药明巨诺
JW Therapeutics

JW Therapeutics (2126.HK)

2024 Annual Results Presentation

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JW Therapeutics 2024 Business Review

R&D Progress

- **Carteyva® Hematology Programs made significant progress in 2024,** including:

1) 2L LBCL patient recruitment was ahead of plan and enrollment was completed in Q4 2024. The NMPA had granted Breakthrough Therapy Designation to Carteyva® for this indication, the primary endpoint was met, and we plan to submit an NDA application in the first half of 2025.

2) r/r MCL sNDA was approved in August, 2024. Carteyva® is the only cell therapy product in China that has been approved for 3 indications

- **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 was nearly completed 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 in 2024 and dose escalation is ongoing.
- **In-house Pipeline:** The first dual targeting autologous CAR-T study was initiated. Patient enrollment in this study is currently ongoing.

Commercialization

- As of December 31, 2024, Carteyva® has been listed in more than **80** commercial insurance products and **102** local governmental complementary medical insurance programs.
- Enhanced our commercialization strategy with a streamlined organization to drive future sales revenue.

Manufacturing

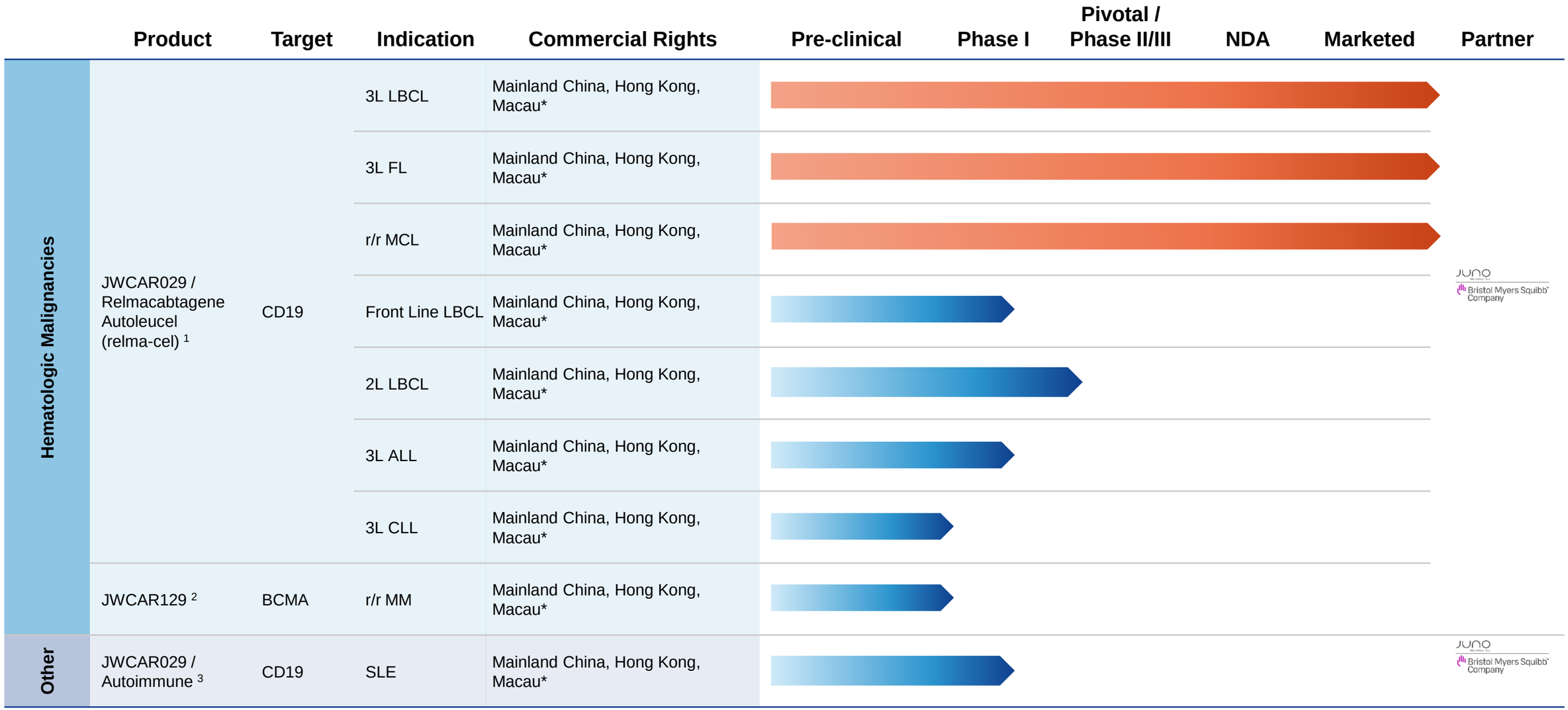
- Cost reduction plan implemented successfully. Continue with key materials localization and will source additional raw materials from domestic suppliers.
- Continued high manufacturing success rate of **98%** for Carteyva®

Financial Update

- Revenue in 2024 reached RMB**158.2** million. GP achieved RMB**77.3** million, GP margin was **48.9%**
- G&A expenses decreased **14.2%**, R&D expenses decreased **31.6%**.
- Cash balance amounted to RMB**757.4** million.

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

药明巨诺 JW Therapeutics



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.

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
- Patients are mainly elderly male patients, most of whom are in the advanced stage at diagnosis and have a poor prognosis.
- In recent years, treatment options have evolved from traditional chemotherapy to new targeted drugs such as Bruton's tyrosine kinase inhibitors (BTKi), which have improved the prognosis of some r/r MCL patients, but the vast majority of patients will still progress or relapse, and the overall survival (OS) of patients who fail treatment is short (6-10 months).

Clinical Progress:

- Carteyva®: was granted Breakthrough Therapy Designation in patients with r/r 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, 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

- The overall CRS incidence was 81.40%, with only 6.8% of CRS at or above grade 3.
- The overall NT incidence was 13.6%, with only 6.8% of NT at or above grade 3.

Carteyva®: Advancing in CD19+ Indications: 2L transplant-ineligible r/r LBCL

Carteyva® is expected to become the first CAR-T cell product for the treatment of 2L transplant-ineligible patients with r/r LBCL

- Large B-cell lymphoma (LBCL) is the most common lymphoma subtype in adults. After first-line treatment, 30-40% of patients still have refractory or relapsed disease and urgently need second-line treatment.
- LBCL patients who fail first-line treatment have a poor prognosis, and more than half of them are not suitable for ASCT due to various reasons such as advanced age and comorbidities. There is currently no standard treatment for such patients, and the prognosis is extremely poor, with significant unmet clinical needs.

Clinical Progress:

- The NMPA had granted Breakthrough Therapy Designation to Carteyva® for the second-line therapy for transplant-ineligible patients with r/r LBCL
- We expect to submit NDA application in the first half of 2025.

Carteyva® demonstrate excellent efficiency and safety profile in clinical trails

48 patients with r/r LBCL who were not eligible for transplantation as second-line therapy, including

- Non-GCB subtype accounted for 79.6%
- IPI high-risk patients (3-5 points) accounted for 53.1%
- Refractory patients accounted for 59.2%
- Multiple extranodal involvement accounted for 28.6%

Competitive efficacy data received, Primary endpoint achieved

- Best ORR is 81.3% among 48 assessable patients
- Best CRR is 54.2% among 48 assessable patients

Comparable Safety profile with low rate of serve CRS and NT

- The overall CRS incidence was 75.5%, with only 4.1% of CRS at or above grade 3.
- The overall NT incidence was 12.2%, with no NT at or above grade 3.

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: diagnosis 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 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

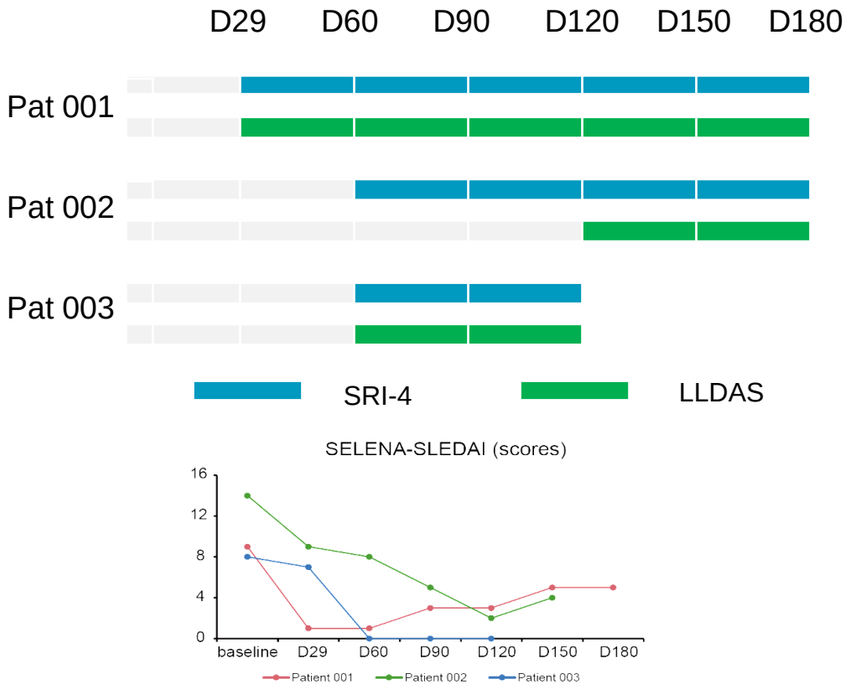
Relma-cel Development Plan in SLE

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 was nearly completed in Q4 2024. 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,

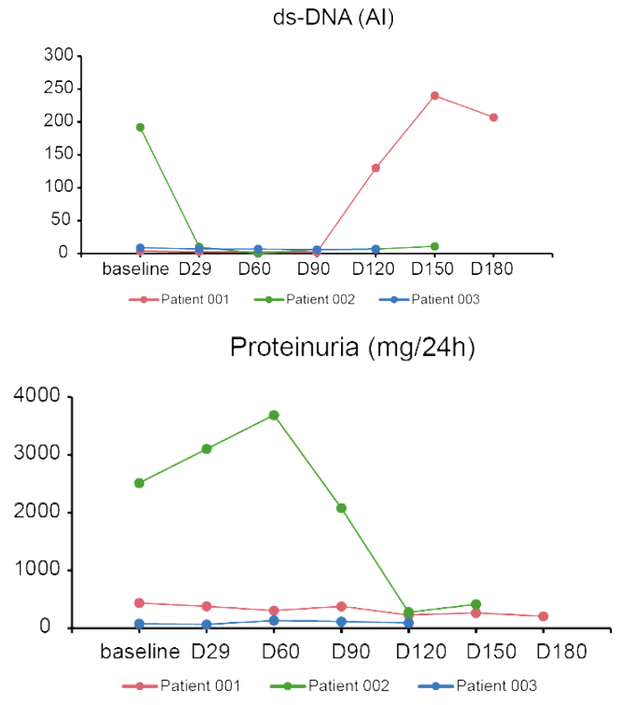
Very Promising Efficacy Signal Observed in the FIH Study

- 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.

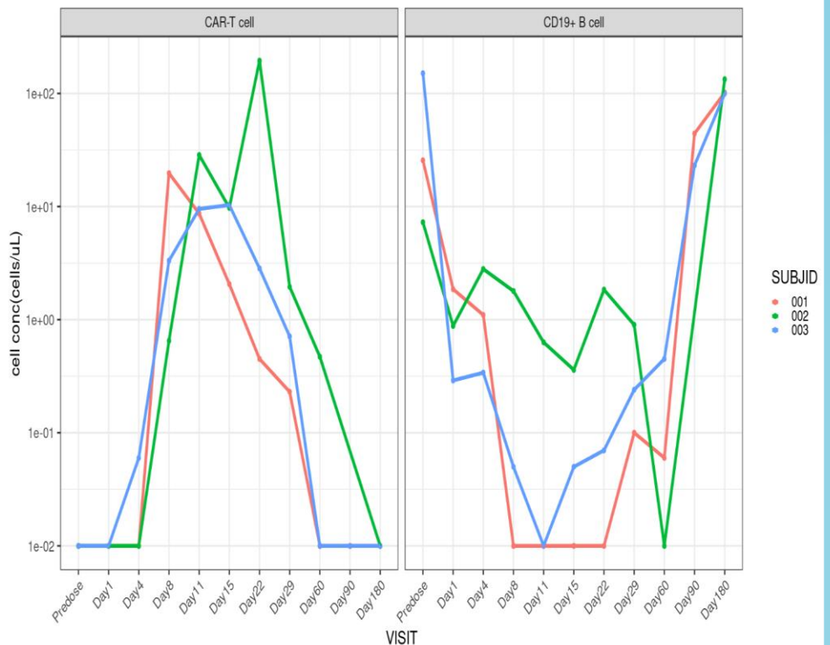


Overall trend:

- 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.

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. FIH study initiated in 2024 and dose escalation is ongoing

(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

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		Initiated in Q4 2024
B-cell malignancies	Dual Targeting	Worldwide		Initiated in Q3 2024
Solid tumor 1	TBA	Worldwide		Expected in Q3 2025
Solid tumor 2	TBA	Worldwide		Expected in Q3 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

- Application of dual-target CART in autoimmune diseases
- Strengthen the application of CAR-T in hematological malignancies
- Accelerate the development of CAR-T cells equipped with next-generation modified elements to treat solid tumors

2024 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® increased the four-year survival rate of patients with late-line large B-cell lymphoma 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

- In Europe and the United States, the application of CAR-T continues to increase. Among them, the application rate in relapsed and refractory non-Hodgkin's lymphoma has reached **10-12%**
- However, China's market cultivation is still imperfect, resulting in a relatively low penetration rate of less than 3%

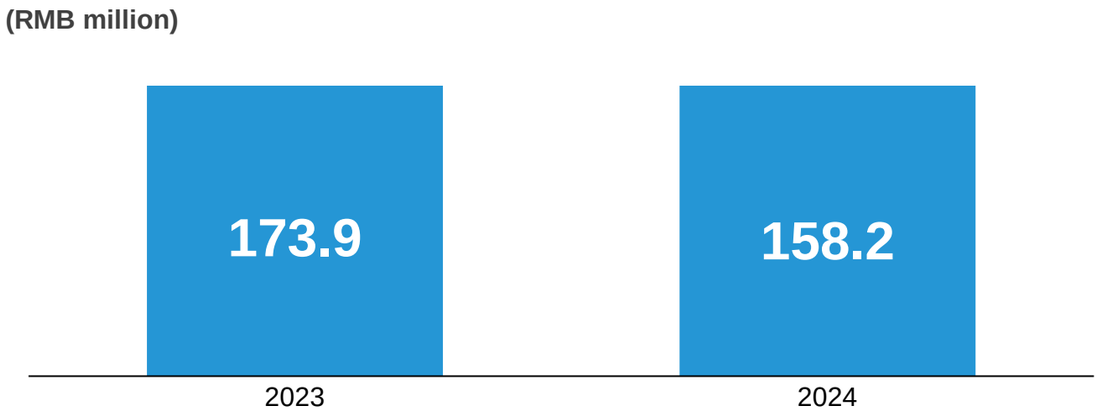
CAR-T market has high barriers to entry.

- 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

Sales Maintained with Dynamic Market Changes

Revenue Achieved by Sales of Carteyva®



Broader Insurance Coverage to Improve Affordability

102 Local Governmental Complementary Medical Insurance Programs

80+ Commercial Insurance

Financial Update

Revenue

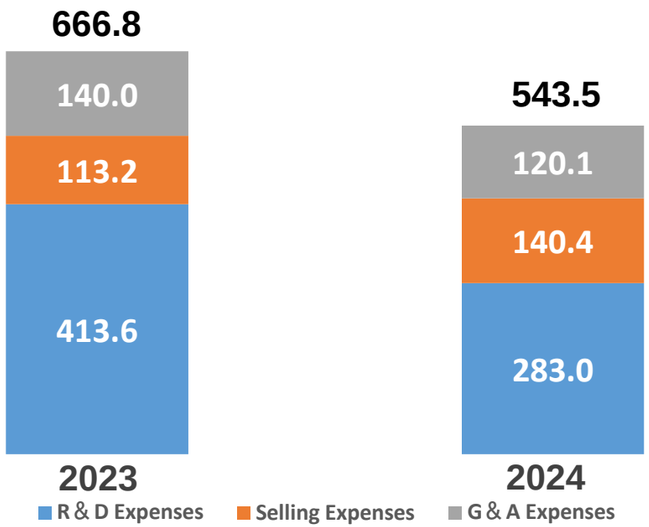
(RMB million)

Gross Margin

(RMB million)

Operation Expenses

(RMB million)



Cash Reserve

(RMB million)