# Legend Biotech Corporate Presentation

September 2023



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These statements include, but are not limited to, statements relating to Legend Biotech's expectations for CARVYKTI®, and statements about regulatory submissions for CARVYKTI®, and the progress of such submissions with the FDA, the EMA and other regulatory authorities; and expected results of clinical trials; Legend Biotech's expectations on advancing their pipeline and product portfolio; and the potential benefits of Legend Biotech's product candidates. 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. 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 U.S. litigation process; competition in general; government, industry, and general product 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 Legend Biotech's Annual Report on Form 20-F filed with the Securitie

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# Legend Biotech Highlights

Years Since Inception

1,500+

**Employees** 

Marketed Product: CARVYKTI®†#

Pipeline Programs Covering:

- Hematologic malignancies
- Solid tumors

Core Technologies:

- CAR-T, including universal CAR
- CAR-NK
- $\gamma \delta T$

Global Manufacturing Sites:

- US
- EU\*
- China\*

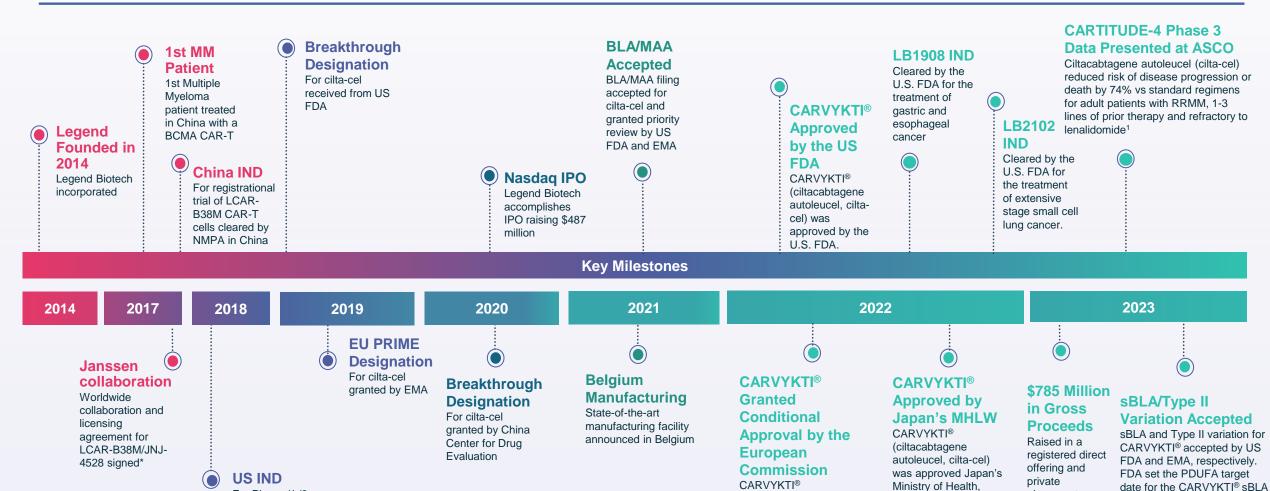
\$1.5 Bn

in Cash and Cash Equivalents, Deposits, and Short-Term Investments

<sup>\*</sup>EU and China manufacturing site construction is in progress

<sup>†</sup>In collaboration with Janssen

# **Key Milestones Achieved**





to April 5, 2024.

placements

Labour and Welfare

(MHLW)

This presentation is for investor relations purposes only – Not for product promotional purposes

(ciltacabtagene autoleucel,

Conditional Approval by

cilta-cel) granted

the FC

For Phase 1b/2

cilta-cel cleared

clinical trial of

by FDA

# Cell Therapy Platform

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 and solid tumors.



# We Are A Fully Integrated Global Cellular Therapy Company



### COMPELLING DATA WITH AN INNOVATIVE PIPELINE

- Ciltacabtagene autoleucel (cilta-cel) may have the potential to deliver deep and durable anti-tumor responses in earlier line settings of multiple myeloma
- Broad portfolio of autologous and allogeneic product candidates targeting both hematologic and solid cancers



### **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 \$315 million in milestone payments to date
  - Earned an additional milestone payment of \$20 million on August 4, 2023
  - Eligible for potential significant future milestone payments



### INTEGRATED CELL THERAPY PLATFORM

- In-house antibody generation and CAR-T specific functional screening technologies
- Early clinical proof-of-concept, working with KOLs in China, the US and globally
- Building large-scale manufacturing facilities in the United States, Europe and China
- 1,500+ employees worldwide in US, China and Europe



# Global R&D Strategy

Institutional R&D Model that accelerates Cell Therapy Discovery and Development



People: ~300 employees
One of the largest global
cell therapy R&D teams



Science: Global innovation development US, China, Europe



Patients: Potential bestin-class proprietary technology platforms



IP: Strong intellectual property position

## **CLINICAL DEVELOPMENT**



Clinical programs in US



Clinical programs in China

## **CORE TECHNOLOGIES**

CAR-T

NK

γδ - Τ

## **PRODUCT PLATFORMS**

Autologous

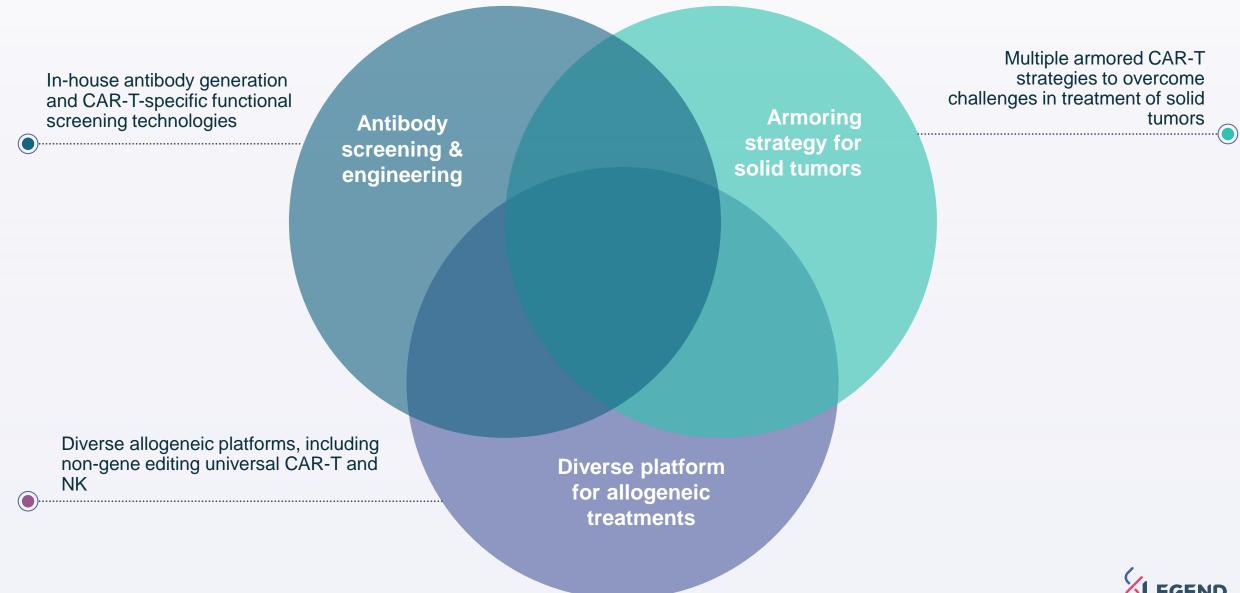
Allogeneic

## **DISEASE AREAS**

Hematologic malignancies
Solid tumors



# Our Strengths in R&D

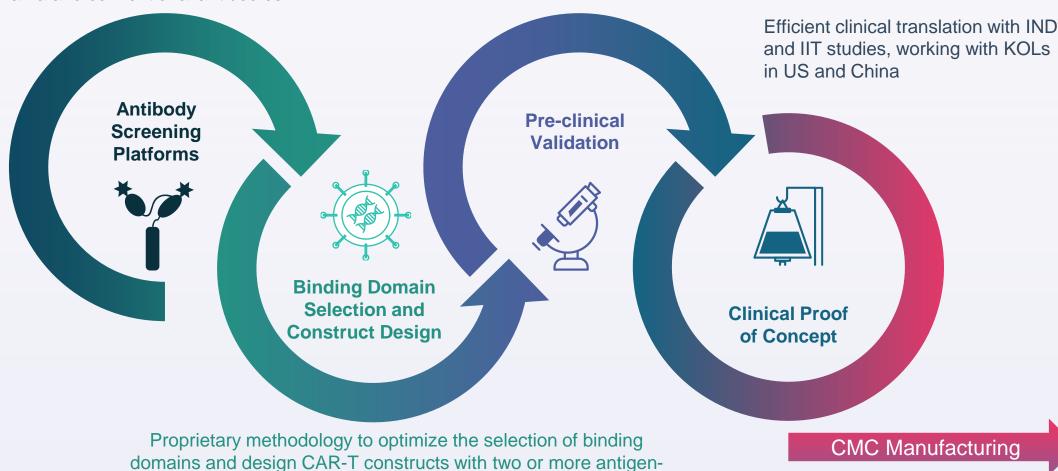




# Our End-to-End R&D Capability

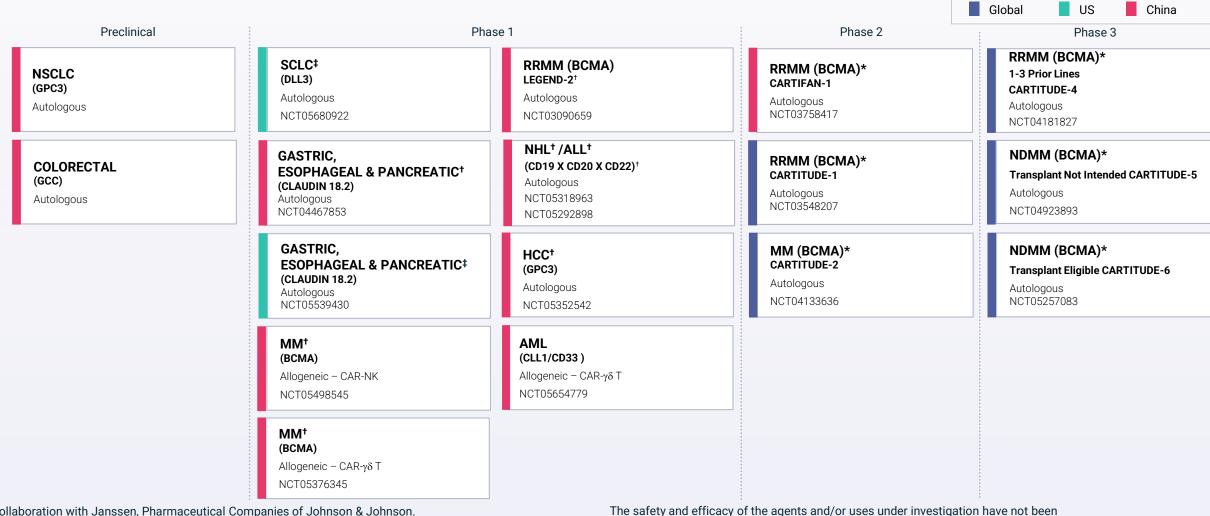
High-throughput antibody screening and engineering capability, including single-domain antibodies generated from Ilama and conventional antibodies

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



binding domains

# Our Pipeline



\*In collaboration with Janssen, Pharmaceutical Companies of Johnson & Johnson. †Phase 1 IIT in China.

‡IND applications have been cleared by the U.S. FDA.

ALL, acute lymphoblastic leukemia; AML, acute myeloid leukemia; BCMA, B-cell maturation antigen; DLL3, delta-like ligand 3; GPC3, glypican-3; GCC, guanylyl cyclase C; HCC, hepatocellular carcinoma; IIT, investigator-initiated trial; MM, multiple myeloma; ND, newly diagnosed; NHL, non-Hodgkin lymphoma; NSCLC, non small cell lung cancer; RRMM, relapsed or refractory multiple myeloma; SCLC, small cell lung cancer.

The safety and efficacy of the agents and/or uses under investigation have not bee established.

There is no assurance that the agents will receive health authority approval or become commercially available in any country for the uses being investigated. Additionally, as some programs are still confidential, certain candidates may not be included in this list.



# A Highly Experienced Management Team



**YING HUANG Chief Executive Officer** 









LORI MACOMBER **Chief Financial Officer** 









**Guowei Fang** Chief Scientific Officer & Head of Business Development









Mythili Koneru Chief Medical Officer







**Steve Gavel** Commercial Development (Celgene ≣IQVIA

MILLENNIUM AMGEN



**Elizabeth Gosen** Global Manufacturing





**Alan Kick** Global Quality







Dendreon

Johnson-Johnson



**Yuhong Qiu** Global Regulatory **b** NOVARTIS Johnson Johnson



**Dong Geng** Early-stage Drug Development





Bristol Myers Squibb\* REGENERON



**Elaine Qian Human Resources** GenScript Make Research Easy



**Tracy Luo** Clinical Development **AMGEN** AstraZeneca 2



Simon Wu General Manager, Greater China





**Chong Yang** Commercial Development

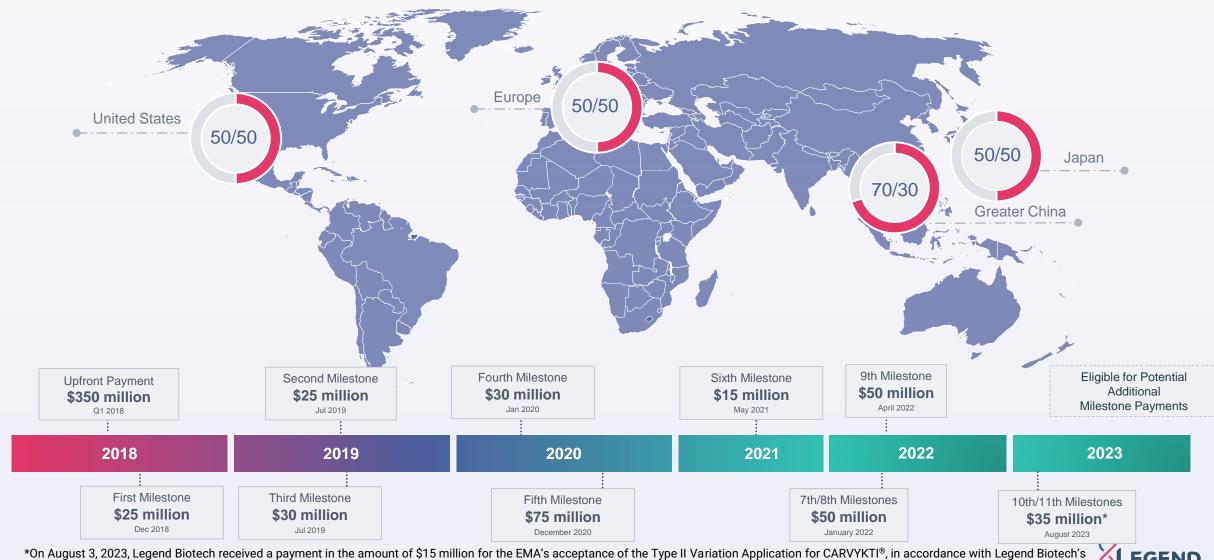






# Legend and Janssen Global Collaboration

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







# Global Manufacturing Footprint

## **US Facilities**



Raritan, NJ

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



US / EU / JP Legend Clinical Supply Site

## **EU Facilities**



Ghent, Belgium

#### **Future Commercial Site**

■ Construction ongoing



#### **Future Commercial Site**

■ Construction ongoing

## **China Facilities**



Legend China Clinical Supply Site & Potential BCMA China Launch Site

✓ GMP Operational



#### **Potential Future Commercial Site**

Construction ongoing



**Building E** 

# Cilta-cel Clinical Development



# Multiple Myeloma: Blood Cancer with a High Unmet Need



### 3RD 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>



**32,119,** with mortality of 13,426<sup>5</sup>



**50,918,** with mortality of 32,495<sup>6</sup>

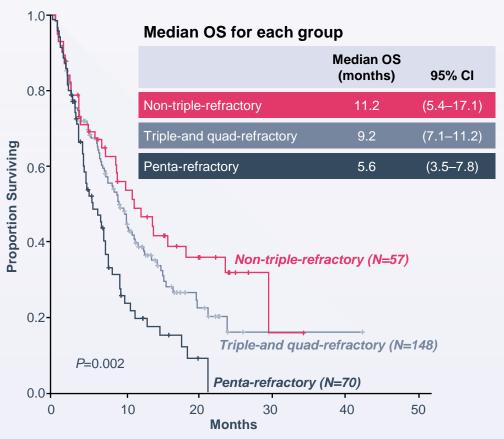


**21,116,** with mortality of 16,182<sup>7</sup>

## POOR SURVIVAL OUTCOMES IN MULTIPLE REFRACTORY MM

## Median OS < 12 months

in patients refractory to anti-CD38, ≥ 1 PI(s) and / or ≥ 1 IMiD(s)8



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

1. Cancer Stat Facts: Myeloma. <a href="https://seer.cancer.gov/statfacts/html/mulmy.html">https://seer.cancer.gov/statfacts/html/mulmy.html</a>. Accessed June 2021. 2. Facts and Statistics. <a href="https://www.lls.org/facts-and-statistics/facts-and-statistics/facts-and-statistics-overview">https://gco.iarc.fr/today/data/facts-and-statistics-overview</a>. Accessed June 2021. 3. Globocan 2020 World Fact Sheet: <a href="https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/900-world-fact-sheets/populations/908-europe-fact-sheets.pdf</a>. Accessed June 2021. 6. Globocan 2020 World Fact Sheet: Europe. <a href="https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf">https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf</a>. Accessed June 2021. 7. Globocan 2020 World Fact Sheet: China. <a href="https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf">https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf</a>. Accessed June 2021. 8. Gandhi UH, et al. Leukemia. 2019;33:2266-75.



# Clinical Program - Cilta-cel Studies in Multiple Myeloma

#### **Late Line Studies of Therapy Earlier Lines of Therapy** NCT03548207 NCT04133636 Global, multi-cohort study Phase 1b/2, multi-center registrational study Phase II open-label study of cilta-cel in various clinical **CARTITUDE-1**1 **CARTITUDE-24** of cilta-cel in RRMM settings Enrolling Completed NCT04181827 NCT03758417 Global, randomized, registrational study Phase II, multi-center registrational, Phase III open-label study of cilta-cel vs DPd or PVd in confirmatory, study of cilta-cel in RRMM **CARTIFAN-12** CARTITUDE-45 patients with RRMM, 1-3 lines of prior therapy and Enrollment completed in China refractory to lenalidomide **Enrollment completed** NCT03090659 NCT04923893 Global, randomized, registrational study Phase 1, multi-center study of LCAR-B38M Phase III open-label study of VRd followed by cilta-cel vs. CAR-T cells in RRMM LEGEND-23 **CARTITUDE-56** VRd followed by Rd maintenance, in patients with NDMM Fully enrolled and ongoing in China for whom ASCT is not planned as initial therapy Enrolling NCT05257083 Global, randomized, registrational study Phase III open-label study comparing DVRd followed by CARTITUDE-67 cilta-cel vs. DVRd followed by ASCT in NDMM patients who are transplant eligible Not yet enrolling

ASCT, autologous stem cell transplant; DPd, daratumumab, pomalidomide, dexamethasone; DVRd, daratumumab, bortezomib, lenalidomide, dexamethasone; EU, European Union; JP, Japan; NDMM, newly diagnosed multiple myeloma; PVd, pomalidomide, bortezomib, dexamethasone; RRMM, relapsed and/or refractory multiple myeloma; SoC, standard of care; US, United States; VRd, bortezomib, lenalidomide, dexamethasone.

1 Clinicaltrials.gov: NCT03548207. 2 Clinicaltrials.gov: NCT03758417. CARTIFAN-1 is registration study for China only; 3 Clinicaltrials.gov: NCT03090659. 4 Clinicaltrials.gov: NCT04133636. 5 Clinicaltrials.gov: NCT04181827 6 Clinicaltrials.gov: NCT04181827 6 Clinicaltrials.gov: NCT04183636. 5 Clinicaltrials.gov:

Clinicaltrias.gov: NC103548207. Clinicaltrials.gov: NC103758417. CARTIFAN-1 is registration study for China only; Clinicaltrials.gov: NC103090659. Clinicaltrials.gov: NC104133636. Clinicaltrials.gov: NC104181827 Clinicaltr

# Updated Clinical Profile for Cilta-cel from ASCO 2023

			LEGEND-2 <sup>1,2,a</sup>	CARTITUDE-1 <sup>3-6, #</sup>	CARTITUDE-4 Intent-to-treat (n=208) <sup>6,b</sup> As	CARTITUDE-4 -Treated (n=176) <sup>6,7,b</sup>
	Median number of prior LOT		3	6	2	-
	Median follow-up (mo)		65.4	33.4	15.9	15.9
	Efficacy	ORR	87.8%	97.9%	84.6%	99.4%
		≥CR	73.0%	82.5% <sup>c</sup>	73.1%	86.4%
		12mo PFS	~60%	76%	76%	90% <sup>d</sup>
		Median PFS (mo)	18.0	34.9	NR	NE
		Median OS (mo)	55.8	NR	_e	_e
		Median DOR (mo)	23.3	33.9	NR	NE
	Safety	CRS Gr3+	9.5%	5.1%	-	1.1%
		Neurotoxicity Gr3+	0%	12.3%	-	2.8%
		ICANS Gr3+	0%	2%	-	0%
	Safety	Median PFS (mo)  Median OS (mo)  Median DOR (mo)  CRS Gr3+  Neurotoxicity Gr3+	18.0 55.8 23.3 9.5% 0%	34.9 NR 33.9 5.1% 12.3%	NR _e NR  _	NE _e NE 1.1% 2.8%

<sup>-,</sup> not reported; CR, complete response; CRS, cytokine release syndrome; DOR, duration of response; Gr3+, grade 3 or higher; ICANS, Immune effector cell-associated neurotoxicity syndrome; LOT, lines of therapy; mo, months; NE, not estimable; NR, not reached; ORR, overall response rate; OS, overall survival; PFS, progression free survival.

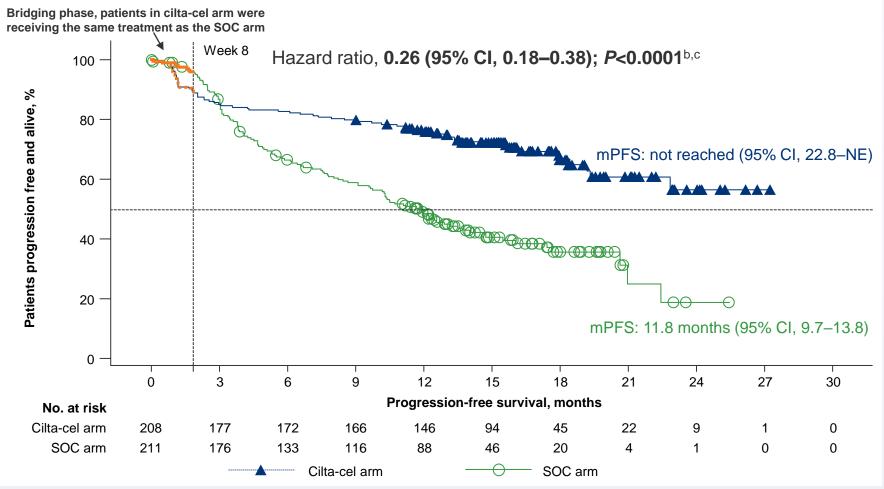
aStudy investigating LCAR-B38M, a similar CAR construct to cilta-cel. In the CARTITUDE-4 study, 419 patients were randomized, with 208 patients in the cilta-cel arm and 211 patients in the SOC arm. Among intent-to-treat (ITT) patients in the citla-cel arm (n=208), 32 did not receive cilta-cel as study tx due to disease progression or death during bridging therapy/lymphodepletion and 176 patients received cilta-cel as study treatment and were assessed for CAR-T related toxicities. Stringent complete response. From apheresis. Overall survival data were immature at data cutoff.

<sup>1.</sup> Mi JQ, Zhao WH, Chen LJ, et al. ASCO Annual Meeting: June 2-6, 2023; Chicago, Il & Virtual; Abstract #8010, 2, Zhao WH, Wang BY, Chen LJ, et al. J Hematol Oncol, 2022;15(1):86, Published 2022 Jul 6, doi:10.1186/s13045-022-01301-8. 3. Lin Y, Martin T, Usmani SZ, et al. ASCO Annual Meeting; June 2-6, 2023; Chicago, II & Virtual; Abstract #8009. 4. Martin T, Usmani SZ, Berdeja JG, et al. J Clin Oncol. 2023;41(6):1265-1274. doi:10.1200/JCO.22.00842. 5. Berdeja JG, Madduri D, Usmani SZ, et al. Lancet. 2021;398(10297):314-324. doi:10.1016/S0140-6736(21)00933-8. 6. Dhakal et al. ASCO Annual Meeting; June 2-6, 2023; Chicago, Il & Virtual; Abstract #LBA106. 7. San-Miguel J, Dhakal B, Yong K, et al.. N Engl J Med. 2023;389(4):335-347. doi:10.1056/NEJMoa2303379. 47 #Please read Prescribing Information for full safety information: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/CARVYKTI-pi.pdf

# CARTITUDE-4:Primary Endpoint – PFS (ITT Population)

## Cilta-cel vs SOC

- 12-month PFS rate: 76% vs 49%
- SOC performed as expected



aMedian follow-up, 15.9 months. bConstant piecewise weighted log-rank test. cHazard ratio and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable, including only progression-free survival events that occurred >8 weeks post randomization.

cilta-cel, ciltacabtagene autoleucel; HR, hazard ratio; ITT, intent-to-treat; mPFS, median progression-free survival; NE, not estimable; SOC, standard of care.



## **CARTITUDE-4: TEAEs**

	Safety population					
Select TEAE ≥15%, n (%)	Cilta-cel	(n=208)	SOC (n=208)			
	Any grade	Grade 3/4	Any grade	Grade 3/4		
Any AE	208 (100)	201 (96.6)	208 (100)	196 (94.2)		
Serious AE	92 (44.2)	67 (32.2)	81 (38.9)	70 (33.7)		
Hematologic	197 (94.7)	196 (94.2)	185 (88.9)	179 (86.1)		
Neutropenia	187 (89.9)	187 (89.9)	177 (85.1)	172 (82.2)		
Anemia	113 (54.3)	74 (35.6)	54 (26.0)	30 (14.4)		
Thrombocytopenia	113 (54.3)	86 (41.3)	65 (31.3)	39 (18.8)		
Lymphopenia	46 (22.1)	43 (20.7)	29 (13.9)	25 (12.0)		
Infections	129 (62.0)	56 (26.9)	148 (71.2)	51 (24.5)		
Upper respiratory tracta	39 (18.8)	4 (1.9)	54 (26.0)	4 (1.9)		
Lower respiratory tract <sup>b</sup>	19 (9.1)	9 (4.3)	36 (17.3)	8 (3.8)		
COVID-19 <sup>c</sup>	29 (13.9)	6 (2.9)	55 (26.4)	12 (5.8)		

## Hematologic TEAEs most common

- 85–90% **neutropenia**, almost all grade 3/4
- Most high-grade cytopenias resolved to grade ≤2 by day 30
- Grade 3/4 infections similar between arms

## Second primary malignancies:

- Cilta-cel, 4.3% (n=9); most commonly cutaneous/noninvasive and hematologic
- SOC, 6.7% (n=14); most commonly cutaneous/noninvasive<sup>d</sup>

## Deaths due to TEAEs

- Cilta-cel, n=10<sup>e</sup> (7 due to COVID-19<sup>f</sup>)
- SOC,  $n=5^g$  (1 due to COVID-19)

alncludes preferred terms upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, tonsillitis, pharyngitis, laryngitis, and pharyngotonsillitis. Includes preferred terms lower respiratory tract infection, pneumonia, and bronchitis. Treatment-emergent COVID-19 only; includes preferred terms COVID-19, COVID-19 pneumonia, and asymptomatic COVID-19. With 1 case of peripheral T-cell lymphoma in the cilta-cel arm. The due to COVID-19, and 1 each due to neutropenic sepsis, pneumonia, and respiratory failure. The did not covid to the higher number of fatal events in the first year. In each due to COVID-19, progressive multifocal leukoencephalopathy, respiratory tract infection, septic shock, and pulmonary embolism.

AE, adverse event; cilta-cel, ciltacabtagene autoleucel; TEAE, treatment-emergent adverse event; SOC, standard of care.



# CARTITUDE-4: CRS and CAR-T Cell-Related Neurotoxicity

	As-treated patients (n=176)					
AEs, n (%)	Any grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n	
CRS	134 (76.1)	2 (1.1)	8	3	134	
Neurotoxicity <sup>a</sup>	36 (20.5)	5 (2.8)				
ICANS	8 (4.5)	0 <sub>p</sub>	10	2	8	
Other <sup>c</sup>	30 (17.0)	4 (2.3)				
Cranial nerve palsy <sup>d</sup>	16 (9.1)	2 (1.1)	21	77	14	
Peripheral neuropathy	5 (2.8)	1 (0.6)	63	201	3	
MNT	1 (0.6)	0	85	-	0	

## In the cilta-cel as-treated population:

- 30 patients had non-ICANS neurotoxicities<sup>c</sup>
  - 16 cranial nerve palsies (14 recovered)
  - 5 peripheral neuropathies
  - 1 MNT (grade 1)
- Lower incidence and severity of CRS, ICANS, MNTs, and some cytopenias<sup>e</sup> observed with CARTITUDE-4 vs CARTITUDE-1
  - Cilta-cel may be better tolerated when used earlier in treatment
  - Effective bridging therapy enables better control of tumor burden prior to CAR-T infusion
  - MNTs were lower likely related to patient management strategies implemented to mitigate this risk



<sup>&</sup>lt;sup>a</sup>There were no fatal neurotoxicities. <sup>b</sup>Grade 3 syncope reported as a symptom of grade 2 ICANS. <sup>c</sup>Other neurotoxicities include AEs reported as CAR-T cell neurotoxicity that are not ICANS or associated symptoms. <sup>d</sup>Cranial nerve palsies most commonly affected cranial nerve VII; supportive measures included corticosteroids (14 patients). No clear risk factors for cranial nerve palsies have been identified, and the mechanism is not understood. <sup>e</sup>Data for cytopenias not shown.

AE, adverse event; CAR-T, chimeric antigen receptor T cell; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; DPd, daratumumab, pomalidomide, and dexamethasone; ICANS, immune effector cell—associated neurotoxicity syndrome; MNT, movement and neurocognitive treatment-emergent adverse event.

# Select Programs in Clinical Development



# LB1908 (LCAR-C18S): Legend CAR-T Targeting CLDN18.2

For gastric cancer, esophageal cancer and pancreatic cancer



## **TARGET**

- Claudins (CLDN) are a family of tight junction proteins<sup>1</sup>
- CLDN18.2 is expressed in gastric cancer and pancreatic cancer<sup>2</sup>
- CLDN18.2 is highly conservative cross species



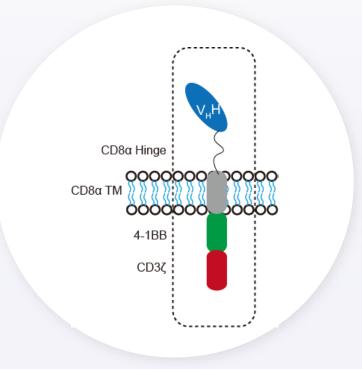
## MOA/SCIENTIFIC RATIONALE

- LB1908 targets CLDN 18.2 via a proprietary VHH antibody
- High selectivity against the closely related CLDN 18.1



## **CLINICAL DEVELOPMENT STRATEGY**

- POC achieved and 43 patients enrolled
  - Adult Claudin 18.2 positive patients with recurrent or metastatic advanced solid tumors (including advanced gastric cancers and non-gastric cancers) and have failed prior lines of systemic treatment
- US IND was cleared on June 1, 2022





# LB2102: Legend Armored CAR-T Targeting DLL-3

For SCLC



## **TARGET**

- DLL-3, a promising target with prevalent & homogeneous expression in SCLC (~80% positive) and other neuroendocrine tumors
- Minimal to no expression in normal tissues
- SCLC has limited treatment options & high unmet needs



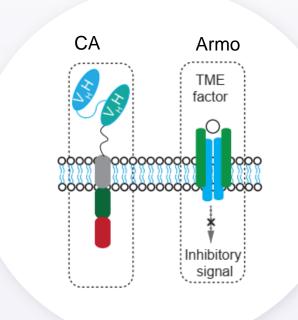
## MOA/SCIENTIFIC RATIONALE

- Tandem humanized binders with high affinity and specificity
- An armor overcoming suppressive TME to promote CAR-T cell expansion, persistence and infiltration



## PRECLINICAL & CLINICAL DEVELOPMENT STRATEGY

- Well-tolerated in vivo in s.c and pulmonary orthotopic xenograft models
- US IND was cleared on November 21, 2022
- Orphan Drug Designation was granted by FDA on June 21, 2023
- The US clinical trial is actively recruiting at two sites as of August 2023





# Our Strengths

Why Legend continues to show growth and excellent performance





<sup>\*</sup>A Biologics License Application seeking approval of cilta-cel has been approved by the U.S. FDA and commercialized under the brand name CARVYKTI®. The product has also been approved by the Ministry of Health, Labour and Welfare in Japan and received conditional marketing authorization by the European Medicines Agency.

# THANK YOU