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# 2023 1H: Comprehensive Enhancement of Operational Efficiency to Accelerate Commercialization and Pipeline Development



# **Financial Update**



- 2023 1H revenue reached RMB 87.7 million, representing an increase of 32.9% YoY.
- Gross profit reached RMB 44.8 million, representing an increase of 93.9% YoY.
- Gross profit margin increased to **51.1%**. Cost of sales per batch reduced **30%** from launch of the product.
- G&A expenses decreased 13.4%, selling expenses decreased 28.7%, R&D expenses slightly increased 10.5%.
- Net cash outflow decreased to RMB 110.4 million. Cash balance amounted to RMB1,272.9 million.

### Commercialization



- Generated 94 prescriptions and completed 85 infusions in 2023 1H.
- Covered by 62 commercial insurance products and 91 local government complementary medical insurance programs.
- 49% of Carteyva®-infused patients received insurance reimbursements with an expense coverage ranging from 38% to 100%.
- Optimized commercial organization with less spending to drive revenue growth.

# **R&D Progress**



- Carteyva® Hematology Programs made significant progress, including:
  - > 1) r/r MCL patient enrollment was completed in August 2023 2) New 2L LBCL IND approved 3) Initiated 1L LBCL IIT studies
- Relma-cel use extended to SLE: NMPA approved IND application relating to relma-cel as a treatment for SLE in April 2023. clinical study is actively enrolling and received very promising efficacy and safety data from initial dose level.
- JWATM204 and JWATM214 transitioned to clinical stage: Ph1 studies initiated for both in HCC.
- MAGE-A4 TCR-T and DLL3 CAR-T: Process development are ongoing. Clinical studies are being prepared.
- Established 4 products with global commercial right in pre-clinical stage.

### Manufacturing



- Continued high manufacturing success rate of 98%.
- Achieved 100% product delivery.
- Completed multiple raw materials localization and will source more raw materials from domestic suppliers.

# Carteyva® to Sustain Strong Growth with Promising Untapped Market Potential





30K

r/r B-NHL patients in China<sup>1</sup>

2%

**Receiving CAR-T treatment<sup>2</sup>** 

# **Continuously Drive Operational Excellence**

32.9%

**Revenue YoY Growth** 



**Selling Expense** 

# Best in Class Efficacy & Safety in 3L LBCL Patients

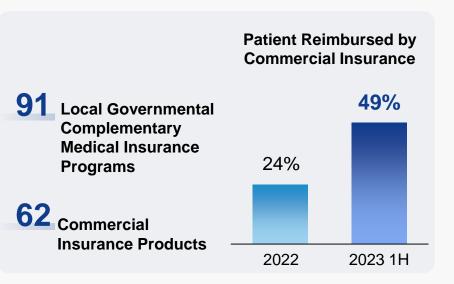
77.6% 53.5% 69.3% 2 Year OS 5.1% 3.4%

Liso-cel demonstrated **superior efficacy** in TRANSFORM<sup>3</sup> and was approved for 2L r/r LBCL by FDA

# Best Production Reliability and Consistency

98% 100%
Success Rate Delivery Rate

# Broader Insurance Coverage to Improve Affordability



≥3 Grade CRS

≥3 Grade NT

<sup>1.</sup> Globocan 2020; China lymphoma subtype distribution with 10,002 samples.

Transmedia 2023 1F

<sup>3.</sup> Liso-cel 63rd ASH Annual Meeting 2022, New Orleans, LA, Abstract 655; Lancet 399 (10343):2294-2308 [2022]; TRANSFORM Study.

# JW's R&D Strategies



Expand Relma-cel Use in Heme Indications >>>	
With successful approvals in LBCL & FL, Pursue 2L & 1L LBCL, MCL & pALL	01
Evpand Palma cal Indications into Autoimmuna Diseases 222	
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	02
Advance Products Targeting Hepatocellular Carcinoma [HCC] >>>>	
Advance Multiple Programs to treat HCC with novel CAR-T platforms with promising PoS	03
Build Innovative Solid Tumor Program with World-class Cell Therapy Partners >>>>	
Advance MAGE-A4 TCR-T & DLL3 CAR-T Programs to treat solid tumors with novel CAR-T platforms and promising PoS	04
Through Research, Create Products to Improve Anti-tumor Activity and Access Global Markets >>>	
Establish proprietary CARs and armored elements to overcome solid tumor barriers for use worldwide	05

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





Abbreviations: LBCL = large B-cell lymphoma; FL = follicular lymphoma; MCL = mantle cell lymphoma; ALL = acute lymphoblastic 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, Macau and Taiwan refer to Mainland China), respectively.

<sup>1.</sup> Relma-cel is based on the same CAR construct as the product lisocabtagene maraleucel (Breyanzi or lisocabtagene or liso-cel) of Juno Therapeutics, which was approved by the U.S. Food and Drug Administration in February 2021.

<sup>..</sup> JWCAR129 is based on the same CAR construct as Juno Therapeutics' product orvacabtagene autoleucel (orva-cel).

<sup>3.</sup> SLE is a chronic autoimmune disease characterized by the production of autoantibodies and abnormal B-lymphocyte function. To further extend Relma-cel's potential in broader disease area, we are planning a study to evaluate the safety, tolerability, and pharmacokinetic profile of Relma-cel in Chinese patients with moderately or severely active SLE.

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# Carteyva®: Approved for 2 Indications to Meet the Needs of NHL Patients

### A Competitive Profile today, and competitive for the future



### Comparable Efficacy<sup>1</sup>

\* Not from a head-to-head comparison study

	ORR	CRR
Carteyva <sup>®</sup>	77.6%	53.5%
	ORR	CR
Yescarta	72%	51%

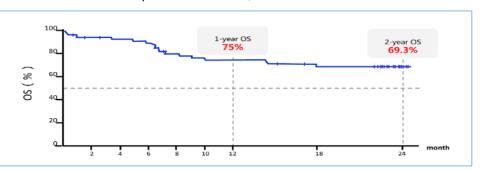
### Superior Safety Profile<sup>1</sup>

\* Not from a head-to-head comparison study

	Indication	NT (Any)	sNT (≥Grade 3)	CRS (Any)	sCRS (≥Grade 3)
Carteyva®	Carteyva <sup>®</sup> r/r LBCL		3.4%	47.5%	5.1%
	Indication	NT (Any)	sNT (≥Grade 3)	CRS (Any)	sCRS (≥Grade 3)

### **Excellent long-term efficacy: 2Y OS 69.3%**

Median follow-up time: 18 months, median OS was not reached



# 3L FL Approved in 2022

### **Efficacy Comparison**

\* Not from a head-to-head comparison study

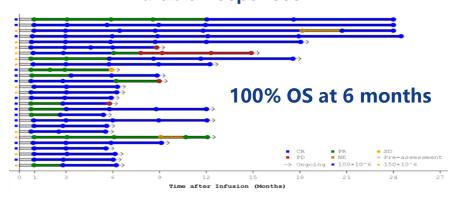
	ORR	CRR
Carteyva <sup>®</sup>	100%	92.6%
	ORR	CR
Yescarta	91%	60%

### **Safety Profile Comparison**

\* Not from a head-to-head comparison study

	Indication	NT sNT (Any) (≥Grade		CRS (Any)	sCRS (≥Grade 3)
Carteyva <sup>®</sup>	3L FL	18%	4%	43%	0
	Indication	NT (Any)	sNT (≥Grade 3)	CRS (Any)	sCRS (≥Grade 3)
Yescarta	3L FL	77%	21%	84%	8%





### Source:

# 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

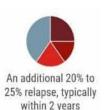
Many Don't Benefit from **SoC Chemo** 



candidates for R-CHOP (fitness, comorbidities, cardiac dysfunction)



~15% will have primary refractory disease with R-CHOP induction



### 2<sup>ND</sup> LINE THERAPY

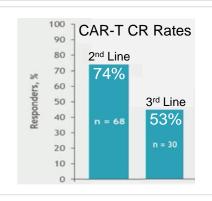
- CAR-T the New SoC, but **Toxicity Rates Matter:** 
  - ZUMA7: CRS 92%, sCRS 6%; NT 60%, sNT 21%

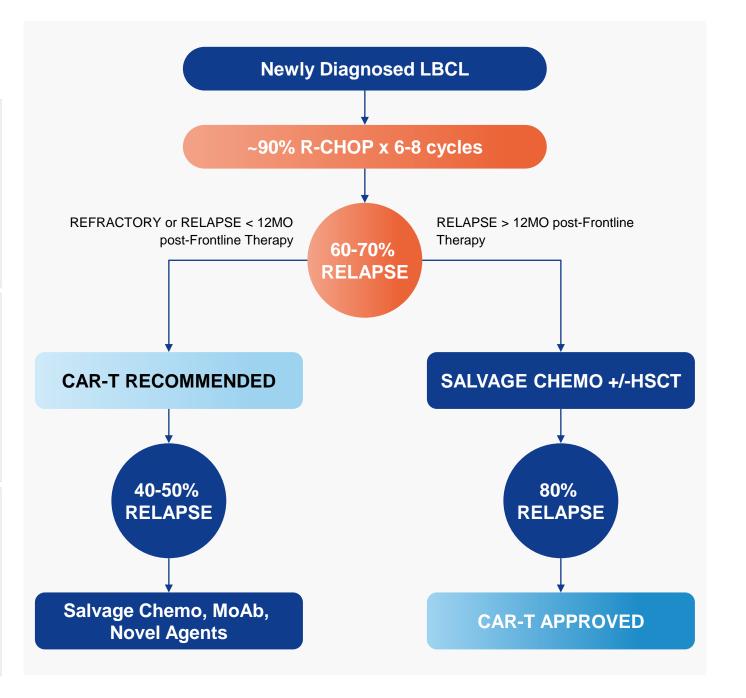
### TRANSFORM: PFS per IRC (ITT set) Stratified HR = 0.400 (95% CI, 0.261-0.615) 70 -NR (95% CI, 12.6-NR) 6.2 months (95% CI, 4.3-8.6) 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34

### 3RD LINE THERAPY



Beneficial, but Earlier Better





# Carteyva® Development in Early Line Treatment of LBCL



# Carteyva® in 2<sup>nd</sup> 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<sup>2</sup>]

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

# Broadening Carteyva® Use to 2<sup>nd</sup> Line and 1<sup>st</sup> Line treatment in LBCL

Study	Population	Status
JW029-216	2 <sup>nd</sup> Line non-transplant eligible	IND-approved
JW029-010	2 <sup>nd</sup> 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

<sup>1.</sup> JW Therapeutics- data on file

# Carteyva®: Advancing in CD19+ Indications: MCL



### MCL

- Carteyva® was granted Breakthrough Therapy Designation in patients with MCL by NMPA
- Historically, standard therapy has provided brief responses or no response
- Evaluating very poor risk MCL patients; those who failed of stopped BTK inhibitors
- Enrollment completed in August 2023 and plan to submit sNDA by end of 2023
- Update data will be published on ASH 2023

# 59 high risk patients who failed BTK inhibitors, including

- Relapse or refractory to BTKi [91.6%]
- high Mantle Cell International Prognostic Index [45.8% IPI>3]

- Extranodal organ involvement [50.8%]
- Bulky disease [≥5 cm 28.8%]

# Competitive efficacy data received, Primary endpoint achieved

- Best ORR is 80% among 50 assessable patients
- Best CRR is 64% among 50 assessable patients

### Comparable Safety profile with low rate of serve CRS and NT

- Overall CRS rate is 52.5%, with only 5% G3 CRS and no G4 CRS
- Overall NT rate is 10.2%, with only 6.8% G4 NT and no G3 NT

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



### **Large Need:**

**SLE** has few disease modifying therapies

Needed for long-term organ preservation

### **Measurable Therapy Goal:**

Disease control for organ preservation

Preventing organ failure key to extending survival in SLE

### **Clear POC:**

CD19 CAR-T led to durable remissions in academic trial

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

### **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



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

Lopez R et al. Rheumatology 2012;51:491498 [Page 496, Page 495]

Becker-Merok A and Nossent HC J Rheumatology. 2006 Aug;33(8):1570-7 [Page 1570, 1572]

Mak A et al. Nat Rev Rheumatol. 2013 May;9(5):301-10 [301]

<sup>4.</sup> Ali M. Al Dhanhani et al. Arthritis Care & Research. 2015 Nov; 67(11):1536-44 [Page 1536]

# First in Human Study of Relma-cel in SLE



### First in Human study kick off from 1Q 2023 and actively enrolling, promising efficacy and Safety data received from initial dose level

Target Population

Patients with moderate-to-severe, refractory/relapse Systemic Lupus Erythematosus (SLE)

**Key Eligibility** 

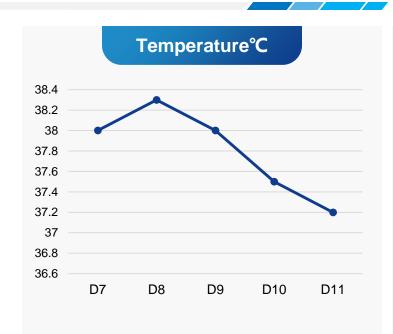
- SLE Classification: Have a clinical diagnosis of SLE per ACR Classification
- SLE Treatment: Stable SLE treatment regimen for a period of at least 2 months prior to lymphodepletion
- The subjects with positive test for anti-nuclear antibody (ANA) or anti-dsDNA serum antibody or anti-Smith antibody
- 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

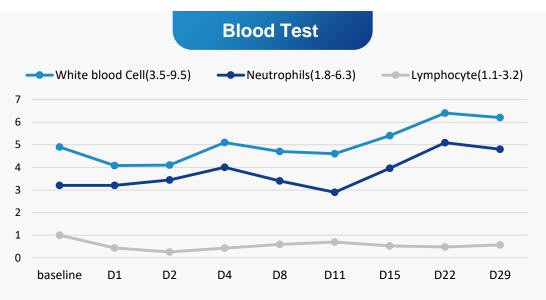
# Relma-cel Development Plan in SLE >>>>

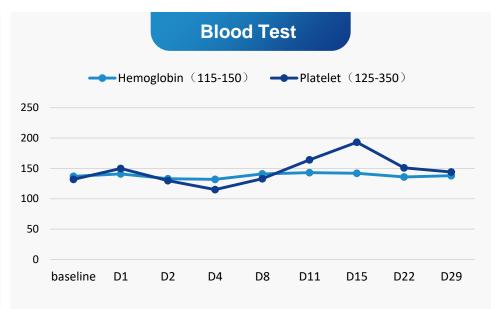
- 1 First in Human study enrollment will be closed in 2023, Preliminary Safety Profile, Pharmacodynamics Data and Preliminary Efficacy data will be disclosed around end of 2023
- 2 IND approval received in Apr 2023 and sites are in initiation
- 3 Primary data as well as further registration plan will be discussed with CDE and pivotal study is expected to initiate in 2024

# **Very Promising Efficacy and Safety Signal from IIT Study**

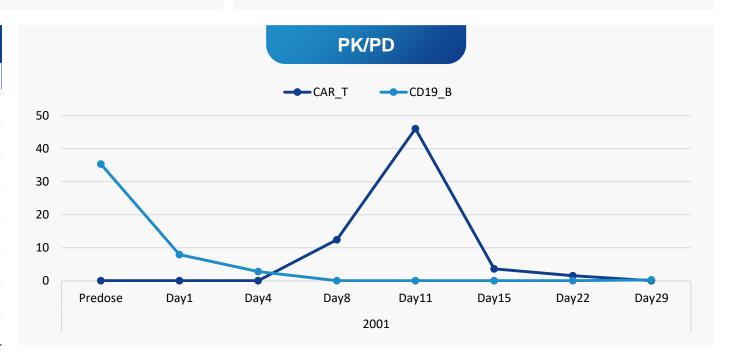








	Baseline	D29
Urinary protein (mg/24h)	7022	3065
ds-DNA (<7 IU/mL)	> 100	38.92
Anti-SM ( < 25)	80	76
ANA (Negative)	1:1280	1:320
C3(0.4-1.7g/l)	0.6	0.996
SELENA-SLEDAI (Score)	14	6
BILAG-2004 (Grade)	В	В
PGA (Score)	1.5	1.1
SRI-4		meet



# 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
	JWATM204 <sup>1</sup>	GPC3	НСС	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						EUREKA
	JWATM204	GPC3	NSCLC/HAS	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						EUREKA
ទិ	JWATM214 <sup>2</sup>	GPC3	НСС	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						Lyell & EUREKA
Solid Tumors	JWATM203 <sup>1</sup>	AFP	НСС	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						EUREKA
У	JWATM213	AFP	НСС	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*						EUREKA THERAPELITES
	JWTCR001	MAGE-A4	various solid tumors	Mainland China, Hong Kong, Macau	New Product					<b>2seventy</b> bio 7™
	JWCAR031	DLL3	SCLC	Mainland China, Hong Kong, Macau	New Product					ر <sup>الا</sup> 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;

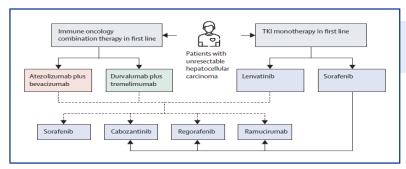
<sup>\*</sup> Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.

<sup>1.</sup> JWATM204 is in a Phase I investigator-initiated trial in China. Eureka's products based on the CAR constructs underlying JWATM203 and JWATM203 an Track Designation to Eureka's counterpart to JWATM203 for the treatment of hepatoblastoma ("HB") and HCC in pediatric disease designation for the treatment of HB. In February 2022, the FDA granted Orphan Drug Designation to Eureka's counterparts to JWATM203 and JWATM 204.

Developing using Lyell technology.

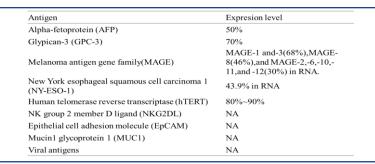
# JWATM204 & 214: GPC3 CAR-T in HCC





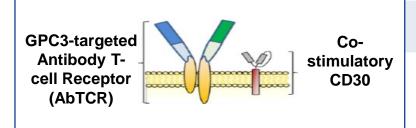


- ~80% pts are initially-diagnosed as advanced/metastatic stage [unresectable] disease
- HCC has poor prognosis (5-ys OS rate ~12%) with currently available therapies



# Target Potential: Cell surface expression of GPC3 in >70% HCC

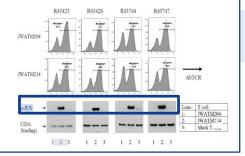
Mostly higher density expression



# POC: CAR-Ts targeting GPC3 have shown clinical anti-tumor activity

Clinical PoC for Target: ORR observed in 40-50% of pts in small Ph1 studies

### High c-Jun **Expression in** JWATM214



# Two Novel Elements: Unique CAR construct & cJun technology

- Artemis CAR has unique costimulatory signaling domain associated with tumor localization
- cJun expression can improve T cell function in tumor micro-environment V

Saunders LR. Sci Transl Med. 2015 Aug 26;7(302):302ra136.

# **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)





40-60% CR&PR

In metastatic melanoma & synovial cell sarcoma

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





50% PR(6/12)

In HPV-associated cancers

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





50% PR(8/16)

In melanoma, synovial cell sarcoma, head & neck & others (4)

# **Novel Technology Licensed from 2seventy Bio**

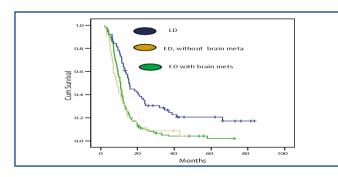
- MAGE-A4 binder restricted by HLA-A2 alleles common in China
- Using additional FLIP receptor to overcome TME
- Manufacturing to use prior process development experience
- Plan FIH trials for rapid test of PoC in multiple tumor indications

(4) Immatics topline data release

<sup>(1)</sup> P.F.Robbins et al 2011J cin Oncol.29(7):917.

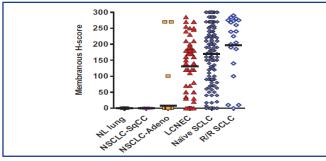
# JWCAR031: DLL3 CAR-T in SCLC





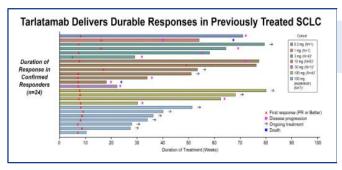
# Need: ~80K SCLC cases newly diagnosed in China annually

- ES-SCLC accounts for ~70% SCLC
- 2<sup>nd</sup> Line therapy in ES-SCLC has mOS<6m (ORR~15%)



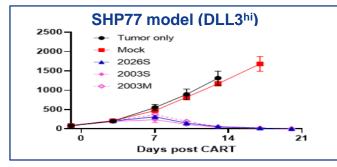
# Target Potential: Cell surface expression of DLL3 in 72% SCLC

~85% SCLC expressed positive DLL-3



# POC: Tarlatamab, a T cell engager against DLL3

Clinical PoC for Target: Overall Response Rates ~23%, Complete Response Rate ~2%



# Novel CAR: Juno/BMS generated multiple CARs with potent activity in vitro

Selected Lead Candidate CAR to move to clinical trials; Research working to add functional modules

- Saunders LR. Sci Transl Med. 2015 Aug 26;7(302):302ra136.
- DLL3= delta-like ligand 3, TME=Tumor microenvironment, PoC=Clinical Proof-of-concept, SCLC=Small Cell Lung Cancer, mOS=median Overall Survival, ES-SCLC=Extensive Stage Small Cell Lung Cancer.

# **Progress of Solid Tumor Projects**



# 01

# **JWATM 204 & 214** (GPC3 CAR-T)

- Both studies in HCC are actively enrolling
- Dose escalation almost completed for JWATM 204 study and patients are following for more data

02

# JWTCR001 (MAGE-A4 TCR-T)

- Process development is ongoing and preliminary result received
- Pre-clinical study is ongoing.
- Site is in initiation and plan to screen patient from Q42023 and start to dose patient Q1 2024

03 JWCAR031 (DLL3 CAR-T)

- Process development is ongoing
- Study Site is in preparation

# 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 Q2/3 2024
B-cell malignancies	Dual Targeting	Worldwide		Expected in Q4 2024
Solid tumor 1	TBA	Worldwide		Expected in Q1 2025
Solid tumor 2	ТВА	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

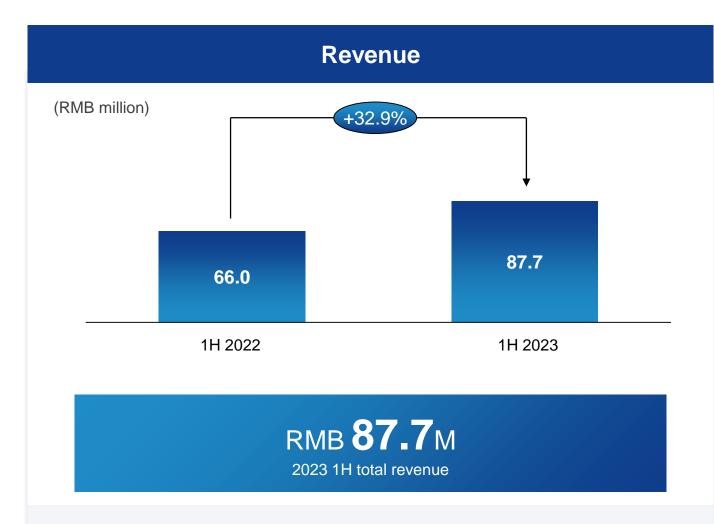
### **Indications**



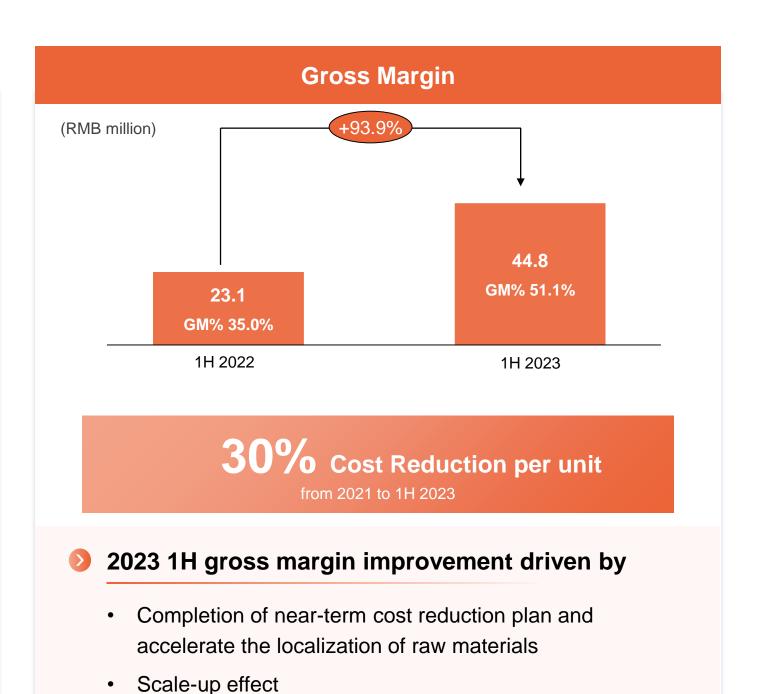
- Strengthen Heme CAR-T
- Advance next generation armored CAR-T cells in solid tumors
- Plan to enter clinic in 2024/2025

# **Key Financial Update**





- 2023 1H revenue increase supported by
  - Higher market penetration
  - Multi-layer medical care system

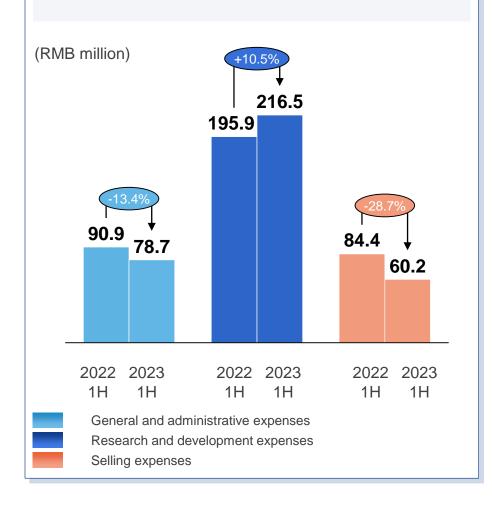


# **Key Financial Update**



### Operating expenses

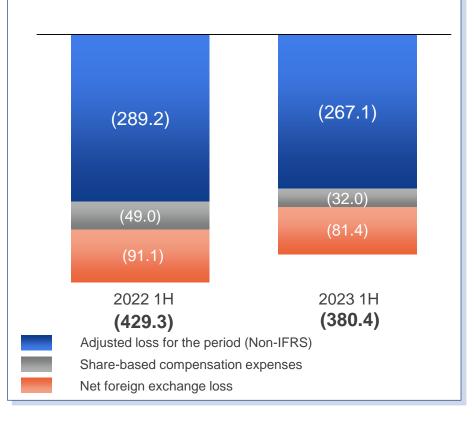
- Stringent control on G&A expenses
- 2023 1H R&D expenses is slightly higher than 2022 1H, mainly due to expense increase of Suzhou vector project, pre-clinical research and different phases of clinical trials.
- Rationalize selling expenses to accelerate revenue growth



# Loss for the period

· Loss for the period narrowed down due to higher gross profit and less operating expenses

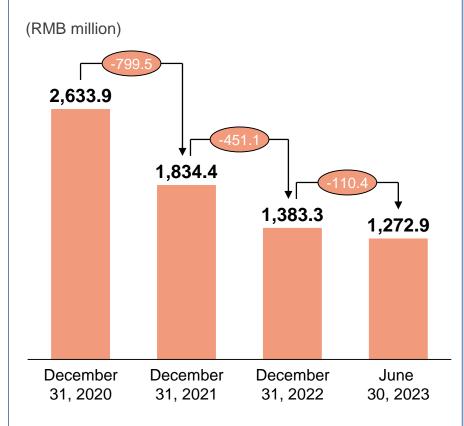
(RMB million)



### Cash balance \*

Net cash outflow decreased primarily due to:

- · Continuous cash inflow generated from revenue
- · Improving operational efficiency
- favorable bank facility



<sup>\*</sup> Cash balance is cash and cash equivalents plus highly liquid financial assets



# THANK YOU!