

# InnoCare Pharma 2025Q1 Results

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## **Our Mission & Vison: Science Drives Innovation for the Benefit of Patients**









**Autoimmune** 

**Our Therapeutic Focus** 

# **Key Achievements in 2025Q1**



Robust Commercial Acceleration & Solid Financial Foundation

Diversified Product Portfolio & Multiple Ph3 Studies to Address Unmet Medical Needs

- Total revenue reached RMB 381 million, representing a yoy increase of 129.92%
- Orelabrutinib achieved RMB 311 million sales with 89.22% yoy growth
- Net profit for January to March 2025 was RMB 14 million
- Gross profit margin reached 90.5%, an increase of 5.1 p.p. compared to the same period of last year
- Strong cash position of RMB 7.8 billion
- Orelabrutinib 1L CLL/SLL NDA approved in China and other indications NDA submitted in overseas
- Tafasitimab BLA for r/r DLBCL accepted under priority review
- Zurletrectinib (ICP-723) registrational study done, NDA accepted under priority review
- Mesutoclax (ICP-248)
  - Combo with Orelabrutinib entered into Ph3 registrational trial for 1L CLL/SLL; patient enrollment ongoing
  - Approved to initiate a single-arm Ph 2 registrational study for BTKi failure r/r MCL; the first BCL-2 inhibitor in China to receive Breakthrough Therapy Designation
- ♦ Orelabrutinib in Autoimmune Diseases
  - **PPMS**, global Ph3 registrational trial, targeting FPI by 2<sup>nd</sup> half of 2025
  - > SPMS, global Ph3 registrational trial, targeting FPI by 2<sup>nd</sup> half of 2025
  - ITP, Ph3 registrational trial, targeting NDA submission in 2026H1
  - > SLE, Ph2b enrollment completed, data readout in 2025Q4
- Soficitinib (ICP-332) (TYK-2/JAK1)
  - > Atopic dermatitis: Ph3 registrational trial; patient enrollment is accelerating
  - > Vitiligo: Ph2 trial initiated; patient enrollment underway
- CP-488 (TYK-2, allosteric) Ph3 registrational trial for Psoriasis in China initiated; patients enrollment ongoing

### In 2025 Q1, Total Revenue Achieved 129.9% yoy Growth, Drug Sales Achieved 89.1% yoy Growth, Total Profit Turns to Positive INNOCARE



### 2025 Q1 total revenue achieved 381M with 129.9% growth vs. prior year, drug sales achieved 312M with 89.1% growth vs. prior year



-*\*(

Total profit of 2025 Q1 turns to positive, which is attributed to drug sales growth, BD revenue, and cost efficiency improvement

## **Driving for Sustained Growth and Strong Cash Position Provides Flexibility**





YTD Gross profit margin keeps increasing to 90.5%, attributing to the orelabrutinib manufacturing efficiency improvement, and additional gross margin from BD revenue R&D expenses increased for strategic investment for innovative technology platform, and increased resources to clinical trials for our prioritized programs Robust cash and related balance of RMB 7.8B (~US\$1.1B) provides flexibility to expedite the clinical development and to invest in a competitive pipeline





Payment

Hilestone Payment

Wilestone Payment

Royalty

Tiered Royalties on<br/>Net Product Sales

Capitalization and Equity

A Stake in<br/>Prolium

Under the terms of the agreement, Prolium will receive the rights to develop and commercialize ICP-B02 in the global non-oncology field and the oncology field outside of Asia.

## **Orelabrutinib Commercialization:**

Driving High Sales Growth through Outstanding Product Data, Expanding Indications and Treatment Areas, and Recommended by Authoritative Guidelines



### **Capturing the High-Potential MZL Market**

- First and only BTKi for the treatment of r/r MZL
- ✓ MZL: The second largest NHL indication with significant market potential
- Committed to becoming a market leader in MZL

### Further Expanding the Indications and Market Potential of CLL/SLL and MCL

- 1L CLL/SLL approved, further unlocks market potential and is expected to drive significant growth in market penetration
- ✓ r/r CLL/SLL and r/r MCL approved and included in NRDL
- Prolonging treatment duration with strong efficacy and safety

# Recommended in the 2025 CSCO Lymphoma Guidelines

- CLL/SLL: First-line and r/r CLL/SLL Grade I recommendation
- MZL: Grade I recommendation
- MCL: First-line treatment of MCL Grade II recommendation.

<sup>1</sup>Indications included in NRDL: adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy (r/r CLL/SLL), adult patients with mantle cell lymphoma who have received at least one prior therapy (r/r MZL)

#### -*\*( Innovative Pipeline: Accelerating Portfolio Towards Value Realization INNOCARE



#### Pre-IND

Oral

Oral

#### ADC

Solid tumor

IL17

Autoimmune disease

- Others
  - Autoimmune disease

Mesutoclax (ICP-248)
r/r NHL(CHN, US)
AML(CHN, Global)
Soficitinib (ICP-332)
<ul> <li>Prurigo nodularis (Global)</li> </ul>
ICP-189+EGFRi
NSCLC (CHN)
ICP-B02
NHL (CHN)
ICP-490
MM (CHN)
NHL (CHN)
ICP-B05
Hemato-oncology (CHN)
Solid Tumor (CHN)

Phase 1/2

BCL2

TYK2/JAK1

CD3XCD20

E3 Ligase

CCR8

Phase 2

SHP2

Orelabrutinib	втк
TN MCL (CHN)	
<ul> <li>MZL confirmatory (CHN)</li> </ul>	
ITP (CHN)	
SLE (CHN)	Phase 2b
PPMS (Global)	
SPMS (Global)	
Tafasitimab	CD19
DLBCL (CHN)	
Mesutoclax	BCL2
• TN CLL/SLL (CHN)	+Orela
• BTKi failure r/r MCL	Phase 2 registrational
Soficitinib (ICP-332)	TYK2/JAK1
• Atopic Dermatitis (CHN)	
<ul> <li>Vitiligo (CHN)</li> </ul>	Phase 2/3
ICP-488	TYK-2
Psoriasis (CHN)	

Phase 3

Registration		Approved
Orelabrutinib	втк	Orelabrutinib
• r/r MZL (SG)		• TN CLL/SLL (CHN)
• r/r MCL (AU)		• r/r CLL/SLL (CHN)
Tafasitimab	CD19	• r/r MCL (CHN)
• r/r DLBCL (Mainland CH	N)	• r/r MCL (SG)
Zurletrectinib	NTRK	• r/r MZL (CHN)
NTRK fusion-positive cancers     (CLN)		Tafasitimab
(CHN)		• r/r DLBCL (GBA)
		• r/r DLBCL (HK)
		• r/r DLBCL (Macao)
		• r/r DLBCL (TW)

Orelabrutinib	втк
TN CLL/SLL (CHN)	
• r/r CLL/SLL (CHN)	
• r/r MCL (CHN)	
● r/r MCL (SG)	
• r/r MZL (CHN)	
Tafasitimab	CD19
Tafasitimab • r/r DLBCL (GBA)	CD19
	CD19
• r/r DLBCL (GBA)	CD19
<ul> <li>r/r DLBCL (GBA)</li> <li>r/r DLBCL (HK)</li> </ul>	CD19



- Solid Tumor

# A Leading Hematooncology Franchise

## Hemato-oncology: Marketed and Phase 3 Clinical Products



	Assets	Target	Indication	Clinical Trial Regis	tration Market
			r/r CLL/SLL		🛨 СНИ
			r/r MCL		🛨 СНN,SG
	Onelahmatinik	DTK	r/r MZL		
Adabratinih Tablets and material and a second and a secon	Orelabrutinib	BTK	1L CLL/SLL		🛧 СНИ
IN NOCARE			1L MCL	Global Ph3 ongoing	
			MZL Confirmatory Trial	Ph3 ongoing	
MINUUI.200mg powder for concentrate for solution for infusion					🛨 нк, мс,
tafasitamab kara a high tafasitamab kara a ps traf tafasitamab kara a tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitamab tafasitam	Tafasitamab CD19	r/r DLBCL	Mainland China BLA accepted by CDE		
fter) Tvia		DLBCL of	DLBCL Confirmatory Trial	Ph3 ongoing	
			1L CLL/SLL	Ph3 registrational trial ongoing, combo with Orela	
	Mesutoclax (ICP-248)	BCL2	r/r MCL (BTKi treated)	Ph2 registrational trial approved to initiate	
			1L AML	Clinical trials ongoing in CHN & global	
arketed	Others (ICP-490, -B02, -B05, etc.)		Hemato-oncology	Clinical trials ongoing in multiple indications	
nical					

# Tafasitamab (CD19): BIC Profile for r/r DLBCL, Expected to Launch in 2025





Tafasitamab		ICP-CL-00901 (N=52)
		IRC
	Ν	%
ORR	38	73.1%
CR	18	34.6%
PR	20	38.5%
DCR	44	84.6%

## **Tafasitamab (CD19): BIC Profile for r/r DLBCL, Expected to** Launch in 2025



Comparison of Selected Novel Therapy in r/r DLBCL
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Company	Target	Therapy	Phase	ORR (%)	CR (%)	mDOR (m)	mPFS (m)	mOS (m)
Incyte/InnoCare	CD19	Tafasitamab + Lenalidomide	Approved ex-China	57.5	40	43.9	11.6	33.5
ADC Therapeutics	CD19 ADC	Loncastuximab tesirine	Approved ex-China	48.3	24.1	10.25	4.93	9.92
Roche	CD79b ADC	Polatuzumab vedotin + BR vs BR	Approved	42 vs 18	23 vs 3	12.6 vs 7.7	9.5 vs 3.7	12.4 vs 4.7
Roche	CD20/CD3	Glofitamab	BLA	52	39	10.4	3.8	11.5
Amgen/ Beigene	CD19/CD3	Blinatumomab	П	43	19	11.6	3.7	5.0
Regeneron/ Zai Lab	CD20/CD3	Mosunetuzumab	П	33	21	N/A	N/A	N/A
AbbVie	BCL-2	Venetoclax+R+Pola	11	65	31	5.8	4.4	11

# **Mesutoclax (ICP-248):** A Novel BCL-2 Inhibitor with Clinical Advantages





## **Venetoclax Pharmacological Properties**

M27, a major metabolite of Venetoclax, shows ~80% AUC of the parent drug within 24 h

M27 has no pharmacological activity but has hematological toxicity\*

Significant inhibition of CYP2C8 and CYP2C9 by Venetoclax and M27 with IC50  $\leq$  0.82  $\mu M$ 

Significant inhibition of P-gp and BCRP by Venetoclax and M27 with IC50  $\leq$  1.48  $\mu M$ 



\* Venetoclax FDA non-clinical toxicology review

CYP: Cytochrome P450 proteins; BCRP: breast cancer resistance protein; DDI: drug-drug interaction; PK: Pharmacokinetics



BTKi + BCL-2i for 1L CLL/SLL					
Orela+Mesutoclax Ibru + Ven <sup>1</sup> Acala + Ven					
Sample Size	42	106	291		
ORR	100%	86.8%	92.8%		
CRR	53.4%*	36.7%	NA		
uMRD	46.2%** <sub>W12</sub>	45.3% EOT+3	34.4% EOT		
TLS	0	0	0.3%		

Cutoff date: 2025/01/03

\* Target lesion by imaging; at RP3D

\*\* Median duration of combo treatment: 5.5m

### **BTKi-treated r/r MCL**

(	Mesutoclax	Venetoclax <sup>3,4</sup>	Pirtobrutinib <sup>5</sup>
	BTKi+, N=17	BTKi+, N=17	cBTKi* Pretreated MCL N=90
ORR	70.5%	53%	57.8%
CRR	23.5%	18%	20.0%

Cutoff date: 2025/02/26

\* cBTKi: covalent Bruton tyrosine kinase inhibitor

Ph3 registrational trial Combo with Orelabrutinib for 1L CLL/SLL ongoing in China

Ph2 registrational trial approved to initiate First BCL-2 inhibitor in China to receive Breakthrough Therapy Designation

**1L AML clinical trial ongoing in China and globally** 

# Well Positioned Portfolio in Autoimmune Diseases



#### Ň **Multiple Assets with Large Indications Progressed to Phase 3 Trials** INNOCARE



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## **Orelabrutinib:** Enormous Potential for Treating Autoimmune Diseases



ITP

## MS

- PPMS: Global Ph3 ongoing
- SPMS : Global Ph3 ongoing
- With high target selectivity, favorable PK and the ability to cross the BBB, Orelabrutinib offers a promising therapeutic option for treating PMS
- Best-in-class potential

### ~2.5 million patients worldwide

### Ph3 registrational trial for the treatment of ITP is underway in China, with NDA submission expected in 2026H1

 BTKi treatment for autoimmune diseases is just around the corner

# Over 200,000 new patients globally each year

## SLE

- The world's first and only BTKi
   demonstrating efficacy in Ph2 trial
- Phase 2b Clinical Trial Enrollment Complete, Data Readout Expected in 2025Q4

### ~8 million patients worldwide

# **Soficitinib (ICP-332), ICP-488:** Two Differentiated TYK2 Inhibitors have Great Potential in Multiple Indications



### Soficitinib Ph2 AD



## ICP-488 Ph2 Psoriasis



- Ph3 registrational trial for AD ongoing
- Ph2/3 trial for vitiligo initiated
- ✓ Ph2 global trial for prurigo nodularis is being planned

 Ph3 registrational trial for psoriasis initiated, patients enrollment ongoing

# Oral Therapies for Comprehensive Coverage of Autoimmune Diseases



**Orelabrutinib (BTKi) Nephrology** LN MN Soficitinib (ICP-332) (TYK2/JAK1i) Gastroenterology UC CD **ICP-488 (TYK2i)** Prurigo Dermatology AD **PSO** Vitiligo **Nodularis** IL-17 (small molecule) **Hematology** ITP AIHA AA **Project 40 (cyclic peptide) Neurology** MoG-EM **PPMS** SPMS NMO MG Projects 42 & 43 (small molecule) **Rheumatology** lgG4-RD SLE **PSA** SS RA **Project 44 (molecular glue)** 

InnoCare current coverage

Clinical

Pre-clinical

LN: Lupus Nephritis MN: membranous nephropathy UC:Ulcerative Colitis CD: Crohn disease AA: Aplastic anemia AIHA: Autoimmune hemolytic anemia NMO: Neuromyelitis optica MG:Myasthenia gravis

MoG-EN: MOG antibody-associated encephalomyelitis SS: Sjogren syndrome RA: Rheumatoid Arthritis IgG4 RD:IgG4 related disease

# Innovative Solid Tumor Assets

## **Solid Tumors Strategy**





## **Design & Advantage of InnoCare's Proprietary ADC Platform**





## **ICP-B794:** Robust Anti-Tumor Activity in Animal Models vs. Other Platforms



ICP-B794 Demonstrates Superior Anti-Tumor Activity in Animal Model Compared to Others ICP-B794 Exhibits Superior Tumor-killing Effect in Large Tumors



Note: linker-payload from different platforms conjugated to InnoCare anti-B7H3, all tested articles with DAR≈8

Safety Window is >200 fold in preclinical studies

# Zurletrectinib (ICP-723): 2<sup>nd</sup> Generation TRKi for the Treatment of Tumors with NTRK Gene Abnormalities, NDA accepted under priority review

- Registration trial for NTRK gene abnormalities in adults and adolescents, NDA accepted under priority review

### ✓ ORR: 85.5%

- ✓ Long duration of response (longest beyond 36 months)
- Registrational trial for pediatric patients ongoing, targeting NDA submission later 2025
- Efficacious in TRKi-resistant patients



Significant and durable efficacy observed across diverse tumor types in adult patients

Data cut-off: ICP-CL-00505 (2024-06-11); ICP-CL-00501 (2024-04-18)

# **Key Milestones in Next 12 Months**



	Assets	Milestones
Commercialization	Commercialization	Rapid sales growth   Guidance Raised
& BD	BD	Strive to get BD deals
		NDA approval for 1L CLL/SLL in CHN
Orelabrutinib	Orolohrutinih	NDA approval for r/r MZL in Singapore
	Oreiabrutinib	NDA submission for CLL/SLL, r/r MCL, r/r MZL overseas
		Ph3 registrational trial for combination with ICP-248 in 1L CLL/SLL enrollment completed
Hemato-oncology	Tafasitamab	BLA approval in CHN for r/r DLBCL
field of offooregy	Mesutoclax (ICP-248)	Data readout: BTKi-treated r/r NHL; Combination with orelabrutinib in 1L CLL/SLL Ph2 trial longer efficacy
		Ph3 registrational trial for combination with orelabrutinib in 1L CLL/SLL enrollment completed
		Registration trial initiation in BTKi-treated r/r MCL patients
		Completion of AML dose escalation
		Completion of ITP Ph3 registration trial, NDA submission in 2026H1
	Orelabrutinib	Global Ph3 registrational trial initiation in PPMS, FPI
		Global Ph3 registrational trial initiation in SPMS, FPI
Autoimmune	Data readout: SLE Ph2b study	
Diseases	Soficitinib	Completion of patient enrollment for Ph3 AD trial
	(ICP-332)	Completion of patient enrollment for Ph2 vitiligo trial
	ICP-488	Completion of patient enrollment for Ph3 psoriasis trial
S. Zurletrectinib	Zurletrectinib	NDA submission for adult and adolescent patients in CHN
rent and a second se	(ICP-723)	NDA Submission for pediatric patients in CHN
Solid Tumor	ICP-B794	Initiate clinical trial and try to get PoC in the clinic by the end of 2025
	ICP-189	Data readout: Combo with EGFRi in NSCLC



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**Empowering the Future Together** 

Thank you for your attention !

**SINCE 2015** 

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