

InnoCare Pharma 2023 Annual Results Earnings Call

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March 28, 2024

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

To Become a Global Biopharmaceutical Leader that Develops and Delivers Innovative Therapies for Patients Worldwide

Oncology





Autoimmune

Our Therapeutic Focus



Key Achievements in 2023

Commercialization

- Orelabrutinib revenue +18.5% yoy growth
 - ✓ r/r MZL NDA approved as the first and only BTKi for r/r MZL in China
 - Successful renewal of r/r MCL, r/r CLL/SLL and addition of r/r MZL to NRDL coverage without price cut
- Strengthen commercial team for sustained success

Financial

- Total revenue reached RMB 739mn,
 +18.1% yoy growth
- Gross profit increased by 26.6% to RMB 610.1mn
- Loss for the year decreased by 27.8% to RMB 645.5mn
- Cash balance of RMB 8.2bn providing strong bases for future development and flexibility

Operation

- Removed 'B' in HKEx
- GZ manufacturing site commenced commercial production of Orelabrutinib resulting in cost reduction
- Improved ESG with environmental friendly operations
- Rolled out company 2.0 objectives

NDA Approval / Registrational Trial Progress

Orelabrutinib

- r/r MZL approval in China
- r/r MCL approval in Singapore
- Finished 1L CLL/SLL Ph III enrollment, NDA submission in 2024Q3
- Finished r/r MCL in US Ph II enrollment, NDA submission in 2024Q3

Tafasitamab

- r/r DLBCL approval in Hong Kong
- Early access programs in Hainan & GBA
- Finished r/r DLBCL enrollment in mainland China, BLA submission in 2024Q2

Key Clinical Trials

Orelabrutinib

- 1L MCL global Ph III initiated
- ITP Ph III targeting enrollment completion in 2024
- SLE Ph IIb targeting enrollment completion and interim analysis in 2024
- Combo with ICP-248 in 1L CLL/SLL

ICP-248 (BCL-2)

- PoC in NHL
- US clinical trial initiation

ICP-332 (TYK-2 JH1) finished Ph II study and got PoC in AD

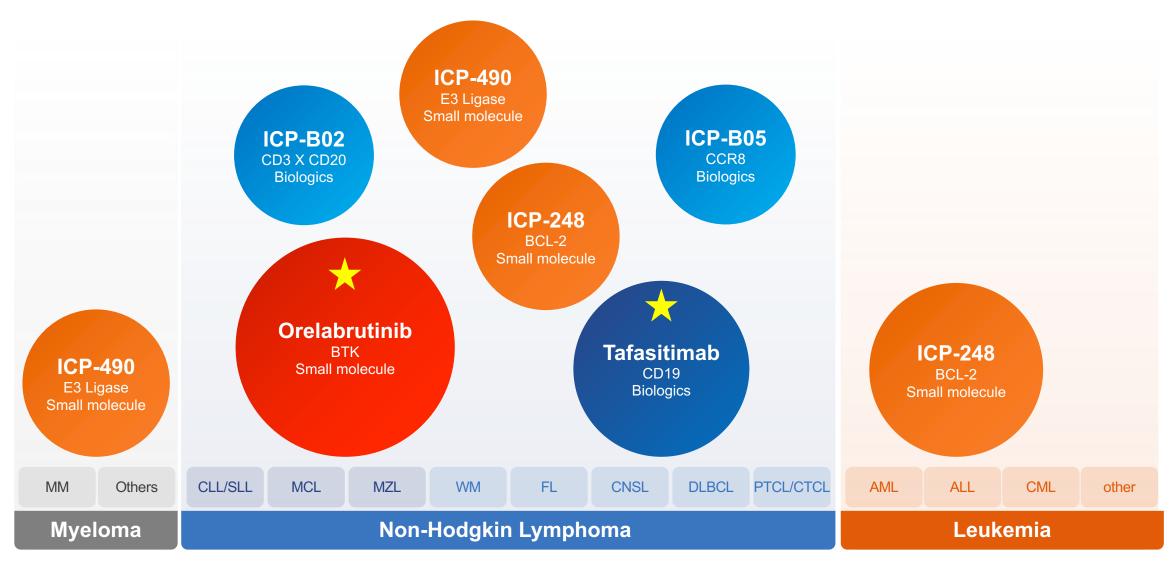
ICP-488 (TYK-2 JH2) PoC in Psoriasis, Ph II data readout by end of 2024

ICP-723 (NTRK) registration trial ongoing, targeting NDA submission in 2024 ICP-189 (SHP2) combo with 3rd gen EGFRi* FPI, targeting PoC in 2024

9 IND approvals



Comprehensive Coverage in Hemato-oncology Indications & MOAs

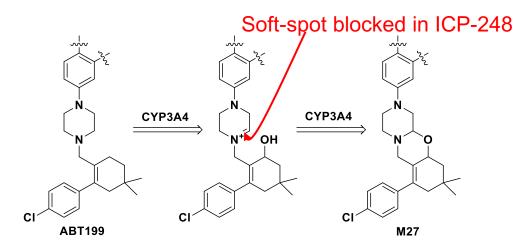


Expand into Front Line Therapies in Large Indications either as Monotherapy or in Combination with Other Agents





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

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

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

Advantages of ICP-248



Eliminated major metabolite



Reduced DDI risks



Improved PK & efficacy

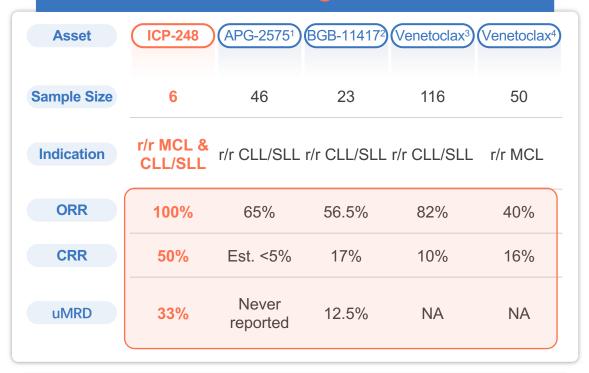


Good safety profile



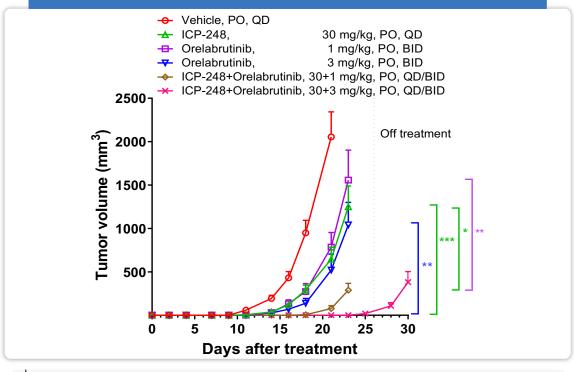
ICP-248 will be Developed as Mono-therapy or in Combination with Orelabrutinib in the Treatment of Hematological Malignancies

ORR 100% at 100 mg QD: 6 out of 6



- 100% efficacy at 100 mg QD (25 patients dosed, 6 evaluated at RP2D)
- **33% uMRD**
- Excellent PK profile
- Safe and well tolerated

Significant Synergy with Orelabrutinib



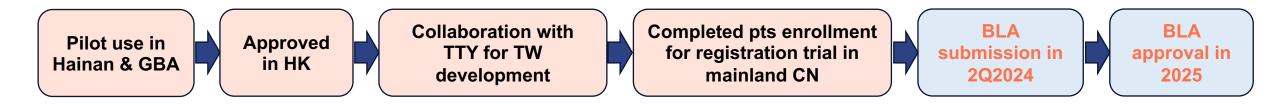
Great combination potential in China and global markets

✓ 1L CLL/SLL fixed duration therapy

✓ 1L AML

CR: Complete response; PR: Partial Response; uMRD: unmeasurable residual disease

Tafasitamab: For the Treatment of r/r DLBCL

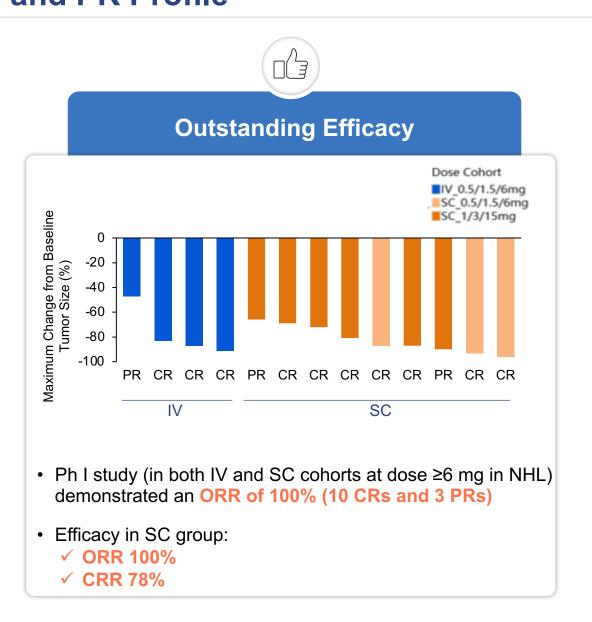


Comparison of Selected Novel Therapy in r/r DLBCL

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	II	43	19	11.6	3.7	5.0
Regeneron/ Zai Lab	CD20/CD3	Mosunetuzumab	II	33	21	N/A	N/A	N/A
AbbVie	BCL-2	Venetoclax+R+Pola	II	65	31	5.8	4.4	11

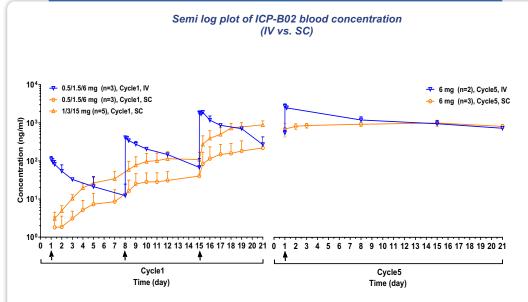
INNOCARE

ICP-B02: Subcutaneous (SC) CD3xCD20 BsAb Shows Outstanding Efficacy and PK Profile



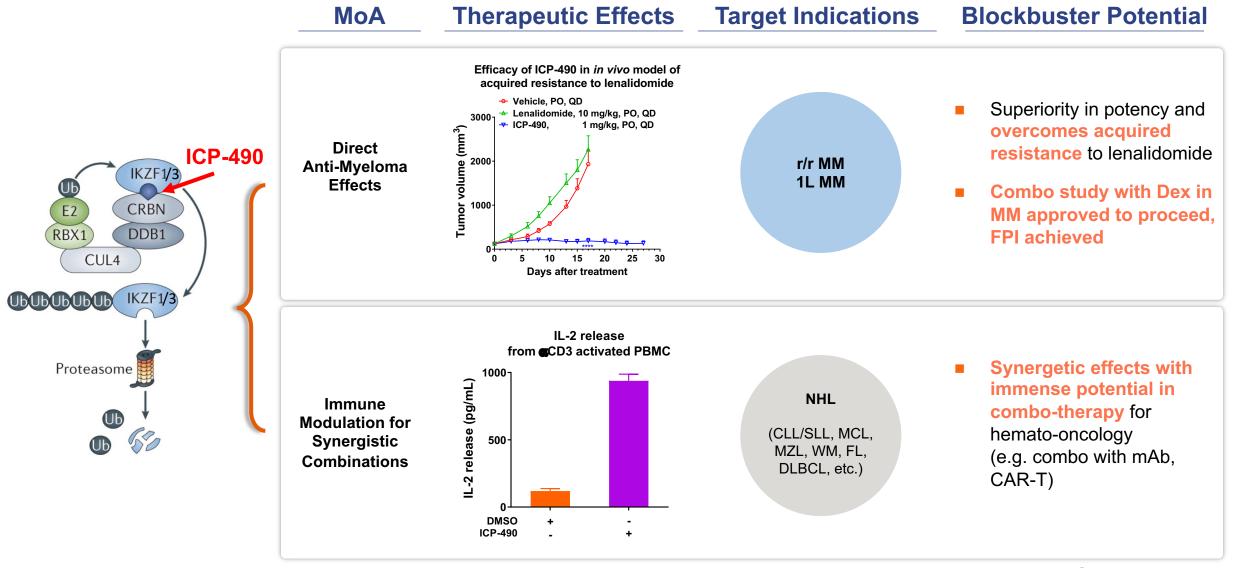


Excellent PK Profile



- ICP-B02 (SC) has demonstrated a favorable linear PK and comparable to IV dosing.
- SC dosing has been selected for further exploration

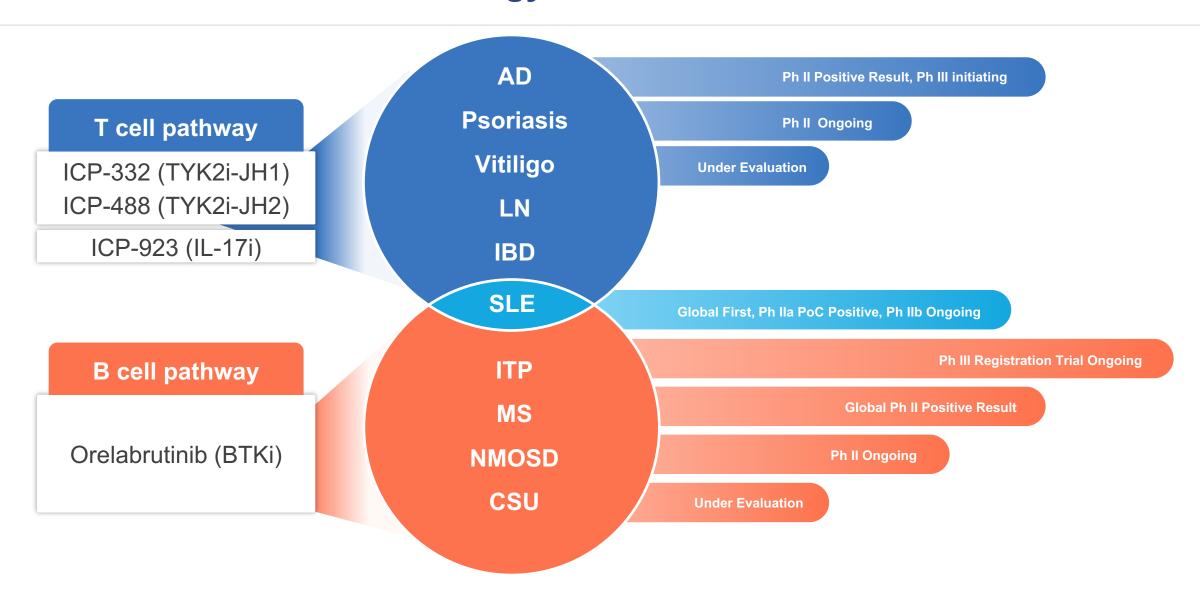
ICP-490: Molecular Glue Provides New Possibility in the Treatment of Multiple Myeloma with Synergistic Effect with Existing Treatment

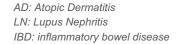


Well Positioned Portfolio in Autoimmune Diseases



Autoimmune Disease Strategy



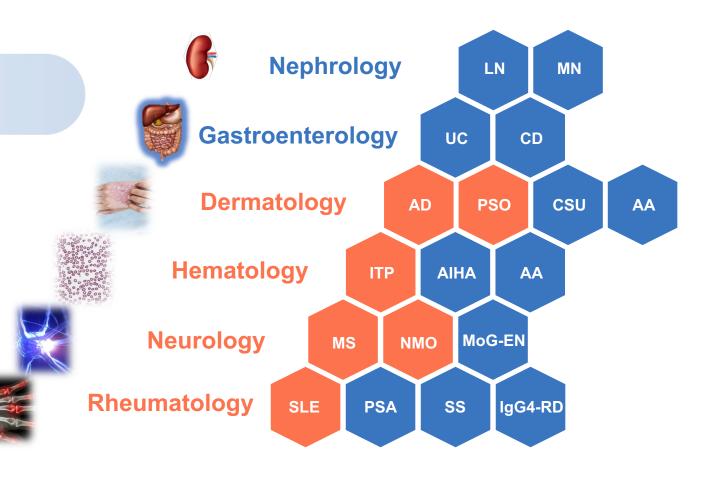


Enormous Unmet Medical Needs Exist in Autoimmune Diseases

>150 autoimmune diseases identified

>500 Mn patients world wide

>40 Mn patients in China



AA: Aplastic Anemia AIHA: Autoimmunehemolytic Anemia CD: Crohn's Disease CLE: Cutaneous Lupus Erythematosus IgG4 RD: Immunoglobulin G4-related disease ITP: Immune thrombocytopenic purpura

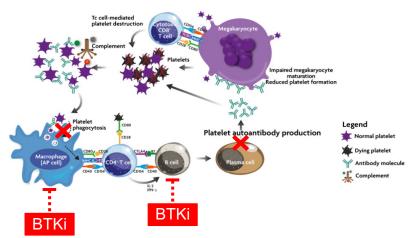
LN: Lupus Nephritis MN: Membranous Nephropathy MoG-EN: MOG encephalomyelitis MS: Multiple Sclerosis NMO: Neuromyelitis optica PsA: Psoriatic Arthritis PsO: Psoriasis SLE: Systemic Lupus Erythematosus SS: Sjogren syndrome



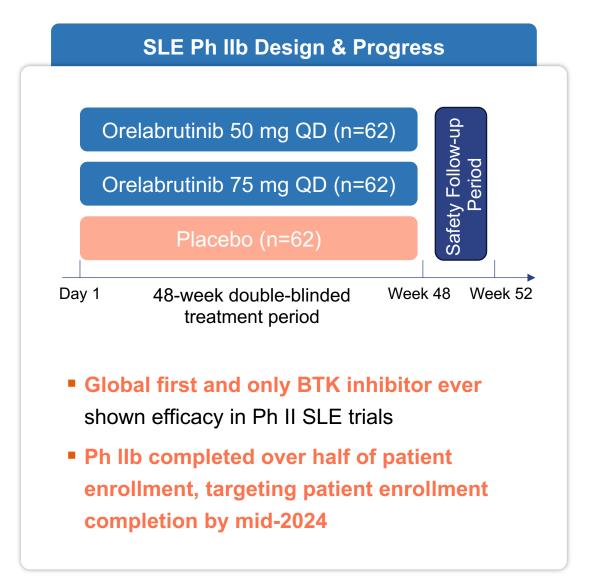
Orelabrutinib: ITP Registrational Trial and SLE Ph IIb Targeting Enrollment Completion in 2024

ITP Ph III Registrational Trial

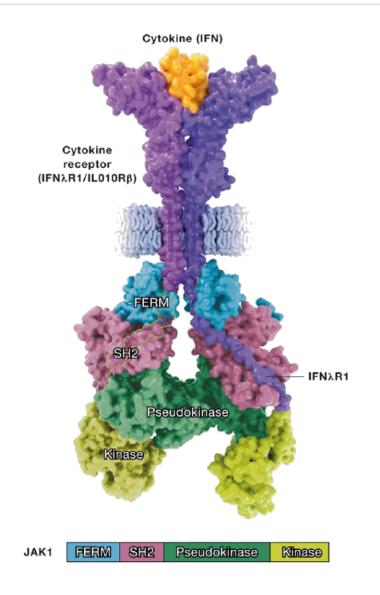
- Ph II result:
 - √ 40% patients met the primary endpoint at 50mg QD
 - ✓ 83.3% achieved durable response among patients who met the primary endpoints
 - √ 75% of patients, who previous responded to GC or IVIG, met the primary endpoint
- Ph III: registrational trial ongoing in China, targeting enrollment completion in 2024

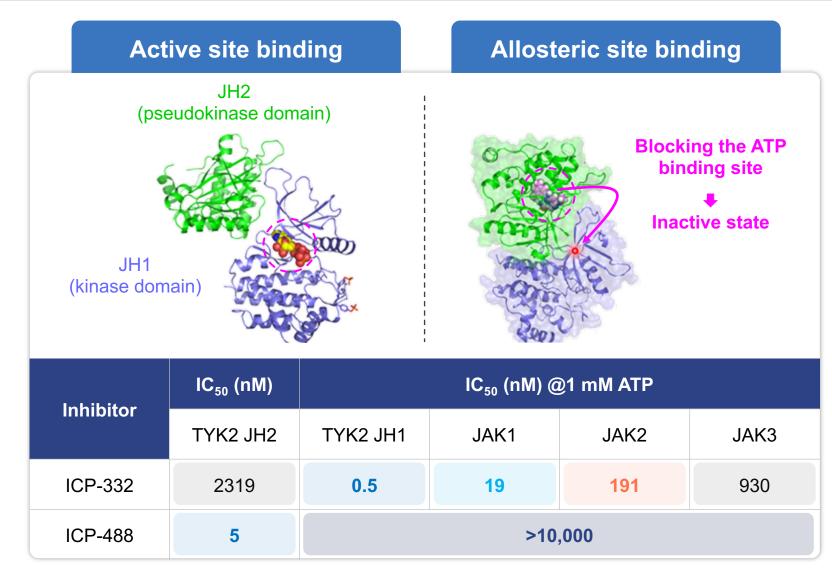


- Decreased macrophage (Fcy receptor)—mediated platelet destruction
- · Reduced production of pathogenic autoantibodies



ICP-332, ICP-488: TYK2 Inhibitors with Different Selectivity Profiles

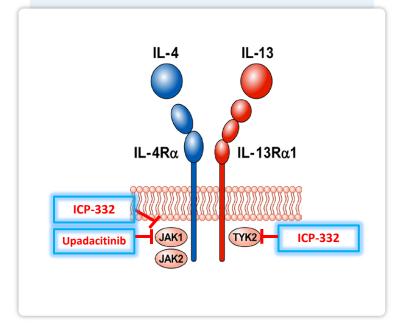




ICP-332: Major TYK2 Plus Minor JAK1 Inhibition Provides New Possibilities for Effective Treatment of Atopic Dermatitis (AD)



Inhibition of TYK2/JAK1 Possesses Potential Synergy



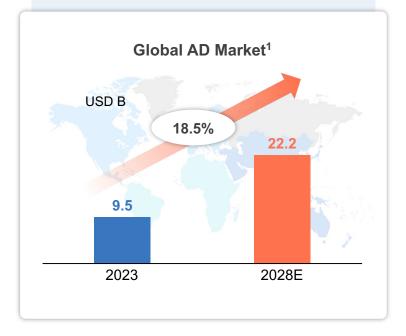


Heavy Disease Burden



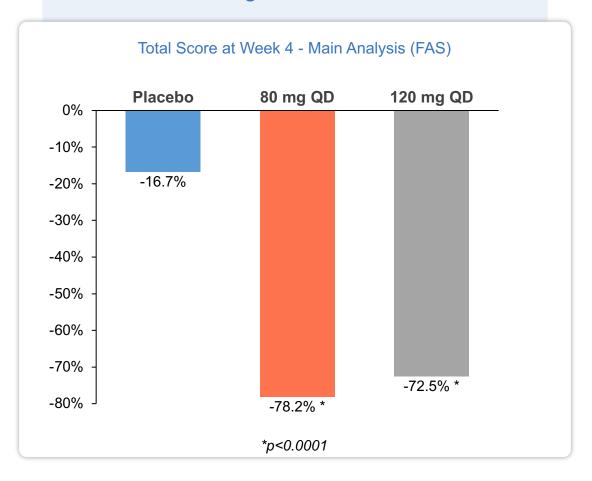


Extensive Market Potential

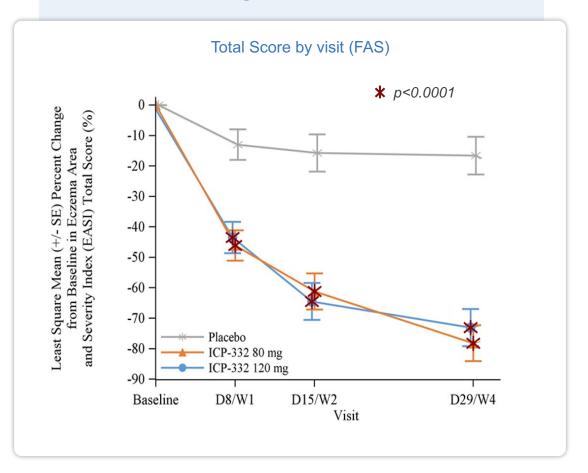


ICP-332 Significantly Improved EASI Scores from Baseline in Phase II for the Treatment of AD Patients

Percent Change from Baseline in EASI



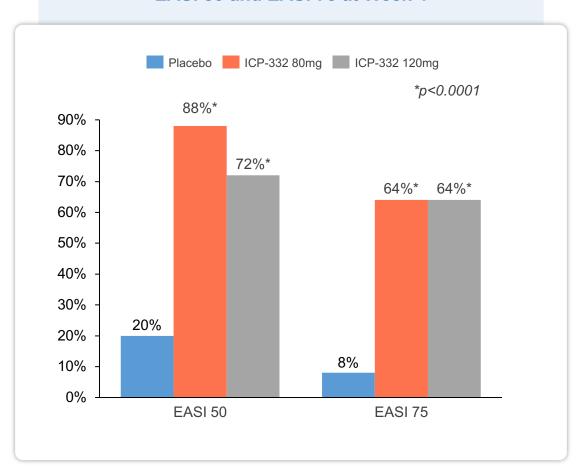
Percent Change from Baseline in EASI



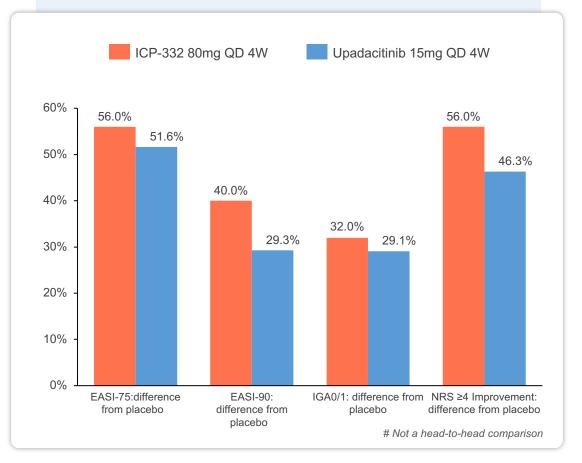
EASI: Eczema Area and Severity Index; FAS: Full Analysis Set

ICP-332 Demonstrated Great Efficacy in All Analyses in Ph II for AD

EASI 50 and EASI 75 at Week 4



Efficacy Comparison of ICP-332 with Upadacitinib at Week 4^{1,#}

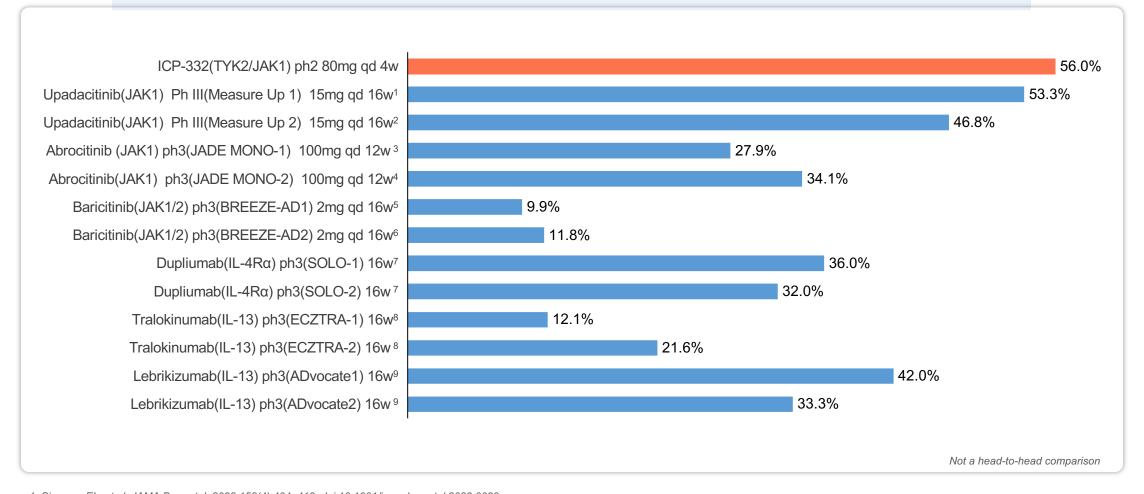


EASI: Eczema Area and Severity Index; FAS: Full Analysis Set Source: 1. Simpson EL, et al. JAMA Dermatol. 2022;158(4):404–413. doi:10.1001/jamadermatol.2022.0029



ICP-332 in Ph II Showed Top Efficacy Profile Across Different Classes / **MoAs of Therapies for the Treatment of AD Patients**

Comparison of ICP-332 with Various Innovative Drugs on EASI 75 (Subtracted Placebo)

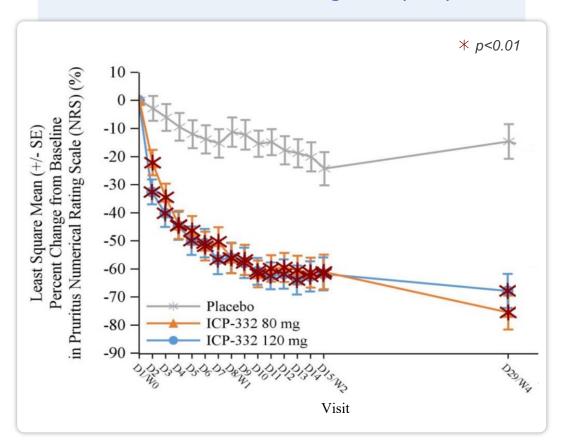




Quick Response in Pruritus Numerical Rating Scale (NRS) and Significant Improvement of Life (DLQI)

Quick and Statistically Significant Response from Day 2

Pruritus Numerical Rating Scale (NRS)



Improvement of Patients' Quality of Life

Dermatology Life Quality Index (DLQI) Score Change from Baseline by Visits (Full Analysis Set)

	Placebo (N=25)	ICP-332 80mg (N=25)	ICP-332 120mg (N=25)
D8/W1	-3.3(-4.8,-1.9)	-6.5(-8.0,-5.1)	-6.8(-8.4,-5.3)
	p-value	0.0027	0.0018
D15/W2	-2.2(-4.2,-0.2)	-8.7(-10.7,-6.7)	-7.9(-9.9,-5.9)
	p-value	<0.0001	0.0002
D29/W4	-1.2(-3.3,0.9)	-10.8(-12.8,-8.8)	-8.9(-11.0,-6.8)
	p-value	<0.0001	<0.0001

Safety and Tolerability Profiles Similar to Placebo

Overall Summary of Treatment-Related Adverse Events (TRAE)

	Placebo (N = 25)	ICP-332 80 mg (N = 25)	ICP-332 120 mg (N = 24)
All TRAEs	9 (36.0%)	6 (24.0%)	10 (41.7%)
Mild	8 (32.0%)	6 (24.0%)	8 (33.3%)
Moderate	1 (4.0%)	0	2 (8.3%)
Severe	0	0	0
Serious TRAEs	0	0	0
TRAEs leading to drug interruption	0	0	1 (4.2)
TRAEs leading to drug withdrawn	1 (4.0%)	0	0
TRAEs leading to death	0	0	0

Infections and Infestations (TRAE)

	Placebo (N = 25)		ICP-332 80 mg (N = 25)		ICP-332 120 mg (N = 24)	
System Organ Class Preferred Term	n (%)	Events	n (%)	Events	n (%)	Events
Infections and infestations	2 (8.0)	2	0	0	2 (8.3)	2
Folliculitis	1 (4.0)	1	0	0	1 (4.2)	1
Upper respiratory tract infection	0	0	0	0	1 (4.2)	1
Nasopharyngitis	1 (4.0)	1	0	0	0	0

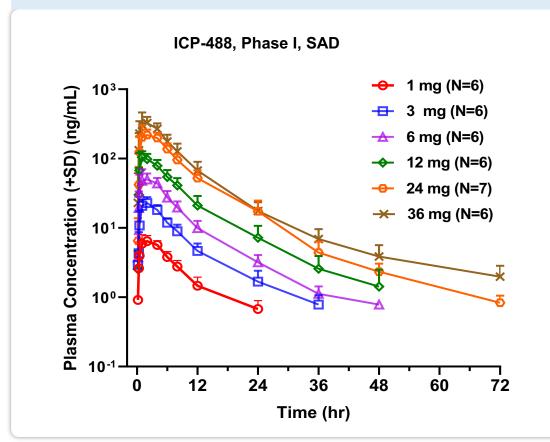
In this study, ICP-332 did not exhibit adverse events of those mentioned in the black box warning* for Upadacitinib



ICP-488: Ph I PK Profile in Healthy Volunteers

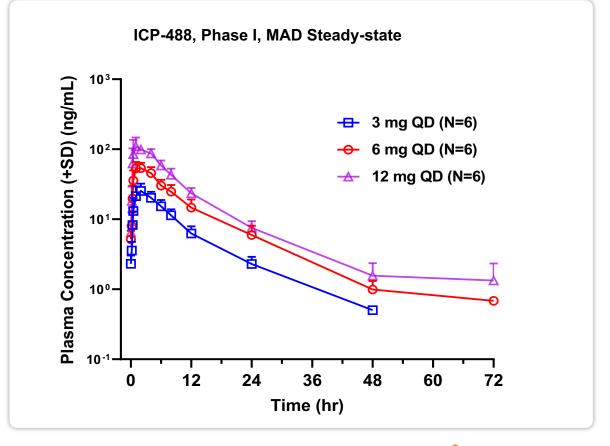
Dose Proportional and Linear PK in SAD

- Linear pharmacokinetics in SAD
- The mean half-life: 7.2-11.2 hrs

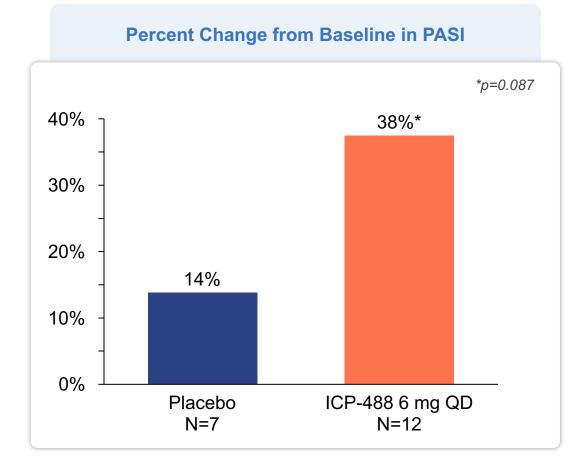


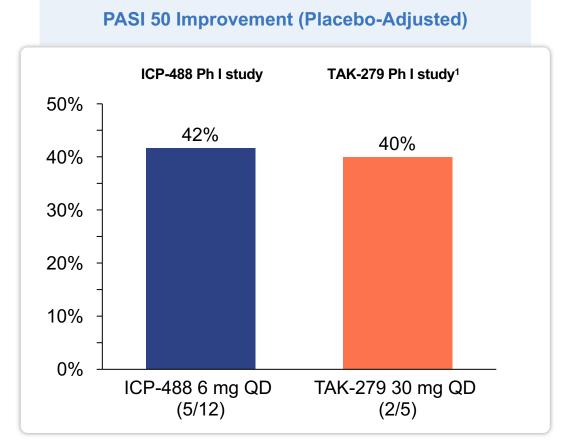
Dose Proportional and Linear PK in MAD

C_{av} at 6 mg QD reached the IC₅₀ of TYK2-mediated signaling inhibition



ICP-488: 4-week Study in Psoriasis Cohort in Ph I

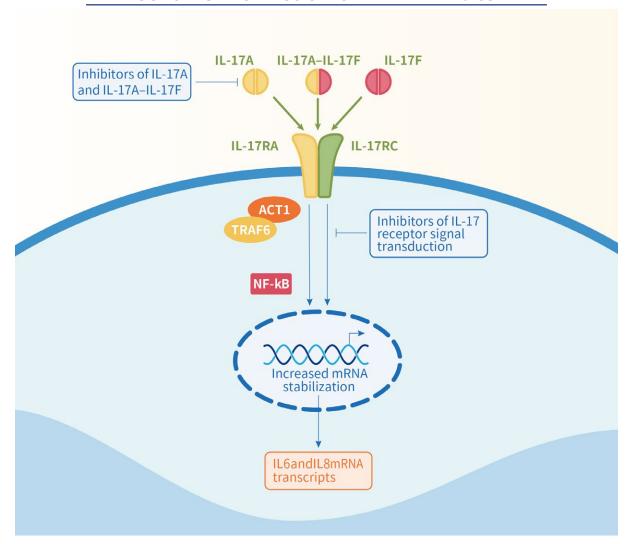




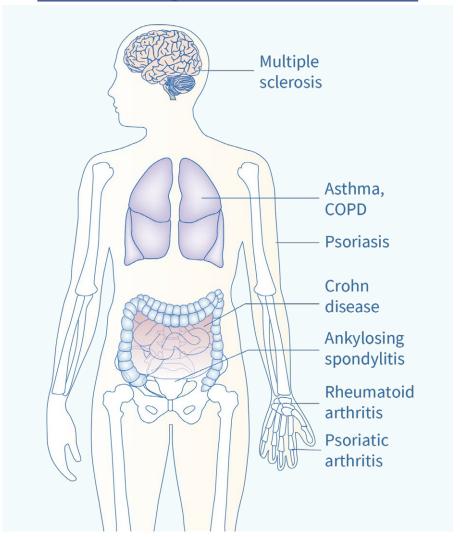
All TEAEs and TRAEs were mild or moderate comparable with placebo arm

IL-17 is Widely Involved in Autoimmune Diseases

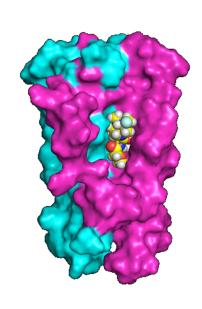
Mechanism of Action of IL-17 Inhibitor



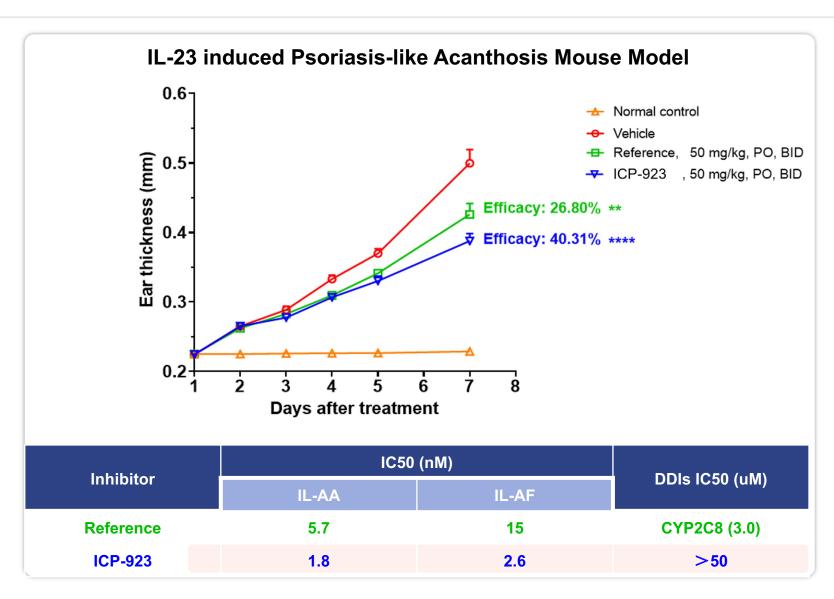
Target Indications



ICP-923: A Novel Small Molecule Inhibitor of IL-17 for the Treatment of Autoimmune Diseases

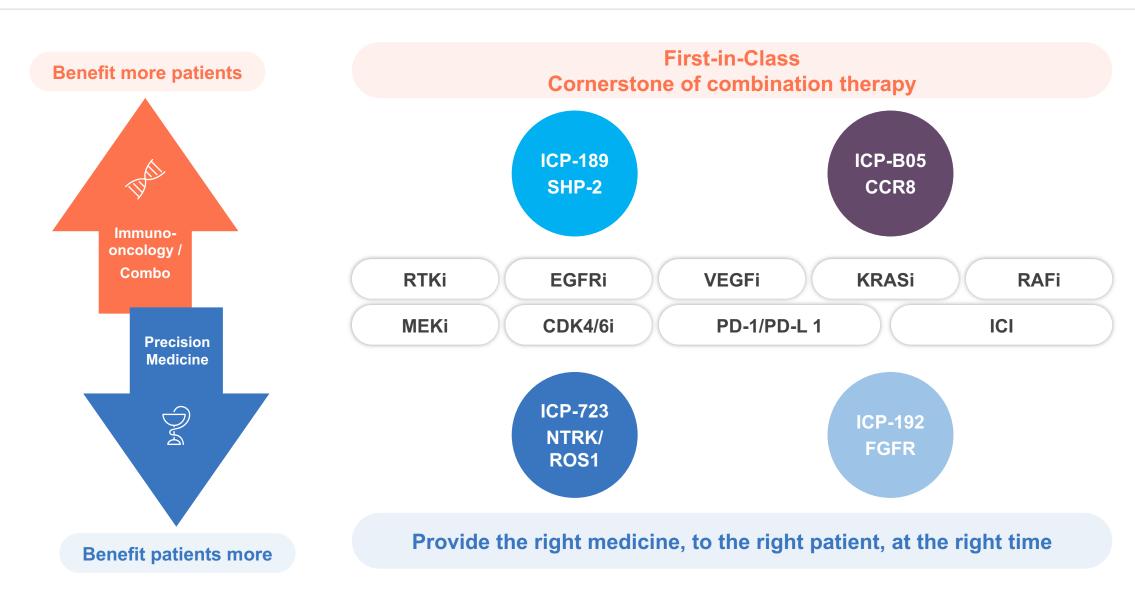


✓ ICP-923 inhibits both IL-17AA and IL-17AF for achieving clinical advantages



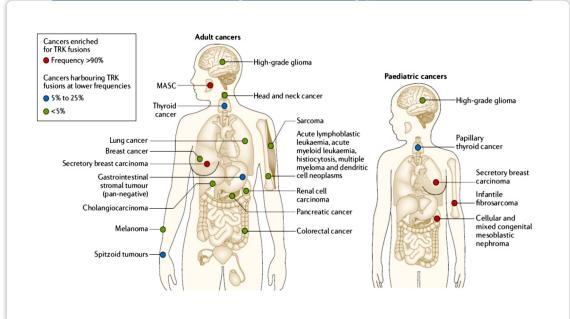


Solid Tumors Strategy



ICP-723: Favorable Clinical Results with Potential Best-in-Class Profile

NTRK Gene Fusion is an Oncogenic Driver for a Variety of Cancer Types





- Ph II registration trial ongoing for NTRK gene abnormalities, NDA submission expected by end of 2024
 - ✓ ORR: 80-90%
 - ✓ Long duration of response (longest beyond 36 months)
- Efficacy observed in pediatric patient
- Efficacy observed in TRKi-resistant patient

ICP-189: SHP2 Inhibitor with Large Potential in Combinational Treatments





ICP-189 SHP2 Inhibitor



Furmonertinib EGFR Inhibitor

Mono-therapy Progress

- First-in-Class
- SHP2 inhibitor for NSCLC & others
- Excellent PK and tolerability demonstrated in Ph I dose escalation
- Single agent efficacy observed
- Class-leading safety profile: No grade 3 or higher TRAEs observed up to 120 mg

Combo-therapy Strategy

- Target major market in NSCLC by combination with EGFRi
 - ✓ SHP2 is involved in EGFR signaling as well as other receptor tyrosine kinases that contribute to EGFR resistance
 - Ph I dose escalation for combo with EGFRi* in NSCLC, FPI achieved
 - ✓ PoC targeting within 2024



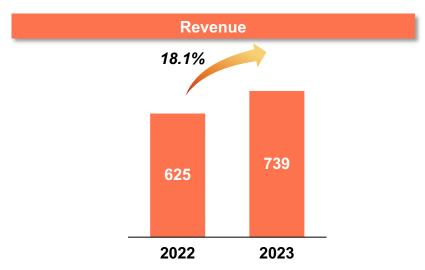
Anticipated Milestones in Next 12 Months

	Assets	Milestones				
		NDA submission for 1L CLL/SLL in CHN				
	Orelabrutinib	NDA submission for r/r MCL in the US				
		Combo with ICP-248 in 1L CLL/SLL data readout to support Ph III initiation				
	Tafasitamab	NDA submission in CHN for r/r DLBCL				
Hemato- oncology	ICP-248	Dose expansion results readout				
	IOF -240	US trial initiation				
	ICP-B05 PoC in NHL					
	ICP-B02	Dose definition for expansion				
Autoimmune Diseases	Orelabrutinib	Completion of SLE Ph IIb patient enrollment				
	Oreiabiatinib	Completion of ITP Ph III patient enrollment				
		Ph III initiation on AD				
	ICP-332	Ph II initiation in vitiligo in CHN				
		US trial initiation				
	ICP-488	Completion of Ph II enrollment				
A S	ICP-189	Combo with EGFRi in NSCLC data readout				
Solid Tomor	ICP-723	Completion of patient enrollment of registrational trial				
Solid Tumor	IOF-123	NDA submission in CHN				

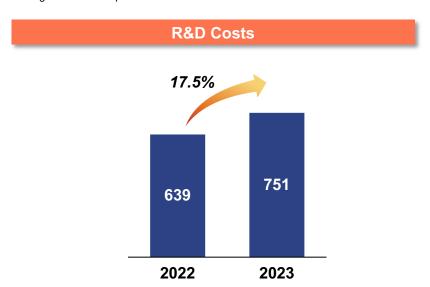


Key Financials for 2023

Based on HKFRSs (RMB million)



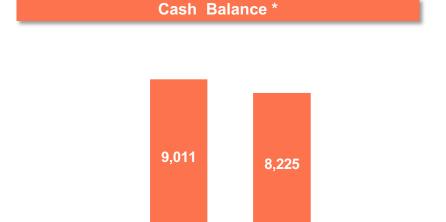
Revenue continued ramping up with new indication approved, as well as increased hospital coverage and broader penetration



R&D expenses increased with significant progress for clinical trials in multiple pipelines and strategic investment in early-stage candidates poised to become future assets



Loss for the year decreased by 27.8% due to revenue sales ramp up, operational efficiency improvement and the less unrealized exchange loss



2023

2022

^{*} Includes cash and bank balances, and Financial assets at fair value through profit or loss.

Robust cash balance of RMB8.2bn (~US\$1.2bn) provides flexibility to expedite the clinical development and to invest in a competitive pipeline.

