药明巨诺
JW Therapeutics

JW Therapeutics (2126.HK)

2024 Interim Results Presentation

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JW Therapeutics 2024 1H Highlights

R&D Progress

- **Carteyva® Hematology Programs** made significant progress, including:

  1) r/r MCL sBLA was approved in August, 2024.

  2) 2L LBCL recruitment is ahead of plan and patient enrollment is expected to be completed in Q4 2024.

- **Relma-cel use extended to SLE**:

  1) IIT study recruitment completed. Preliminary safety profile, pharmacodynamics data and preliminary efficacy data published at EULAR 2024.

  2) Ph1 study recruitment started in Q2 and is expected to complete in Q4 2024. Next step is to align phase 2 design with CDE and initiate pivotal study recruitment.

- **MAGE-A4 TCR-T :** Enter into recruitment stage this year and dose escalation is ongoing.
- **In-house Pipeline:** the first dual targeting autologous CAR-T study initiated.

Commercialization

- Covered by **78** commercial insurance products and **96** effective local governmental complementary medical insurance programs.
- Improved commercial operation efficiency with streamlined organization to drive sustained revenue growth.

Manufacturing

- Continued high manufacturing success rate of **98%.**
- Cost reduction plan implemented successfully. Continue with key materials localization and will source additional raw materials from domestic suppliers.

Financial Update

- Revenue reached RMB**86.8** million.
- GP achieved RMB**43.7** million, GP margin was **50.4%**
- G&A expenses decreased **24.7%**, R&D expenses decreased **30.3%**.
- Cash balance amounted to RMB**869.0** million.

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2024 1H Commercialization Review

CAR-T is an Emerging and Disruptive Therapy

CAR-T is a therapy with unprecedented outcomes in hematological malignancies

- In RELIANCE study, Carteyva® improved later line LBCL patients **4-year OS rate** from less than **20%** to **66.7%**, bringing hope to **~30K** r/r NHL patients in China

CAR-T is now recommended as new standard of care of r/r B-NHL

- Increasing adoption rate observed in US/EU, **10-12%** in NHL
- However, the penetration rate less than **3%** in underdeveloped China market indicating great growth potential

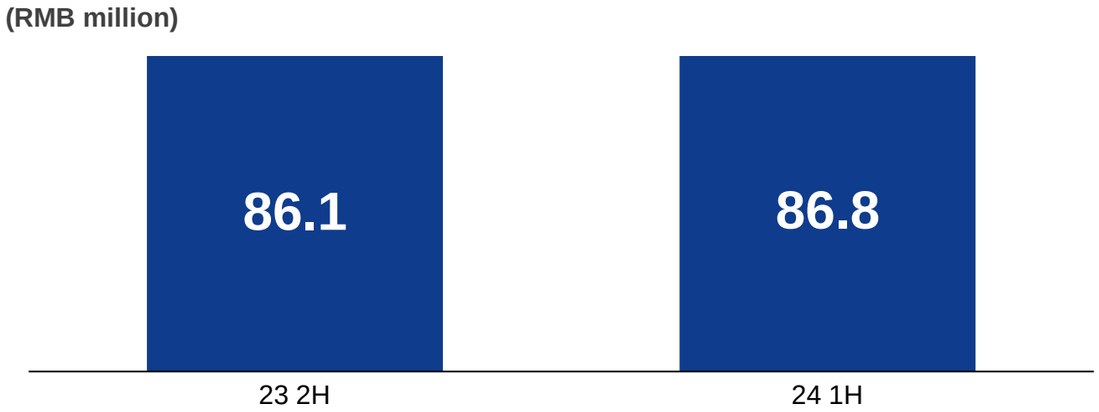
CAR-T market has high barriers to entry.

- High quality and consistent manufacturing and supply chain management is a must
- Whole value chain consolidation with complex vein to vein management is crucial for patient outcome
- Innovative payment schemes need to be further explored

JW's Commercial Progress in 2024 1H

Sales Maintained with Dynamic Market Changes

Revenue Achieved by Sales of Carteyva®



Broader Insurance Coverage to Improve Affordability

96 Local Governmental Complementary Medical Insurance Programs

78 Commercial Insurance

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JW's R&D Strategies

Expand Relma-cel Use in Heme Indications »»

With successful approvals in LBCL, FL & MCL, Pursue earlier line LBCL and pALL

Expand Relma-cel Indications into Autoimmune Diseases »»

With Relma-cel's safety profile and potency, develop CAR-T for the high unmet needs in moderate and severe SLE and other autoimmune diseases

Advance Products Targeting Hepatocellular Carcinoma [HCC] »»

Advance Multiple Programs to treat HCC with novel CAR-T platforms with promising PoS

Build Innovative Solid Tumor Program with World-class Cell Therapy Partners »»

Advance CAR-T Programs to treat solid tumors with novel CAR-T platforms and promising PoS

Through Research, Create Products to Improve Anti-tumor Activity and Access Global Markets »»

Establish proprietary CARs and armored elements to overcome solid tumor & hematology barriers for use worldwide

Abbreviations: LBCL = large B-cell lymphoma; FL = follicular lymphoma; MCL = mantle cell lymphoma; ALL = acute lymphoblastic leukemia; CLL = chronic lymphocytic leukemia; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; SLE = systemic lupus erythematosus.
* Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.

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Our Hematology and Autoimmune Pipeline: Expanding Indications to Benefit Patients Hematologic Malignancies and Autoimmune Diseases

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	Product	Target	Indication	Commercial Rights	Pre-clinical / Phase I / Pivotal / Phase II/III / NDA / Marketed	Partner
Hematologic Malignancies	JWCAR029 / Relmacabtagene Autoleucel (relma-cel) [1]	CD19	3L LBCL	Mainland China, Hong Kong, Macau*	Marketed	JUNO Therapeutics, Bristol Myers Squibb Company
			3L FL	Mainland China, Hong Kong, Macau*	Marketed	
			r/r MCL	Mainland China, Hong Kong, Macau*	Marketed	
			Front Line LBCL	Mainland China, Hong Kong, Macau*	Phase I	
			2L LBCL	Mainland China, Hong Kong, Macau*	Pivotal / Phase II/III	
			3L ALL	Mainland China, Hong Kong, Macau*	Phase I	
			3L CLL	Mainland China, Hong Kong, Macau*	Pre-clinical	
	JWCAR129 [2]	BCMA	r/r MM	Mainland China, Hong Kong, Macau*	Pre-clinical	
Other	JWCAR029 / Autoimmune [3]	CD19	SLE	Mainland China, Hong Kong, Macau*	Phase I	JUNO Therapeutics, Bristol Myers Squibb Company

Abbreviations: LBCL = large B-cell lymphoma; FL = follicular lymphoma; MCL = mantle cell lymphoma; ALL = acute lymphoblastic leukemia; CLL = chronic lymphocytic leukemia; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; SLE = systemic lupus erythematosus.

* Mainland China, Hong Kong, Macau refer to Mainland China, Hong Kong (China), Macau (China), respectively.

1. Relma-cel is based on the same chimeric antigen receptor (“CAR”) construct as the product lisocabtagene maraleucel (Breyanzi or lisocabtagene or liso-cel) of Juno, which was approved by the U.S. Food and Drug Administration (“FDA”) in February 2021.
2. JWCAR129 is based on the same CAR construct as Juno’s product orvacabtagene autoleucel (orvacel).
3. SLE is a chronic autoimmune disease characterized by the production of autoantibodies and abnormal B-lymphocyte function.

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Carteyva®: Advancing in CD19+ Indications: r/r MCL

Carteyva® is the first commercial CAR-T cell product for the treatment of r/r MCL in China

- MCL is a heterogeneous B cell non-Hodgkin lymphoma which is currently incurable with existing therapies
- MCL, associated with a poor prognosis, mainly occurs in elderly men who were not diagnosed until advanced stage
- Significant progress has been made in the last decade as the treatment paradigm has shifted from traditional chemoimmunotherapy toward targeted therapies such as BTK inhibitors. Despite the use of BTKi in r/r MCL has improved their survival outcomes, many patients will ultimately relapse with shortened remission durations (6~10 months)

Clinical Progress:

- Carteyva®: was granted Breakthrough Therapy Designation in patients with MCL by NMPA
- r/r MCL sBLA was approved in August, 2024

Carteyva® demonstrate excellent efficiency and safety profile in clinical trails

59 high risk patients who failed BTK inhibitors, including

- Relapse or refractory to BTKi [100%]
- High Mantle Cell International Prognostic Index [52.5% IPI≥4]
- Extranodal organ involvement [59.3%]
- Bulky disease [≥5 cm 30.5%]

Competitive efficacy data received, Primary endpoint achieved

- Best ORR is 81.36% among 59 assessable patients
- Best CRR is 67.80% among 59 assessable patients

Comparable Safety profile with low rate of serve CRS and NT

- Overall CRS rate is 81.40%, with only 6.8% G3 and above CRS
- Overall NT rate is 13.6%, with only 6.8% G3 NT and above NT

Abbreviations: ORR=Overall Response Rate；CRR=Compete Response Rate；NT=Neurotoxicity；sNT=severe Neurotoxicity；CRS=Cytokine Release Syndrome；sCRS=severe Cytokine Release Syndrome；; r/r = relapsed or refractory；MCL=Mantle Cell Lymphoma；

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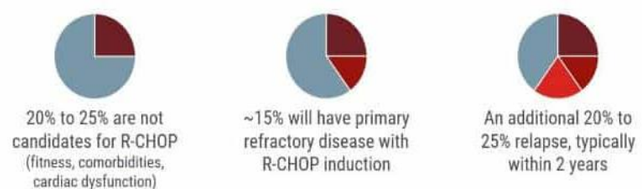
The Changing Landscape in LBCL: Use of CAR-T to Address the Unmet Medical Need in Earlier Lines of Therapy

CAR-T Opportunities in Frontline and 2nd Line Treatment, but Safety Profile Matters

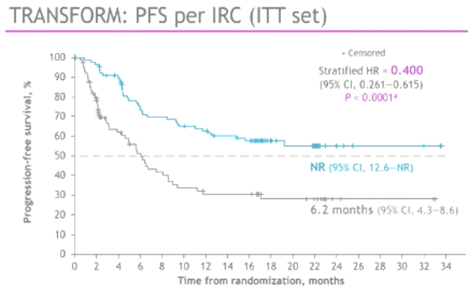
FRONTLINE THERAPY

- **Many Don't Benefit from SoC Chemo**



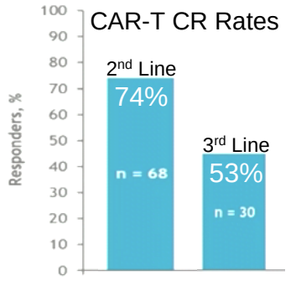
2ND LINE THERAPY

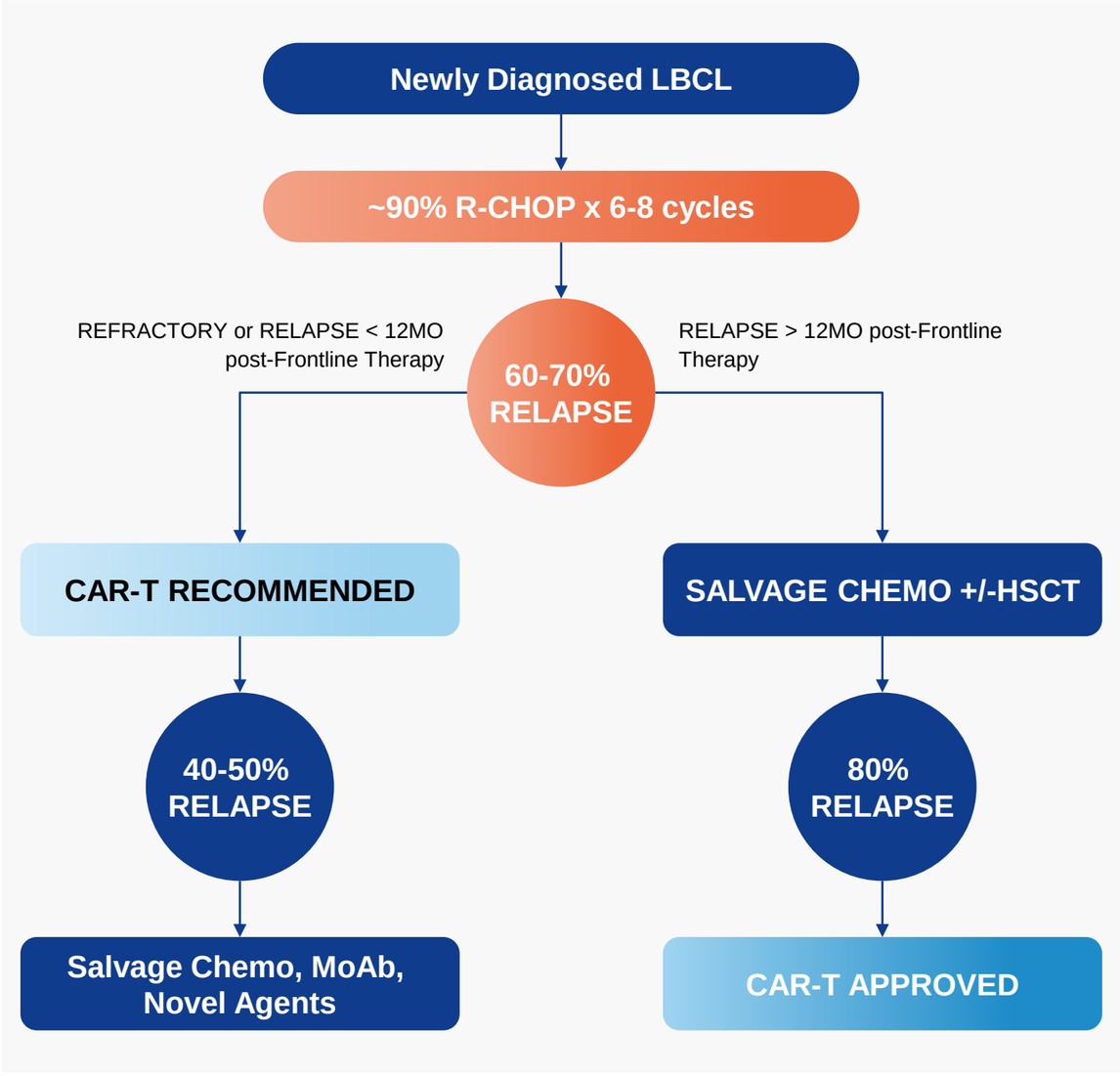
- **CAR-T the New SoC, but Toxicity Rates Matter:**
  - ZUMA7: CRS 92%, sCRS 6%; NT 60%, sNT 21%



3RD LINE THERAPY

- **Beneficial, but Earlier Better**





Need footnote for Sehn NEJM 2021 384:842-858 & Abramson 63rd ASH Annual Meeting 2022, New Orleans, LA, Abstract 655; Lancet 399 (10343):2294-2308 [2022]; USPI for Breyanzi

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Carteyva® Development in Early Line Treatment of LBCL

Carteyva® in 2nd Line LBCL – Study 003 – poor risk primary refractory disease

- **12 patients with poor risk disease, including:**
  - extranodal disease [33%]
  - high International Prognostic Index [75% IPI>3]
  - double or triple hit mutations [91%]
  - high burden disease [67% SPD>5000mm^2]

Response Rate	12 mo OS	CRS	sCRS	ICANS	Severe ICANS
75%	100%	50%	0%	18%	0%

Broadening Carteyva® Use to 2nd Line and 1st Line treatment in LBCL

Study	Population	Status
JW029-216	2nd Line non-transplant eligible	Enrolling
JW029-010	2nd line for patients who are refractory or relapse <12mo after 1L	IND-approved
JW029-011	1st line: Following 2 cycles of Frontline R-CHOP in high risk patients	Enrolling

Source:
1. JW Therapeutics– data on file

Abbreviations: ORR=Overall Response Rate; CRR=Compete Response Rate; NT=Neurotoxicity; sNT=severe Neurotoxicity; CRS=Cytokine Release Syndrome; sCRS=severe Cytokine Release Syndrome; ; r/r = relapsed or refractory; LBCL = large B-cell lymphoma

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Significant Unmet Need in Lupus: An Opportunity for Relma-cel -Conventional Treatments are Inadequate & Organ Damage Continues Over Time

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Large Need:

SLE has few disease modifying therapies

Needed for long-term organ preservation

01

Measurable Therapy Goal:

Disease control for organ preservation

Preventing organ failure key to extending survival in SLE

02

Clear POC:

CD19 CAR-T led to durable remissions in academic trial

5 SLE pts with multi-organ involvement weaned off all meds

03

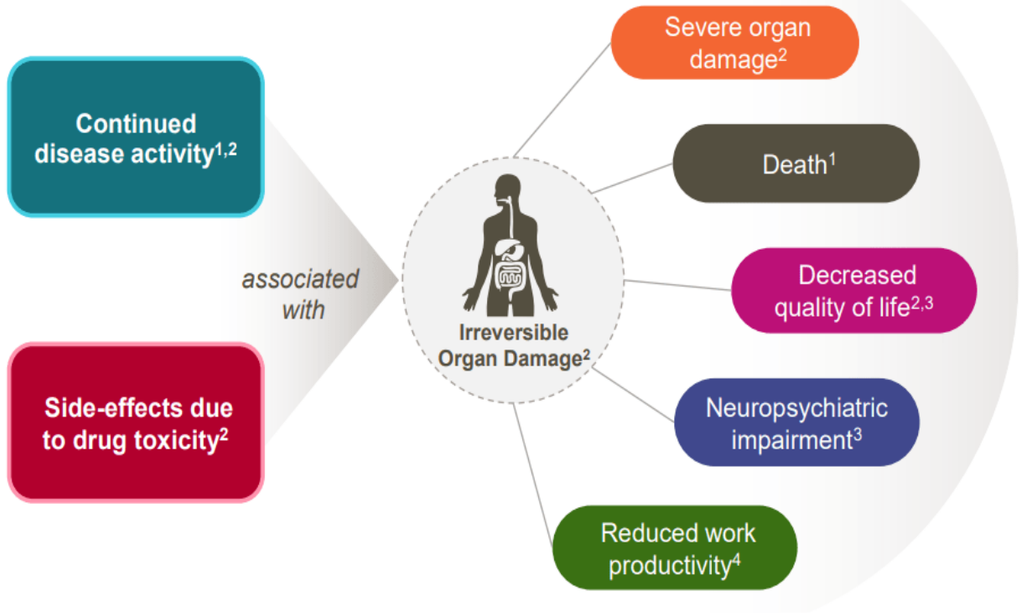
Novel MOA:

CD19 CAR-T cells fully depleted B cells in SLE patients

B cell recovery in a median 110 days resets B cell repertoire

04

SLE Disease Impacts to Health & Survival



1. Lopez R et al. Rheumatology 2012;51:491498 [Page 496, Page 495]
2. Becker-Merok A and Nossent HC J Rheumatology. 2006 Aug;33(8):1570-7 [Page 1570, 1572]
3. Mak A et al. Nat Rev Rheumatol. 2013 May;9(5):301-10 [301]
4. Ali M. Al Dhanhani et al. Arthritis Care & Research. 2015 Nov; 67(11):1536-44 [Page 1536]

SLE=Systemic Lupus Erythematosis, MOA=Mechanism of Action, PoC=proof of Concept,

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First in Human Study of Relma-cel in SLE

First in human study dose escalation completed and in follow up stage, promising efficacy and tolerable safety profile observed

Target Population	Patients with moderate-to-severe, refractory/relapse Systemic Lupus Erythematosus (SLE)
Key Eligibility	SLE Classification: Have a clinical diagnosis of SLE per ACR Classification SLE Treatment: Stable SLE treatment regimen for a period of at least 2 months prior to lymphodepletion The subjects with positive test for anti-nuclear antibody (ANA) or anti-dsDNA serum antibody or anti-Smith antibody Disease not well controlled by standard of care and still moderate to severe activity
Patient Journey in SLE	One-time infusion planned with low dose lymphodepletion and potential for outpatient monitoring Multiple scales, quality of life and B cell recovery are analyzed with 2 year follow up

Relma-cel Development Plan in SLE »

1. IIT study recruitment completed. Preliminary safety profile, pharmacodynamics data and preliminary efficacy data published at EULAR in June.
2. Ph1 study recruitment started in Q2 and is expected to complete in Q4. Next step is to align phase 2 design with CDE and initiate pivotal study recruitment.

FIH=First-in-Human Trial,; FLU/CY=fluarabine/cyclophosphamide;, LD=lymphodepletion, NDA=New Drug Marketing Application, SLE=Systemic Lupus Erythematosis, ACR=American College of Rheumatology,

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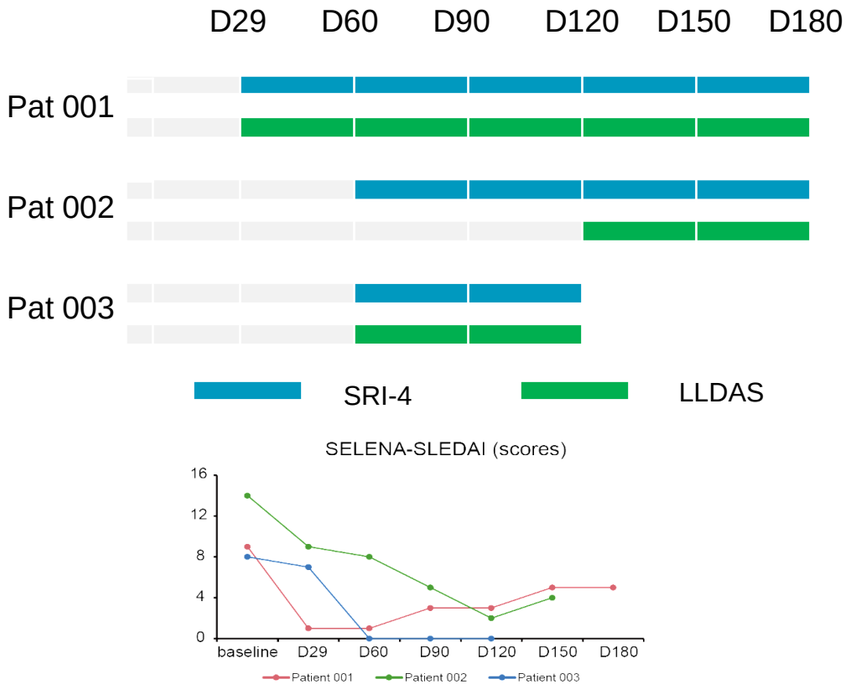
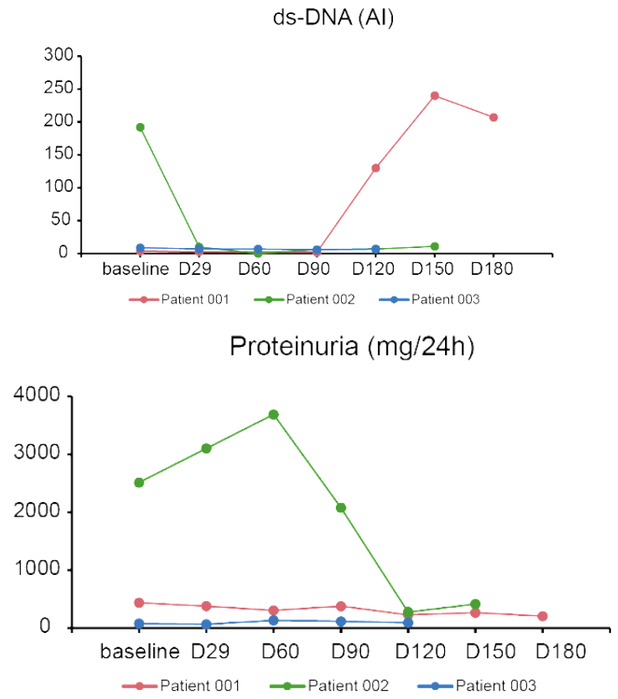
Very Promising Efficacy Signal Observed in the FIH Study

- Three patients were all female, aged 21-36, with multi-organ involvement and prior treatment with high-dose steroids and immunosuppressants.
- Post infusion of 25*10^6 Relma-cel, SLE signs and symptoms improved in all patients, with SRI-4 and LLDAS response in all. SELENA-SLEDAI scores dropped to 0 or 1.

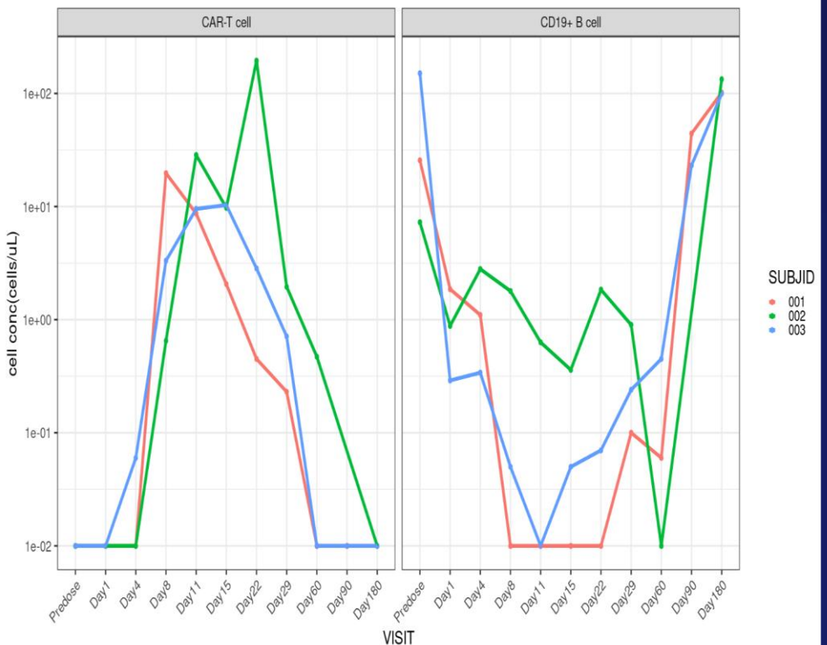


Overall trend:

- Autoantibodies: ds-DNA decreased except 001 patient increased from D90.
- Proteinuria dramatically decreased.



- CAR-T cell expansion reached a Cmax of 19.72 cell/ul, peaking 8-22 days later.
- Complete B cell depletion was observed, with nadirs at Day 8-11, followed by recovery B cell from D60.



Our Pipeline Beyond Heme: Expanding Solid Tumor Indications
High Incidence Diseases in China: HCC, Lung Cancer and More

	Product	Target	Indication	Commercial Rights	Pre-clinical	Phase I	Pivotal / Phase II/III	NDA	Marketed	Partner
Solid Tumors	JWATM204 [1]	GPC3	HCC	Mainland China, Hong Kong, Macau, Taiwan , and member countries of ASEAN*						EUREKA
	JWATM214 [2]	GPC3	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						Lyell EUREKA
	JWATM203 [1]	AFP	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						EUREKA
	JWATM213	AFP	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						Lyell EUREKA
	JWTCR001	MAGE-A4	various solid tumors	Mainland China, Hong Kong, Macau*						2seventybio
	JWCAR031	DLL3	SCLC	Mainland China, Hong Kong, Macau*						Bristol Myers Squibb

Abbreviations: HCC = hepatocellular carcinoma; NSCLC = non-small cell lung cancer; AFP = alpha-fetoprotein; GPC3 = glypican-3; r/r = relapsed or refractory; 3L = third-line; 2L = second-line; HAS= hepatoid adenocarcinoma of the stomach； MAGE A4= melanoma associated antigen A4; DLL3= Delta-like ligand 3;

* Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.

1.JWATM204 is in a Phase I investigator-initiated trial in China. Eureka's products based on the CAR constructs underlying JWATM203 and JWATM204 are currently in Phase I/II trials in the US conducted by Eureka under an IND application. In November 2021, the FDA granted Fast Track Designation to Eureka's counterpart to JWATM203 for the treatment of hepatoblastoma ("HB") and HCC in pediatric patients, as well as "rare pediatric disease designation" for the treatment of HB. In February 2022, the FDA granted Orphan Drug Designation to Eureka's counterparts to JWATM203 and JWATM204.

2.Developing using Lyell technology.

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JWTCR001: MAGE-A4 Autologous TCR-T in Multiple Solid Tumors

JW's TCR-T Product Candidate Employing Novel Technology & Successful Manufacturing Processes

TCR-T has Solid Proof of Concept Through Clinical Trials

Phase 2: NY-ESO-1/HLA-A2(GSK) & MAGE-A4/HLA-A2(ADAP) [1,2]

Adaptimmune

40-60% CR&PR
In metastatic melanoma & synovial cell sarcoma

US BLA was approved on August 2024

Phase 1: HPV E7/HLA-A2(Kite/NcI) [3]investigator-initiated trial

Kite Pharma

50% PR(6/12)
In HPV-associated cancers

Phase 1: PRAME/HLA-A2 (IMTX) [4]

immatics®

50% PR(8/16)
In melanoma, synovial cell sarcoma, head & neck & others [4]

Novel Technology Licensed from 2seventy Bio

01 MAGE-A4 binder restricted by HLA-A2 alleles common in China

02 Using additional FLIP receptor to overcome TME

03 Manufacturing to use prior process development experience

04 Plan FIH trials for rapid test of PoC in multiple tumor indications

(1) P.F.Robbins et al 2011J cin Oncol.29(7):917.
(2) Ramachandran et al. 2019J. immunol can 7:276.
(3) Nagarsheth, N.B., et.al.2021 Nat Med.
(4) Immatics topline data release.

MAGE-A4= Melanoma Antigen A4, TCR-T=T Cell receptor T cell, TME=Tumor microenvironment, PoC=Clinical Proof-of-concept, CR=Complete Response, PR=Partial Response; HPV-human papilloma virus

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In-house Generated New Pipeline with Global Reach

New Autologous CAR Pipeline

Armored

Global Commercial Rights

Next-Gen Manufacturing

Indication	Target	Commercial Rights	Pre-clinical	IIT
Autoimmune diseases	Dual Targeting	Worldwide		Expected in Q3 2024
B-cell malignancies	Dual Targeting	Worldwide		Expected in H1 2025
Solid tumor 1	TBA	Worldwide		Expected in 2025
Solid tumor 2	TBA	Worldwide		Expected in 2025

Autologous Therapies

- Proven approach
- Leveraging on JW infrastructure and experience

New Pipeline Value Drivers

- Targeting unmet needs in China with potential global commercialization
- Use of armored elements engineered to enhance CAR performance in solid tumors
- Utilize JW in-house next-generation cellular manufacturing processes designed to increase product manufacturing speed, potency, and reduce cost

Indications

- Strengthen Heme CAR-T
- Advance next generation armored CAR-T cells in solid tumors
- Plan to enter clinic in 2024/2025

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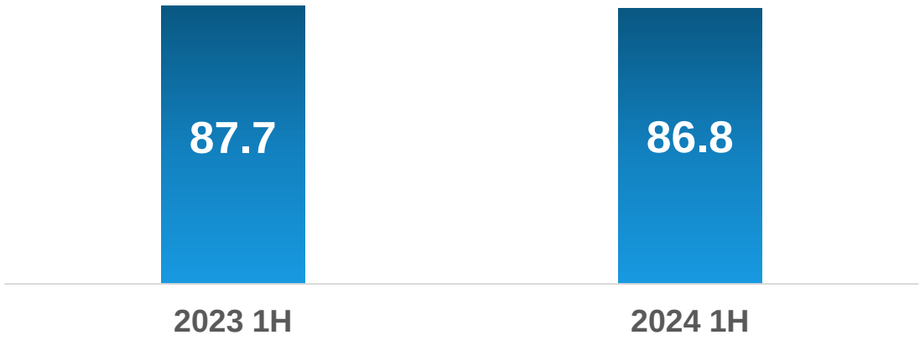
Financial Update

Revenue

(RMB million)

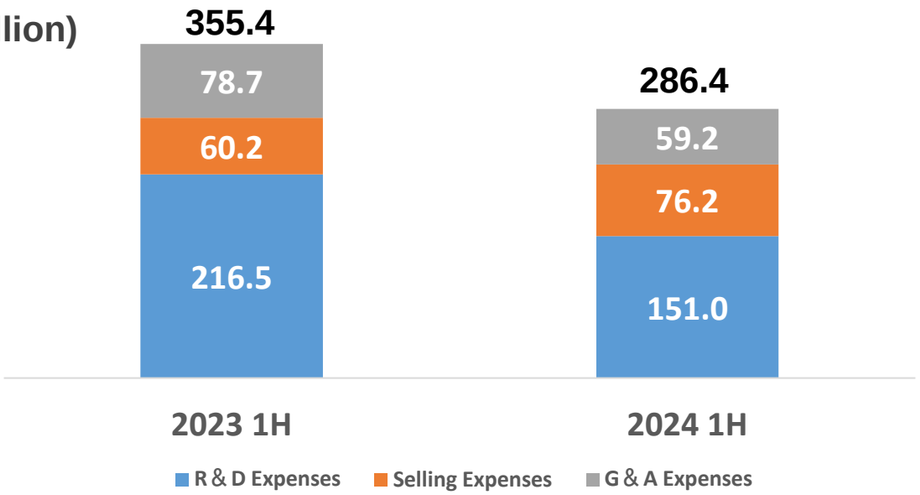


Gross Margin

(RMB million)

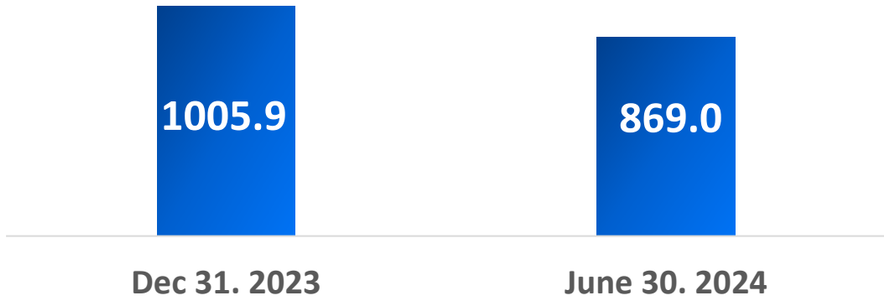
Operation Expenses

(RMB million)



Cash Reserve

(RMB million)



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THANK YOU!