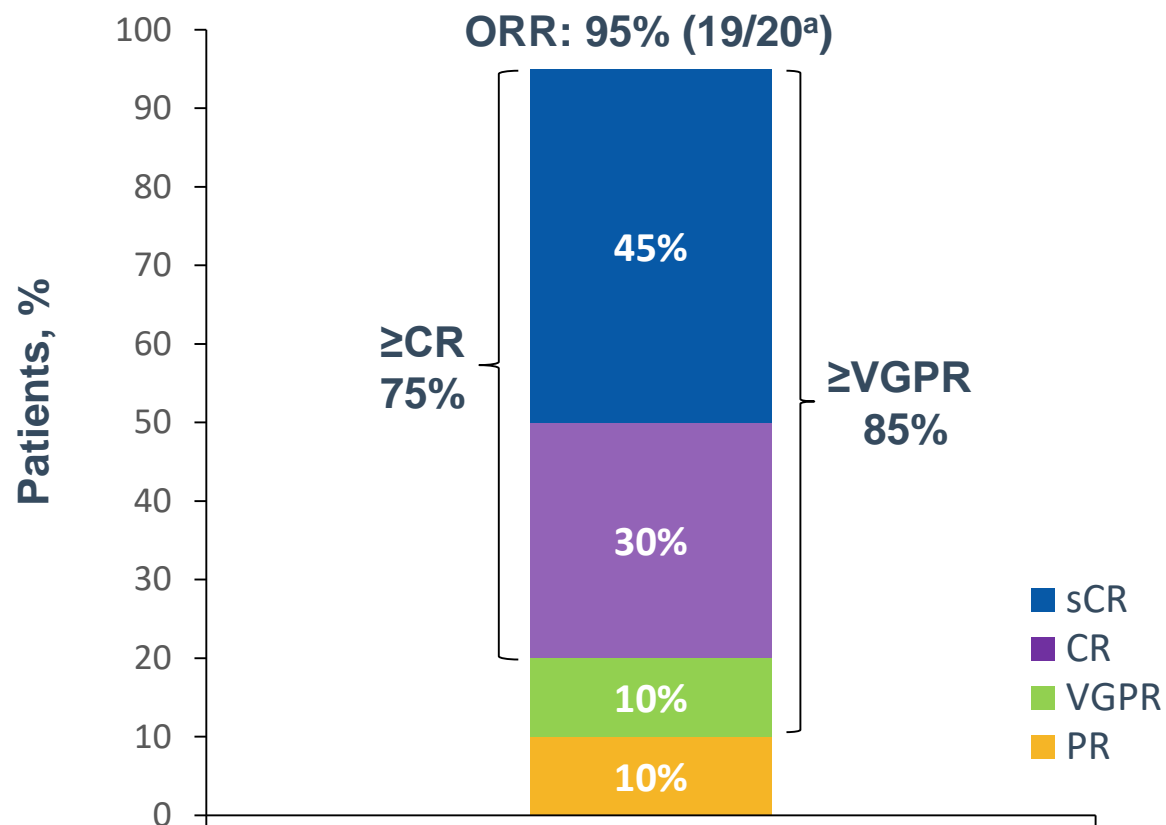
- ORR, duration of response, time and duration of MRD negativity, and incidence and severity of adverse events

### Study Design



# CARTITUDE-2: Phase 2 Multi-Cohort Study

- Cohort A included 20 patients who had progressive MM after 1–3 prior lines of therapy and were refractory to lenalidomide
- Median prior lines of therapy: 2 (range, 1-3); 1 patient treated in an outpatient setting



- No progression of disease at median follow-up of 5.8 months (range 2.5-9.8)
- All patients (n=4) with MRD-evaluable<sup>b</sup> samples at the 10<sup>-5</sup> threshold were MRD negative at data cut-off
- The safety profile was manageable
  - CRS occurred in 85% (n=17); mostly grades 1/2; median time to CRS onset was 7 days (range, 5–9)
  - Neurotoxicities occurred in 20% (n=4) of patients; no grade ≥3; no incidence of movement and neurocognitive TEAEs
  - 1 death occurred 100 days after infusion due to COVID-19 (assessed as tx related by the investigator)

Data cut-off date: Jan 2021; <sup>a</sup>Patient who did not respond had stable disease. <sup>b</sup>MRD was assessed in evaluable samples (ie, patients with identifiable clone at baseline and sufficient cells for testing at 10<sup>-5</sup> threshold in post treatment samples) by next-generation sequencing (clonoSEQ, Adaptive Biotechnologies) in all treated patients.

CR, complete response; MRD, minimal residual disease; ORR, overall response rate; PR, partial response; sCR, stringent complete response; TEAE, treatment-emergent adverse events; VGPR, very good partial response.

Agha M, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8013.

# CARTITUDE Program: Safety

Successful new patient management strategies have been implemented in the CARTITUDE program to prevent and reduce the incidence of neurotoxicity<sup>1-3</sup>

## Movement and Neurocognitive TEAEs<sup>a</sup>

- Occurred in 5 of 97 patients in CARTITUDE-1

### **Risk factors (2 or more)**

- High tumour burden<sup>b</sup>
- Grade  $\geq 2$  CRS
- ICANS
- High CAR T-cell expansion and persistence



## Patient Management Strategies

- Enhanced bridging therapy to reduce tumour burden
- Early and aggressive treatment of CRS and ICANS
- Handwriting assessments and extended monitoring



## CARTITUDE Program Level >100 additional patients have been dosed<sup>c</sup>

- Patient management strategies to prevent or reduce these AEs have been successfully implemented in new and ongoing cilta-cel studies
- This is reliant on effective implementation of these patient management strategies

AE, adverse event; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; TEAE, treatment-emergent AE.

<sup>a</sup>Two patients with ongoing symptoms continued to improve at the time of data cutoff; patient management strategies were implemented, including enhanced bridging therapy to reduce baseline tumor burden, early aggressive treatment of CRS and ICANS, handwriting assessments for early detection of neurotoxicity symptoms, and extended monitoring and reporting time for neurotoxicity beyond the first 100 days post-cilta-cel infusion. <sup>b</sup>Defined as having high tumor burden when any of the following parameters were met: bone marrow plasma cell  $\geq 80\%$ , serum M-spike  $\geq 5$  g/dL, serum free light chain  $\geq 5000$  mg/L. <sup>c</sup>Included patients treated in earlier and later line settings across the CARTITUDE program.

1. Usmani S, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8005. 2. Agha M, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8013. 3. Einsele H, et al. ASCO Annual Meeting (Virtual). June 4-8, 2021. Abstract 8028



# Clinical Program: Cilta-cel Studies in Multiple Myeloma

FIH Study in China  
Long-term Follow-up



Registrational  
Studies



Earlier Lines  
of Therapy



LEGEND-2<sup>1</sup>

NCT03090659

- Phase 1, multi-center study of LCAR-B38M CAR-T cells in RRMM
- Fully enrolled and ongoing in China

CARTITUDE-1  
MMY2001<sup>2</sup>

NCT03548207

- Phase 1b/2, multi-center registrational study of cilta-cel in RRMM
- Fully enrolled and ongoing in US and Japan

CARTITUDE-2  
MMY2003<sup>4</sup>

NCT04133636

- Global, multi-cohort study
- Phase 2 open-label study of cilta-cel in various clinical settings to evaluate MRD negativity
- Enrolling in US/EU/Israel

NCT04181827

- Global, randomized, registrational study
- Phase 3 open-label study of cilta-cel vs DPd or PVd in patients with RRMM, 1–3 lines of prior therapy and refractory to lenalidomide
- Enrolling in US/EU/JP/AUS/Israel/Korea

CARTIFAN-1  
MMY2002<sup>3</sup>

NCT03758417

- Phase 2, multi-center registrational, confirmatory, study of cilta-cel in RRMM
- Ongoing in China

CARTITUDE-4  
MMY3002<sup>5</sup>

NCT04923893

- Global, randomized, registrational study
- Phase 3 open-label study of VRd followed by cilta-cel vs. VRd followed by Rd maintenance, in patients with newly diagnosed MM for whom ASCT is not planned as initial therapy
- Planned in US/Canada/EU/AUS/Israel/Brazil

CARTITUDE-5  
MMY3004<sup>6</sup>

ASCT, autologous stem cell transplant; DPd, daratumumab, pomalidomide, dexamethasone; EU, European Union; JP, Japan; PVd, pomalidomide, bortezomib, dexamethasone; RRMM, relapsed and/or refractory multiple myeloma; SoC, standard of care; US, United States; VRd, bortezomib, lenalidomide, dexamethasone  
<sup>1</sup> NCT03090659. Clinicaltrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT03090659>. Accessed June 2021; <sup>2</sup> NCT03548207. Clinicaltrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT03548207>. Accessed June 2021. CARTITUDE-1 is global registrational study; <sup>3</sup> NCT03758417. Clinicaltrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT03758417>. Accessed June 2021. CARTIFAN-1 is registrational study for China only; <sup>4</sup> NCT04133636. Clinicaltrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT04133636>. Accessed June 2021.; <sup>5</sup> NCT04181827. Clinicaltrials.gov website: <https://clinicaltrials.gov/ct2/show/NCT04181827>. Accessed June 2021. CARTITUDE-4 is global registrational study; <sup>6</sup> NCT04923893. Clinicaltrials.gov website: <https://clinicaltrials.gov/ct2/show/NCT04923893>. Accessed June 2021. CARTITUDE-5 is global registrational study.

# Global Manufacturing Footprint

## US Facilities



Raritan, NJ

BCMA US / EU / JP / ROW  
Launch/ Commercial Site

✓ GMP Operational



Somerset, NJ

US / EU / JP Legend Clinical  
Supply Site

■ construction ongoing

## EU Facilities



Ghent, Belgium

Future Commercial Site

■ Construction in progress



Ghent, Belgium

Future Commercial Site

■ Construction in progress

## China Facilities



Nanjing

BCMA China Launch Site &  
Legend Clinical Supply Site

✓ GMP Operational



Nanjing 75-acre

Future Commercial Site

■ Construction in progress

Building E

# Future Potential Milestone Payments



## Future Potential Milestones

### **Clinical Milestones: \$105M**

*\$105 million for the achievement of specified future development milestones*

### **Regulatory Milestones: \$710M**

*\$710 million for the achievement of specified regulatory milestones*

### **Commercial Milestones: \$210M**

*\$210 million for the achievement of specified net trade sales milestones.*

### **Manufacturing Milestones: \$125M**

*Further milestone payments of up to \$125 million for the achievement of specified manufacturing milestones*

# Program Areas of Development

Legend Biotech is utilizing the extensive cell therapy experience of our leadership and R&D staff, global clinical partners, and expanding research facilities to realize the potential of cell therapy to treat diseases that are thought to be incurable, such as hematologic malignancies, solid tumors and infectious diseases.



# LB1901: Investigational CAR-T for T Cell Lymphoma

## MoA/ Scientific Rationale

- LB1901 targets CD4 antigen that is expressed in most T cell lymphoma (TCL) subtypes and in subsets of normal immune cells
- LB1901 is a CD8-enriched anti-CD4 CAR-T and contains a unique binder to CD4 leading to potential elimination of CD4+ tumor cells

## Target

- CD4 is a surface membrane glycoprotein expressed at high levels on TCL and a subtype of normal T cells<sup>1</sup>
- Anti-CD4 mAb have been investigated in clinical studies for TCL<sup>2</sup>

## Clinical Development

- US IND cleared with FDA
- Ongoing Phase 1 studies in US and China
- Patient population: relapsed/refractory PTCL and CTCL patients

# LB1908: Investigational CAR-T for Gastric Cancer

## MoA/ Scientific Rationale

- LB1908 targets Claudin (CLDN) 18.2 through high-affinity VHH antibody
- VHH antibody, identified via in-house, selectively binds to CLDN 18.2

## Target

- Claudins are a family of tight junction proteins<sup>1</sup>
- CLDN18.2 is commonly expressed on multiple cancers including gastric cancer<sup>2</sup>

## Clinical Development

- Phase I clinical study in China is ongoing for the treatment of adult patients with advanced gastric cancer
- US IND is being developed with planned submission in 1H2022

# LB1905: Investigational Allogenic CAR-T

## MoA/ Scientific Rationale

- LB1905 targets CD20 that is expressed in B cell lymphoma
- LB1905 applied Legend UniCAR technology which is an unique non-gene-editing allogenic CAR-T platform
- Simple and efficient manufacturing promote product homogeneity and accessibility

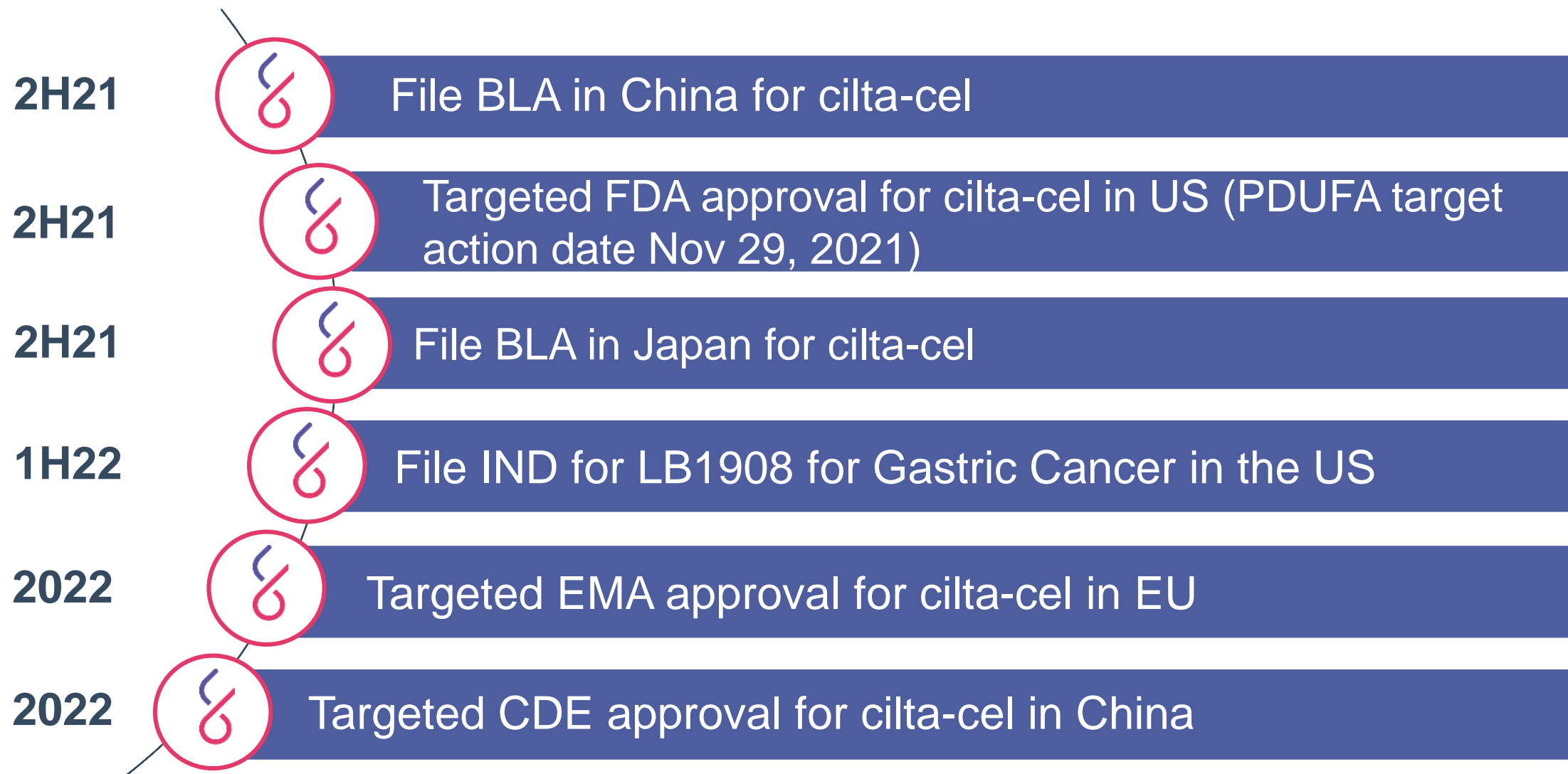
## Target

- CD20 is mainly expressed in pre-B cells and mature B cells. It is expressed in more than 95% of B-cell lymphomas and not in hematopoietic stem cells, plasma cells, and other normal tissues

## Clinical Development

- Allogenic CD20 targeted product for the treatment of adult patients with recurred NHL
- Promising allogenic platform that can potentially be leveraged in Legend clinical development programs

# Near-Term Targets for Legend Biotech





# Investment Highlights



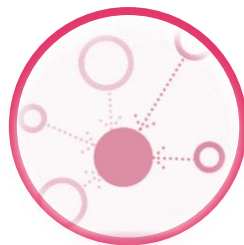
## **Global Collaboration**

*Global collaboration with Janssen for the development of cilta-cel with ongoing clinical trials*



## **Promising Clinical Data**

*Deep and durable anti-tumor responses observed in heavily pretreated patients with MM; BLA for cilta-cel submitted to US FDA (PDUFA target action date Nov 29, 2021); MAA for cilta-cel submitted to EMA*




## **Fully Integrated Platform**

*End-to-end R&D and manufacturing capabilities with two core technologies (CAR and TCR) and two platforms (Autologous and Allogeneic)*



## **Strong Management**

*Experienced team with broad involvement in biopharmaceutical drug discovery, development and commercialization*



*In the world of cell therapy,  
some biotechs have an Eastern perspective.  
Others have a Western perspective.*

We are bridging the gap between *East and West.*



**Thank You !**