

# 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference

Tony Liu, Chairman & CEO January 10, 2024



## Disclaimer



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## Experienced Leadership Team, Endorsed by Top VCs and Big Pharma



## **Senior Management Team**









- Joined AbelZeta 2014 as CFO, CEO/CFO since 2016; Founder, Chairman, CEO, since 2021
- Corporate VP at Alibaba Group responsible for Overseas investments; AliExpress GM, B2B Finance VP
- 19 years at Microsoft in various finance leadership roles: Corporate Strategy GM, MSFT China CFO, Corp. Corporate Accounting Sr. Director



Yihong Yao, PhD Chief Scientific Officer











Jiaqi Huang, MD, PhD SVP, Translational Medicine, Global







Andy Chan, JD, MBA Chief Legal Officer, Secretary









Hui Wan, MD, PhD SVP, Clinical Development, China









Michael Havert, PhD SVP, Regulatory Affairs & Program Head US









## **Strategic Investors**





### **Institutional Investors**











## **Overview**



Leveraging our global R&D capabilities to develop innovative cellular therapies for the treatment of patients with cancer and autoimmune diseases globally

#### **Integrated Capabilities**

State-of-the-art R&D and GMP facilities

**Centers of Excellence** 

Rockville, Maryland - HQ

Shanghai, China to augment our global capabilities

#### **Platform Technologies**

Innovative T cell engineering modalities for multiple diseases

CAR-T
(Mono- / Bi-specific / Armored)
TIL

Solid Tumors
Hematological Cancers
Autoimmune Diseases

#### **Robust Innovative Pipeline**

Proprietary, internally-optimized programs with early clinical validation

- Five clinical stage programs and multiple IIT/pre-clinical stage assets
- Proven targets and optimal design to maximize specificity while minimizing toxicity
- Best-in-class and best-indisease potentials

### **Global Pharma Partnerships**

Two major pharmaceutical deals for global licensing & collaboration

## Johnson&Johnson

Worldwide licensing of two CD20-directed autologous CAR-Ts \*



Solid tumors-focused collaboration

<sup>\*</sup> The legal entity to the worldwide collaboration and license Agreement is Janssen Biotech, Inc., a Johnson & Johnson company.

## **Accelerated Global R&D with Focused US and China Execution**



## **US Strategy**



Leverage our in-house US R&D and manufacturing capabilities along with global partners to accelerate global development

- Generate robust POC data on the safety and efficacy of the key drugs, such as C-CAR039, C-CAR066 for r/r NHL, C-CAR168 for autoimmune disease, and C-TIL051 for NSCLC
- Seek C-CAR039/C-CAR066 BLA approval in all lines of NHL with multi-billion investment in clinical development, CMC, and commercialization
- Dynamic partnership with global pharma to create a win-win scenario by matching our breakthrough innovations with the resources of global pharma

## China Strategy



Utilize KOL and hospital network to conduct IIT and sponsored trials for novel programs to achieve early validation and China development

- Seek C-CAR039 BLA approval in all lines of NHL
- AstraZeneca partnership developing CAR-T therapies for solid tumors (C-CAR031 and C-CAR036)
- Actively generating C-CAR168 POC clinical data for autoimmune diseases
- Leverage our strong manufacturing expertise to address commercialization needs

## **Pipeline**



	Program	Indication	Target	Platform	Preclinical	IIT	Phase I/Ib	Pivotal	Partners
Hematology Malignancies	C-CAR039	r/r B-NHL	CD20/CD19	CAR-T	US China			Johnse	on&Johnson
	C-CAR066	r/r B-NHL including r/r to CD19 CAR-T treatment	CD20	CAR-T	US China			Johnso	on&Johnson
Ϋ́	C-CAR088	r/r Multiple Myeloma	BCMA	CAR-T	China				
	Undisclosed CAR-T	Acute Myeloid Leukemia	Undisclosed	CAR-T	US				
Auto-immune Diseases	C-CAR168		CD20/BCMA	CAR-T	US China	•			
	C-CAR088		BCMA	CAR-T	China				
	A-CAR198		BCMA/CD19	CAR-T	US China				
Solid Tumors	C-CAR031/AZD7003	HCC	GPC3	CAR-T	China			As	straZeneca
	C-CAR036/AZD6422	Solid Tumor	Claudin 18.2	CAR-T	China			As	straZeneca
	C-TIL051	NSCLC	Multiple	TIL	US				
	Armored CAR-T	Ovarian Cancer	Claudin 6	CAR-T	US				
	Armored CAR-T	Neuroblastoma	GD2	CAR-T	US				

## **Janssen Global Partnership**



## \$245 million

**Upfront Payment** 

# Additional Future Milestone Payments

**Tiered Royalty Payments** 

## **CD20-directed Autologous CAR-Ts**

To develop, manufacture and commercialize next-generation Johnson&Johnson CAR-T therapies for B-cell malignancies

#### **Clinical Stage Programs**

**C-CAR039** 

**C-CAR066** 

Novel CD20/CD19 bispecific CAR-T

**Optimized Novel CD20 targeted CAR-T** 

**Territories** 



- Development & Commercialization rights ex-China
- Commercialization rights in China

**IND** transfer



C-CAR039 / JNJ-90014496 Ph1 in US (NCT05421663)

C-CAR066 / JNJ-90009530 Ph1 in US (NCT05784441)

and Australia

**Clinical supply** 

Viral vector and plasmid

**Technology transfer** 

The legal entity to the worldwide collaboration and license Agreement is Janssen Biotech, Inc., a Johnson & Johnson company.

## **Novel Optimized CD20 Directed CART Programs**



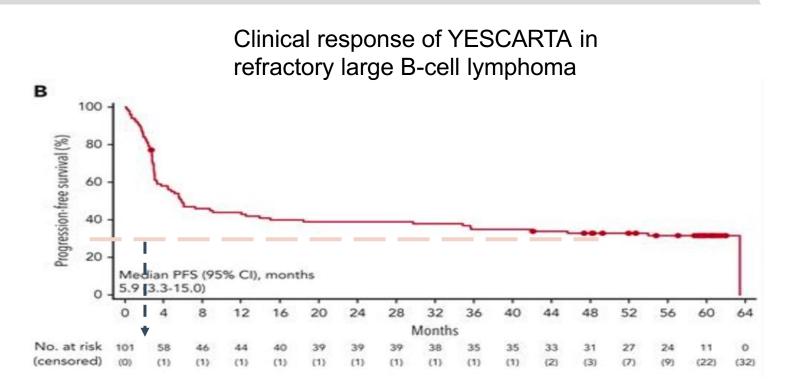
#### **Unmet Medical Needs**

Anti-CD19 CAR T-cell therapies have proven to be efficacious in r/r B-NHL patients. However, ~20% of LBCL patients and ~10% of indolent patients are non-responders <sup>1-5</sup>

50% of LBCL progressed by ~6 months after CD19 CAR-T treatment , < 40% long-term durable response  $^6$ 

Clinical outcomes in patients with relapsed/refractory large B-cell lymphoma (r/r LBCL) following CD19 CAR-T therapy are poor.

- The objective response rate (ORR) and complete response (CR) rate with salvage therapies, including bispecific antibodies and antibody-drug conjugates, were 18–54.1% and 3.8–35%, respectively.<sup>7–14</sup>
- The median progression-free survival (PFS) was 1.4–3.8 months and the median overall survival (OS) was 3.8–9.3 months.<sup>7-12</sup>



Neelapu SS et al., Five-year follow-up of ZUMA-1 supports the curative potential of axicabtagene ciloleucel in refractory large B-cell lymphoma, Blood, 2023.

## Upside Potentials of C-CAR039 and C-CAR066 – Aim for Approvals in All Lines of Therapies

3L+ NHL 2L NHL (R-CHOP failure) 1L NHL (R-CHOP naïve)

- ~47k of treatable patients
- Currently in Ph1b trials in US and China (CD19 CAR-T naïve)
- ~80k of treatable patients

~159k of treatable patients

Data Source: Clarivate, 2021 for G7 countries

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01/10/24 AbelZeta Pharma Inc. Proprietary

<sup>1.</sup> Neelapu SS, et al., N Engl J Med. 2017 Dec 28;377(26):2531-2544. 2. Schuster SJ et al., N Engl J Med. 2019 Jan 3;380(1):45-56. 3. Abramson SJ., et al., Lancet. 2020 Sep 19;396(10254):839-852. 4. Jacobson CA et al., Lancet Oncol. 2022 Jan;23(1):91-103. 5. Fowler NH et al., Nat Med. 2022 Feb;28(2):325-332.. 6. Spiegel JY, et al. Blood. 2021;137:1832–5. 7. Alarcon Tomas A, et al. Leukemia. 2023;37:154–63. 8. Chow VA, et al. Blood. 2022;140:2584–93. 10. Caimi PF, et al. Clin Lymphoma Myeloma Leuk. 2022;22:e335–9. 11. Budde LE. J Clin Oncol. 2022 Feb 10;40(5):481-491. 12. Dickinson MJ,N Engl J Med. 2022 Dec 15;387(24):2220-2231. 13. Thieblemont C, et al. J Clin Oncol. 2023 Apr 20;41(12):2238-2247. 14. Bannerji R. Blood (2020) 136 (Supplement 1): 42–43. r/r, Relapsed or Refractory; B-NHL, B-Cell Non-Hodgkin Lymphoma; ORR, Overall Response; PFS, Progression-Free Survival.

## **C-CAR039 Clinical Results**

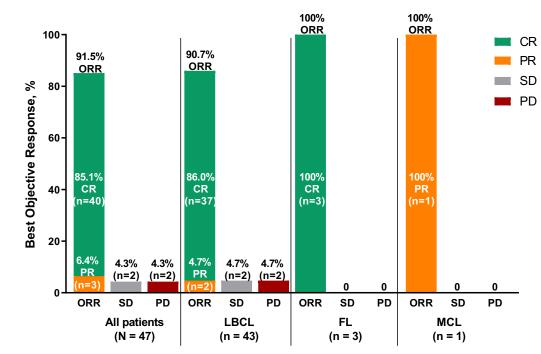


## C-CAR039 is a Promising Therapy for B-NHL (esp. for LBCL) with Excellent Safety Profile and Promising Clinical Efficacy

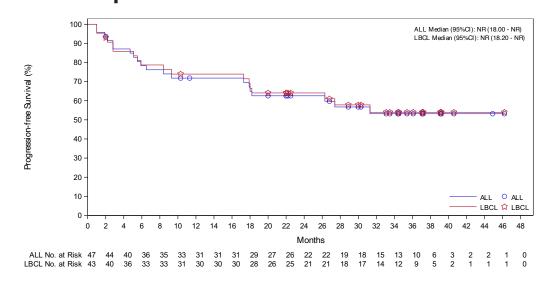
Characteristics	N=48	
Median Age, year (range)	55 (25-71)	
<ul> <li>Age≥65, n (%)</li> </ul>	11 (22.9)	
NHL Subtype, n (%)		
DLBCL, NOS	37 (77.1)	
• tFL	4 (8.3)	
• PMBCL	3 (6.3)	
• FL	3 (6.3)	
• MCL	1 (2.1)	
ECOG PS, n (%)		
• 0	31 (64.6)	
• 1	17 (35.4)	
IPI Score 3/4, n (%)	15 (31.3)	
Ann Arbor Stage III/IV, n (%)	36 (75.0)	
Double-expression Lymphoma, n (%)	15 (31.3)	
Median Number of Prior Lines of Therapy, (range)	3 (1-7)	
• ≥4, n (%)	16 (33.3)	
Never Achieved CR of Prior Therapies, n (%)	22 (45.8)	
Prior Therapy, n (%)		
• CD20	48 (100)	
• ASCT	8 (16.7)	
Received Bridging Therapy, n (%)	12 (25.0)	

AESI, n (%)	N=48
<ul> <li>CRS</li> <li>Grade≥3</li> <li>Median days to onset, d (range)</li> <li>Median days to resolution, d (range)</li> </ul>	45 (93.8) 1 (2.1) 3 (1-12) 5 (2-78)
<ul> <li>ICANS</li> <li>Grade≥3</li> <li>Median days to onset, d (range)</li> <li>Median days to resolution, d (range)</li> </ul>	3 (6.3) 0 6 (5-29) 12 (3-53)
<ul><li>Prolonged Cytopenia</li><li>Neutropenia</li><li>Thrombocytopenia</li><li>Anemia</li></ul>	26 (54.2) 10 (20.8) 10 (20.8)
Infections • Grade≥3	32 (66.7) 12 (25.0)
<ul> <li>Secondary Primary Malignancy</li> <li>Acute myeloid leukemia</li> <li>EBV+ cytotoxic T-cell lymphoma</li> </ul>	3 (6.3) 2 (4.2) 1 (2.1)





 The estimated 24-m PFS rates were 62.6% and 64.1% for all patients and LBCL patients



## **C-CAR066 Clinical Results**



Characteristics	N=14
Median Age, year (range) • Age≥65, n (%)	54.5 (37-67) 2 (14.3)
<ul><li>NHL Subtype, n (%)</li><li>DLBCL</li><li>tFL</li></ul>	10 (71.4) 4 (28.6)
<b>ECOG PS 0-1, n (%)</b>	5 (35.7) 9 (64.3)
IPI Score 3/4, n (%)	8 (57.1)
Ann Arbor Stage III/IV, n (%)	12 (85.7)
Double-expression Lymphoma, n (%)	7 (50.0)
SPD, n (%)  • ≥ 4000 mm <sup>2</sup> • < 4000 mm <sup>2</sup>	6 (42.9) 8 (57.1)
<ul><li>Median (range) number of Prior Lines of Therapy</li><li>≥4, n (%)</li></ul>	5 (2-7) 12 (85.7)
Prior ASCT, n (%)	2 (14.3)
<ul><li>Prior Therapy, n (%)</li><li>CD19</li><li>CD19/CD79b or CD19/CD22</li></ul>	12 (85.7) 2 (14.3)
<ul> <li>Best response of prior CAR-T Therapy, n (%)</li> <li>CR</li> <li>PR</li> <li>SD/PD</li> </ul>	2 (14.3) 10 (71.4) 2 (14.3)
Median (range) DOR of prior CAR-T therapy, months	1.9 (0.4–6.1)
Median (range) time from prior CAR-T to C-CAR066, months	5.5 (3.4–14.2)

**Bridging therapy, n (%)** 

AESI, n (%)	N=14
<ul><li>CRS</li><li>• Grade≥3</li><li>• Median days to onset, d (range)</li></ul>	12 (85.7) 1 (7.1) 5.5 (2–15)
<ul> <li>Median days to resolution, d (range)</li> </ul>	4.0 (1–15)
ICANS	0
Infections • Grade≥3	8 (57.1) 2 (14.3)
<ul><li>Prolonged Cytopenias*</li><li>Neutropenia</li><li>Anemia</li><li>Thrombocytopenia</li></ul>	4 (28.6) 3 (21.4) 2 (14.3) 2 (14.3)
SPM	0

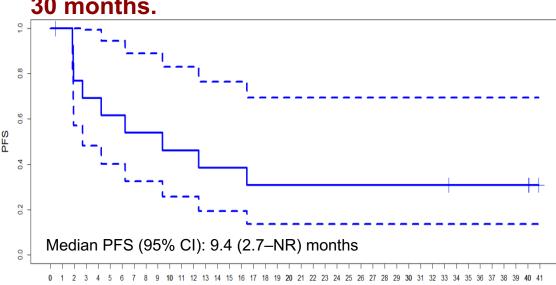
SAEs, n (%)	N=14	Onset Day	
SAEs	4 (28.6)		
C-CAR066-related	1 (7.1)		
CRS	1 (7.1)	Day 11	
Myelosuppression	1 (7.1)	Day 32	
<ul> <li>C-CAR066-unrelated</li> </ul>	3 (21.4)		
Abdominal pain	1 (7.1)	Day 30	
Platelet count decreased	1 (7.1)	Day 112	
Pneumonia	1 (7.1)	Day 404	

- Most cases of CRS were grade 1/2;
- No ICANS and SPM;

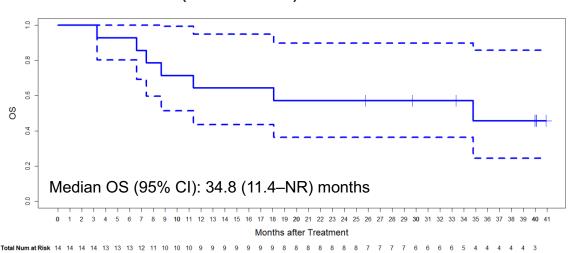
7 (50.0)

Only 2 SAEs in 1 patient were related to C-CAR066, which were CRS and myelosuppression;

- ORR was 92.9%, with a CR rate of 57.1%
- Median DOR was 8.3 months (95% CI, 1.7–NA).
- With the median follow-up of 27.7 months, median PFS was 9.4 months (2.7 NA). 4 (28.6%) patients remained in CR for more than 30 months.



The Kaplan-Meier estimate of **median OS was 34.8 months** (11.4 – NA).



## Inflammation and Immunology (I&I) Assets



## Large addressable markets

- SLE: ~800 thousand new cases in 2022 globally
- ~40% of SLE will develop into Lupus Nephritis, with many having long-term kidney failures
- Major opportunities in orphan indications such as antisynthetase syndrome, IMNM (Immune Mediated Necrotizing Myopathies), Dermatomyositis, NMOSD, SSc, rMS, pemphigus

## Exciting early clinical data emerging from CD19 CAR-T and BCMA CAR-T in multiple I&I diseases

- Academic studies have shown early promising efficacy of CD19 CAR-Ts in SLE, antisynthetase syndrome and SSc
- BCMA CAR-T has shown early positive clinical signal in r/r NMOSD

## Our preclinical data

- Constructs are optimized to ensure maximum target cell killing activity and target specificity
- CD20/BCMA (C-CAR168), BCMA/CD19(A-CAR198) bispecific CARs
- scFvs of αCD20, αCD19, and αBCMA have all demonstrated robust efficacy and safety profiles in early clinical studies presented at ASCO and ASH<sup>1.2,3,4,5,6</sup>

## **Our strategy**

- Simultaneously targeting both B cells and plasma cells to eradicate disease-causing pathogenic Bcells and autoimmune antibodies
- Approach has been endorsed by our SAB comprising of well-respected experts in the field

## **Upcoming Clinical Milestones**

- China IIT initiation Q1 2024
- US IND submission Q2 2024
- US Phase 1 trial initiation 2H 2024

#### **I&I Scientific Advisory Board**



Peter Lipsky M.D.
SAB Chair
Former BoD member,
American College of
Rheumatology (ACR)



Mary Crow M.D.
Professor of
Medicine, Weill
Cornell Medicine



Maria Dall'Era M.D.
Chief of Division of
Rheumatology at
University of
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Francisco (UCSF)



Thomas Dörner M.D.
Prof of Rheumatology &
Clinical Immunology,
Innovative Therapies for
Autoimmune Diseases,
Charité University
Hospitals

<sup>1.</sup> Aibin L et al., Journal of Clinical Oncology 2021 39:15\_suppl, 2507. 2 Aibin Liang, et al., Journal of Clinical Oncology 2021 39:15\_suppl, 2508. 3 Li, P et al., Blood (2023) 142 (Supplement 1): 1025. 4. Li, P et al., Blood (2023) 142 (Supplement 1): 2115, 5 Qu X., Blood (2021) 138 (Supplement 1): 1830. 6 Qu X et al., J Immunother Cancer. 2022 Sep;10(9):e005145.

## **AstraZeneca Partnership in Solid Tumors**



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#### **Unmet Medical Need**

HCC (2022)

- More than 850 thousand new cases occurred in 2022 globally <sup>1</sup>
- Approximately half of the total HCC patients in the world come from China<sup>2</sup>

GC

(2020)

- 5<sup>th</sup> most common neoplasm and the 3<sup>rd</sup> deadliest cancer in the world <sup>3</sup>
- 5.6% of global cancer cases and causing nearly 1 million deaths in 2020 <sup>3</sup>

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## **Upcoming Milestones**

- C-CAR036 China IIT on GC initiated in Q4 2023
- China C-CAR031 IND filling Q1 2024
- China C-CAR031 Phase 1 trial initiation for HCC in H2 2024

## **AstraZeneca Collaboration**



- Co-development of novel innovative armoring CAR-T asset GPC3 armored CAR (C-CAR031) and collaboration for Claudin 18.2 armored CAR (C-CAR036)
- Received upfront payment from AstraZeneca for the codevelopment for GPC-3 (C-CAR031) in China and collaboration for CLDN18.2 (C-CAR036)
- For the collaboration on Claudin 18.2 CAR-T program in China (C-CAR036), AbelZeta is eligible to receive development, regulatory milestones and royalties. In addition, AbelZeta is eligible to receive milestone payments and royalties for the ex-China development of Claudin 18.2 CAR-T (AZD6422) and GPC-3 CAR-T (AZD5851), which are being solely developed, manufactured and commercialized by AstraZeneca outside of China

HCC: Hepatocellular carcinoma, GC: Gastric cancer

<sup>1.</sup> Zou H, et al., Economic Burden and Quality of Life of Hepatocellular Carcinoma in Greater China: A Systematic Review. Front Public Health. 2022 Apr 21;10:801981. 2. Q. Wu and S.-K. Qin Chinese Clinical Oncology 2013 Vol. 2 Issue 4 Pages 38. 3. Sung H, et al., Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021 May;71(3):209-249

## **2024 Milestones**



1H 2024 2H 2024 **C-CAR039 C-CAR039** US Phase 1b results **US Phase 1b Enrollment** (3L+ LBCL, CD19 CAR-T naïve) (3L+ LBCL, CD19 CAR-T naïve) China Phase 2 Enrollment Hematology China Phase 2 Enrollment Malignancies **C-CAR066 C-CAR066** US Phase 1b results US Phase 1b Enrollment (3L+ LBCL) (3L+ LBCL) **C-CAR168 C-CAR168 Autoimmune** US Phase 1 initiation. China IIT 1Q Diseases China IIT update US IND Filing 2Q **C-TIL051 C-CAR031 US Phase 1 Initiation** China Phase 1 Enrollment **C-CAR031 Solid Tumors** China IIT update China IND Filing US Phase 1b Enrollment

