

## InnoCare Pharma 2024 Interim Results

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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

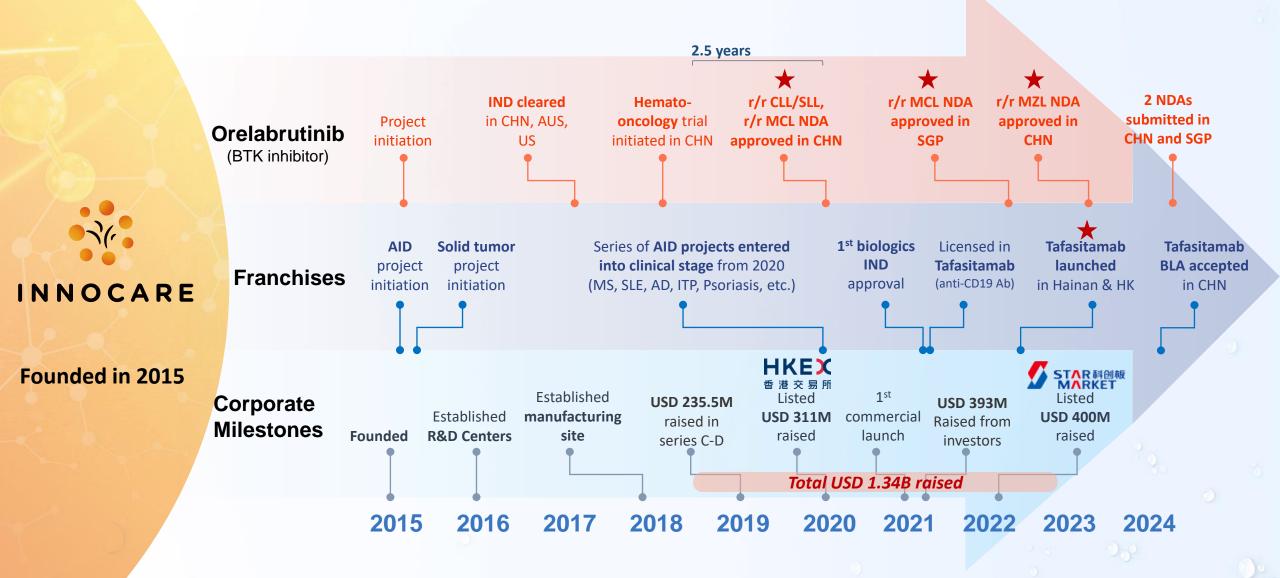




**Autoimmune** 

**Our Therapeutic Focus** 

#### **Exciting 9 Years Journey of Innovation and Development**

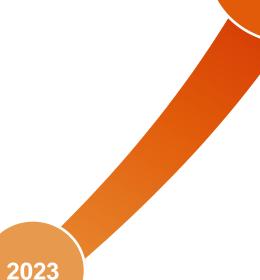




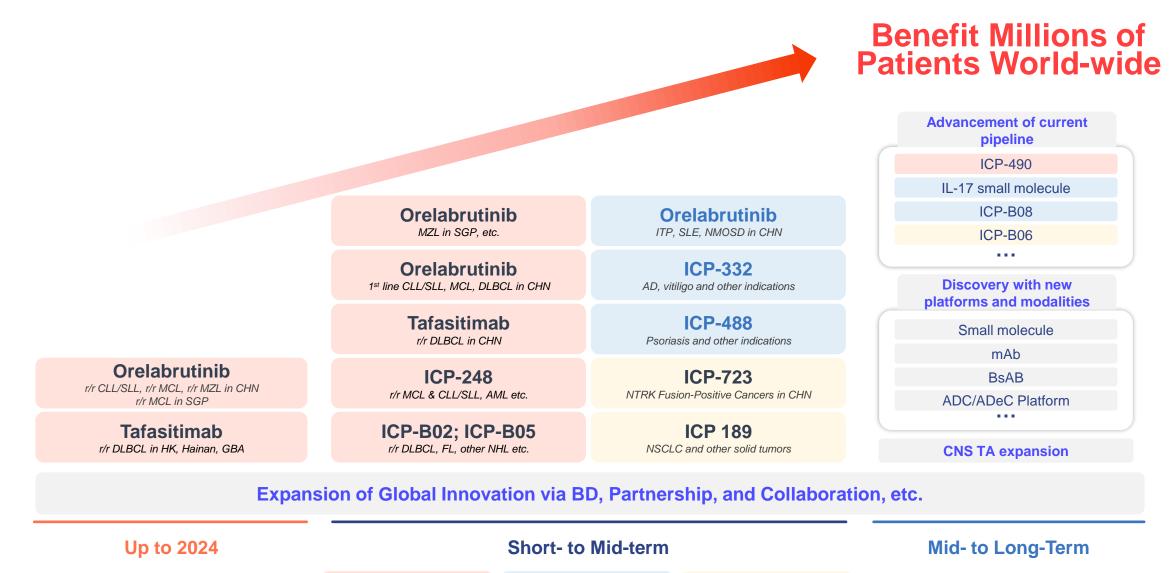
#### 2.0 Objective: Provide More Innovative Drugs to Patients

#### ✓ ≥ 6 commercial products

- Marketed: Orela-Hema①, Tafa\* (Hainan, HK)
- Tafa② (China mainland), ICP-723③
- Orela-AID @ (ITP, SLE, MS); ICP-248 ⑤, ICP-332 ⑥, ICP-488 ⑦
- Others: ICP-490, ICP-189, ICP-B02, ICP-B05...
- A recognized leader in hemato-oncology
- A strong competitor in autoimmune diseases and solid tumor
- ✓ Additional 5-10 well-positioned assets, unique research platforms
- **✓ 3-4 products globalization** (out-license, partnership, etc.)
- ✓ Significant revenue increase
- ✓ Further strengthen R&D, BD, manufacturing and commercialization platforms, operational excellence



## Strong Growth Momentum Secured by Robust Portfolio and Fueled by Global Innovation & Collaboration



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Hemato-oncology

franchise

#### **Business Highlight in H1 2024:**

#### Outstanding performance underpins foundations for future sustainable growth

#### **Increasing Commercial Growth**

- Orelabrutinib revenue achieved RMB417M with 30% yoy growth in H1 2024, 49% yoy growth in Q2 2024
- Expect Orelabrutinib revenue will continue to grow with:
- √ First and only BTKi for r/r MZL in China
- ✓ Class I option of r/r MZL in the CSCO Guidelines for Malignant Lymphoma for 2024
- ✓ New NRDL implemented, r/r CLL/SLL, r/r MCL and r/r MZL are all covered with no price cut
- ✓ Commercial team strengthened, clear marketing strategy and strong execution with
  efficient approach

#### **Strong Financial Result**

- Total revenue reached RMB419.7M in H1 2024
- Gross profit margin continues to improve, increased to 85.7%
- Loss of period decreased by 37.6% compare to last year
- Cash and related balance\* of RMB8B providing strong bases for future development and flexibility

#### **Significant Progress of Clinical Trials**

#### **Orelabrutinib**

- Accelerated 1<sup>st</sup> line trials in hemato-oncology
- 2 NDAs submitted
- Combo with ICP-248 in 1L CLL/SLL, patients enrollment for PII completed

#### **Tafasitimab**

- BLA for r/r DLBCL accepted under priority review
- PIII trial is ongoing

#### ICP-248 (BCL-2)

- Dose escalating and expanding is on going
- US clinical trial initiation
- AML IND submitted, move to clinical stage in 2024

#### **Orelabrutinib**

- ITP Ph III targeting enrollment completion in 2024/2025Q1
- SLE Ph IIb targeting enrollment completion and interim analysis in 2024

#### ICP-332 (TYK-2 JH1)

- Ph III in AD initiated
- IND for Ph II/III trial in Vitiligo submitted
- US clinical trial started

#### ICP-488 (TYK-2 JH2)

 PoC in Psoriasis achieved, Ph II data readout by end of 2024

#### **ICP-723 (NTRK)**

 Entered into Pre-NDA stage, targeting NDA submission in 2025Q1

#### ICP-189 (SHP2)

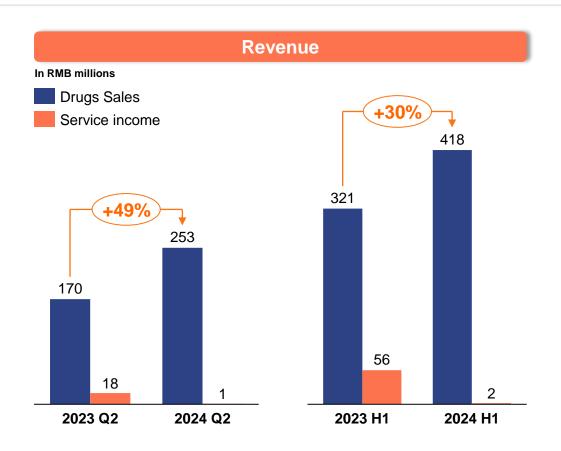
 Combo with 3<sup>rd</sup> gen EGFRi\*\* FPI, promising results observed, targeting PoC in 2024

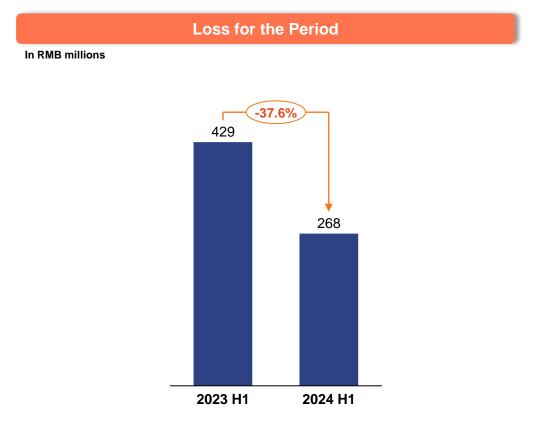
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Financial/Commercial Highlight



#### Q2 Drug Sales Increased by 49%, H1 2024 Total Loss Decreased by 38%





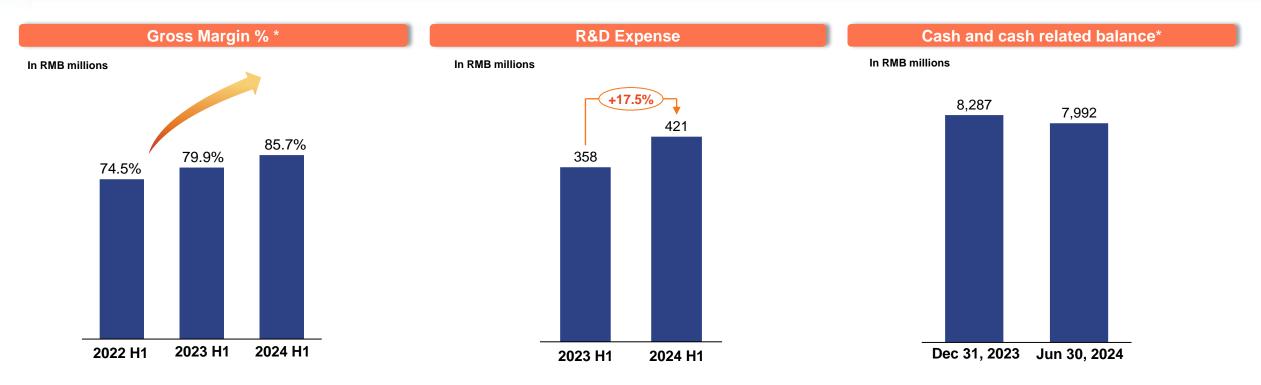
Drug sales growth was increased in Q2, full year drug sales guidance raised to ≥ 35%

Loss of the period narrowed down by RMB161M / 37.6% yoy attributed to drug sales growth, cost improvement and decreased unrealized exchange loss



#### **Driving for Sustainable Business Growth**

Strong cash position to invest in pipeline development with improved efficiency



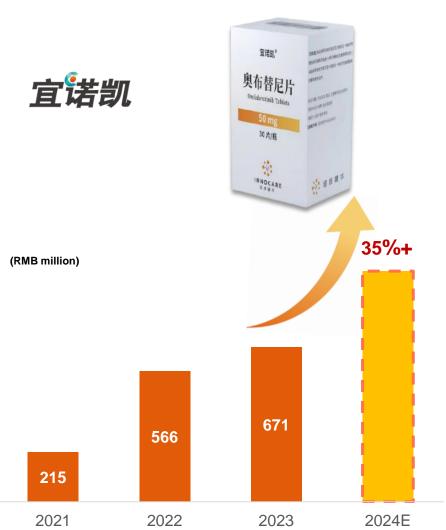
Gross profit margin keeps increasing for 3<sup>rd</sup> consecutive year to 85.7% in 2024H1, attributing to the orelabrutinib revenue increase and changes in revenue composition

R&D expenses increased for strategic investment for innovative technology platform, and increased resources to clinical trials for our prioritized programs

Robust cash and cash related balance of RMB8B (~US\$1.1B) provides flexibility to expedite the clinical development and to invest in a competitive pipeline

#### **Commercialization Review**

Achieved high growth with excellent product profile and strong commercial capability



#### Untapped MZL Market With Huge Potential

- First and only BTKi for r/r MZL in China, MZL is considered to be the2nd largest NHL
- Recommended as a class I regimen in the CSCO Guidelines
- Committed to be market leader for this indication.

#### **Maximizing Potential for r/r CLL/SLL, r/r MCL**

- Extending DOT leveraging preferred efficacy and safety profile
- Enhancing product recognition with multiple real-world studies and evidence
- Advancing hospital access to increase market share

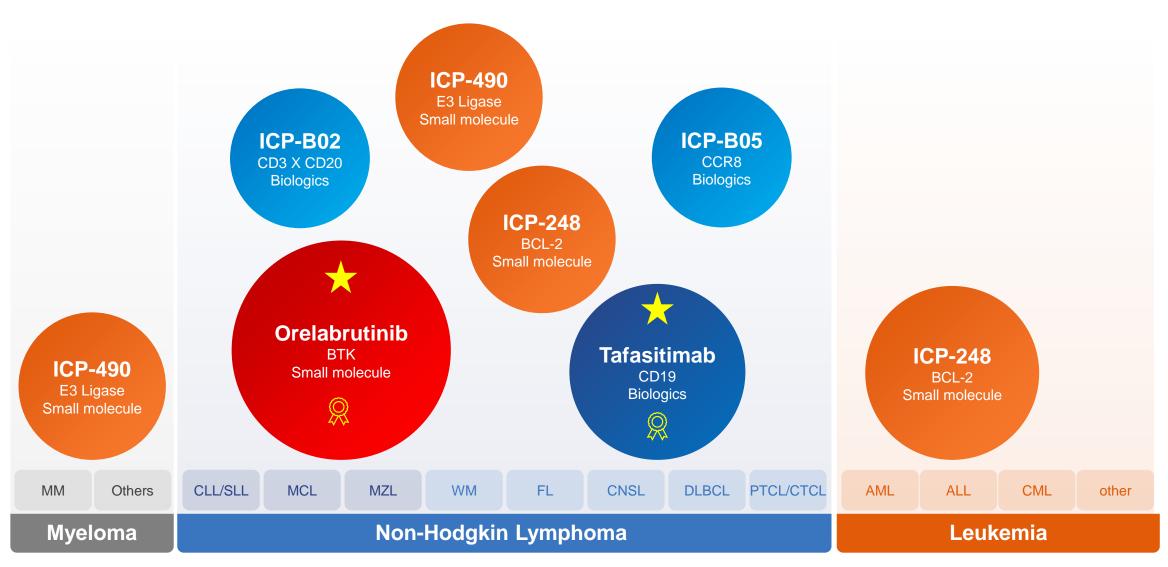
#### **Strong Execution**

- Experienced commercial leadership team in hemato-oncology
- Optimized strategy and quick deployment
- Enhanced productivity and cost efficiency





#### Comprehensive Coverage in Hemato-oncology Indications & MOAs





#### Tafasitamab: For the Treatment of r/r DLBCL

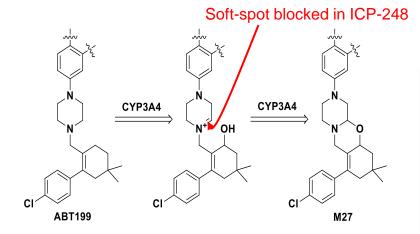


#### **Comparison of Selected Novel Therapy in r/r DLBCL**

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	11	65	31	5.8	4.4	11

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#### 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 ≤ 0.82 µM

Significant inhibition of P-gp and BCRP by Venetoclax and M27 with IC50 ≤ 1.48 µM

#### **Advantages of ICP-248**



Eliminated major metabolite



Reduced DDI risks



Improved PK & efficacy



Good safety profile

#### **ICP-248** development strategy

Dose Expansion at 100mg (r/r CLL/SLL, r/r MCL, Other NHL)

Combo with Orelabrutinib
(1L CLL/SLL)

#### **US trial in NHL**

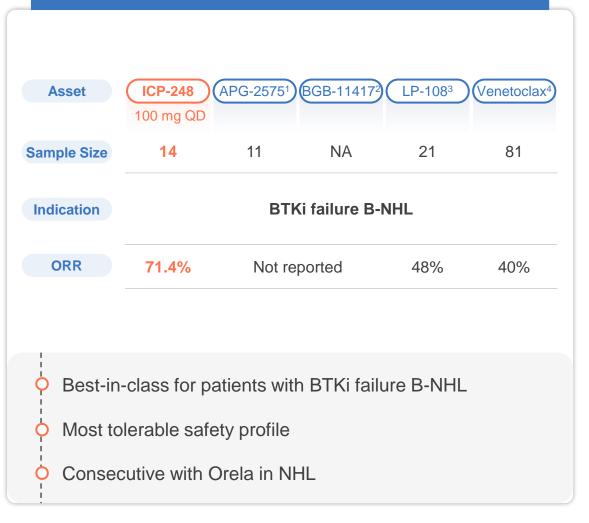
Dose Escalation at 150mg (r/r CLL/SLL, r/r MCL, Other NHL)

1L AML IND Accepted

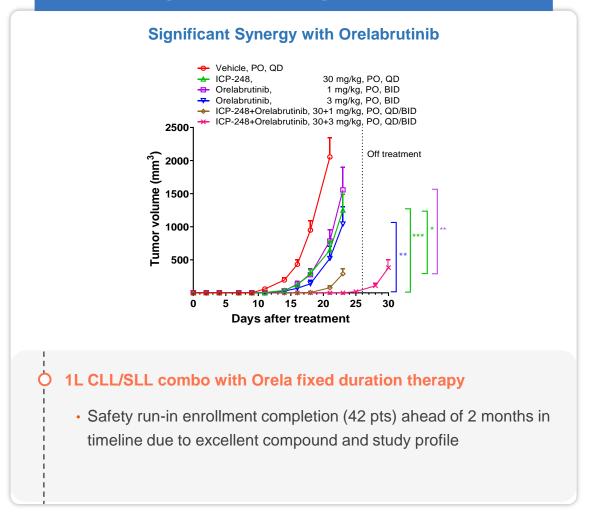


## ICP-248: Mono-therapy or in Combination with Orelabrutinib in the Treatment of Hematological Malignancies

#### **Best-in-class in both efficacy and safety**



#### **Expanding and Evolving ICP-248 Portfolio**



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

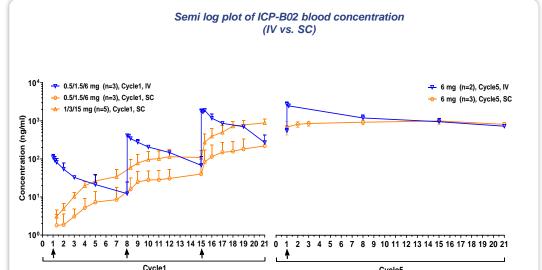




- Ph I study (in both IV and SC cohorts at dose ≥6 mg in NHL) demonstrated an ORR of 100% (10 CRs and 5 PRs)
- Efficacy in SC group:
  - √ ORR 100% (7 CRs and 4 PRs)
  - ✓ CRR 63.6%



#### **Excellent PK Profile**

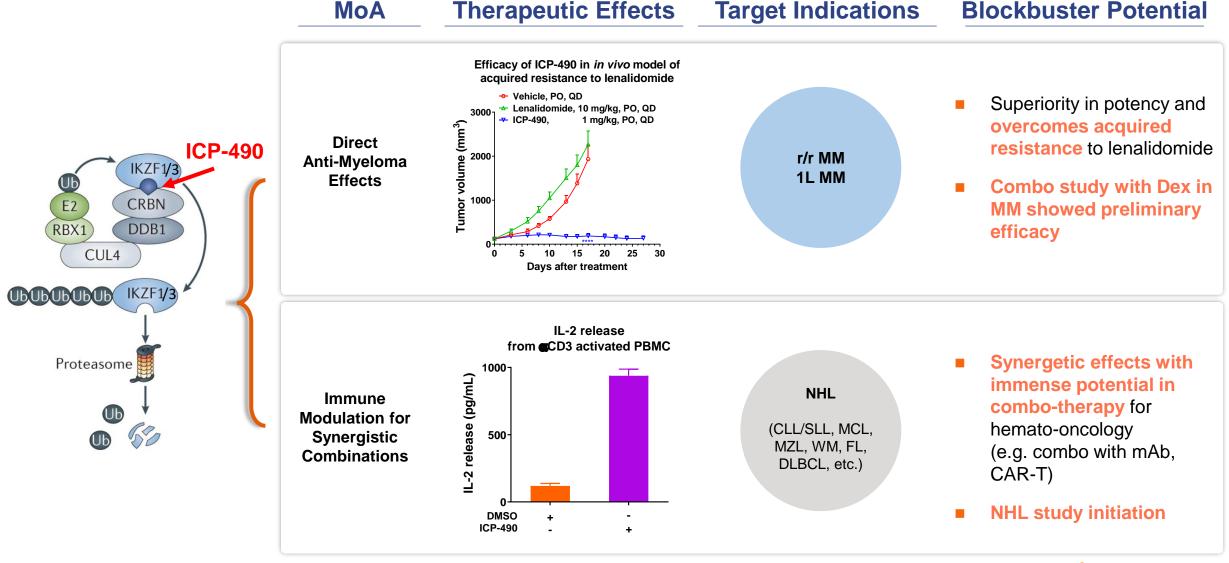


 ICP-B02 (SC) has demonstrated a favorable linear PK and comparable to IV dosing.

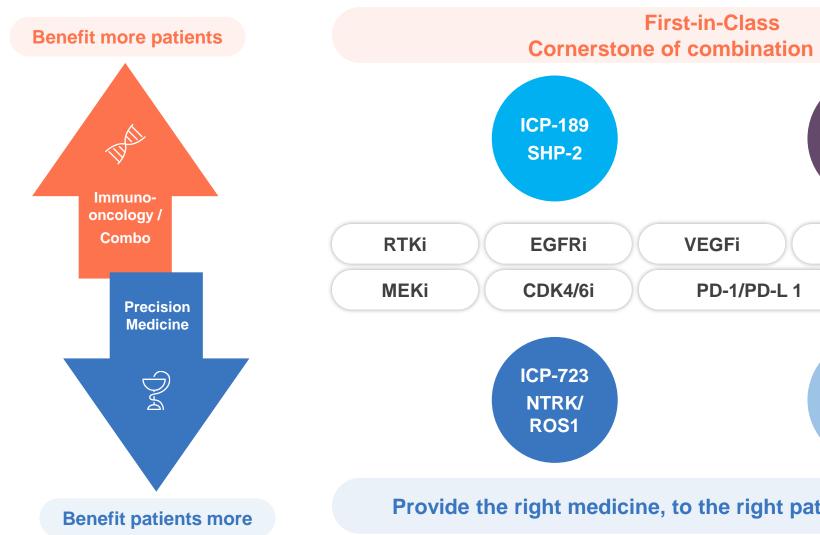
Time (day)

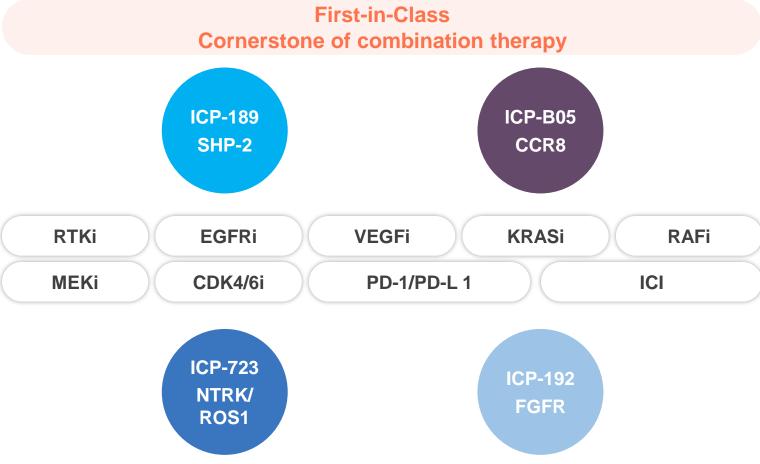
- SC dosing has been selected for further exploration
- Profound and rapid B-cell depletion in peripheral and tissues

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



#### **Solid Tumors Strategy**



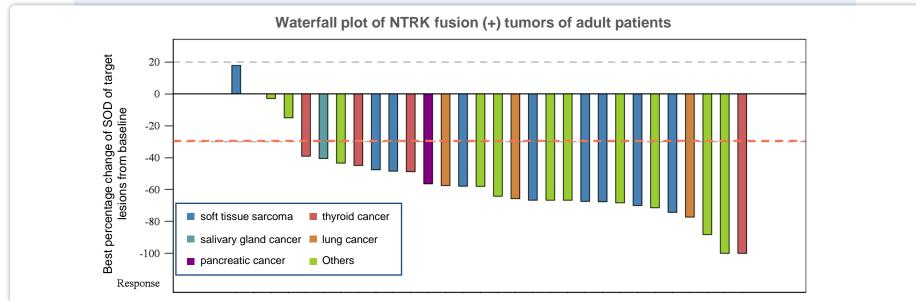


Provide the right medicine, to the right patient, at the right time

#### ICP-723: Entered to Pre-NDA Stage with Favorable Clinical Results

- PII Registration trial for NTRK gene abnormalities, pre-NDA stage
  - ✓ ORR: 80-90%
  - ✓ Long duration of response (longest beyond 36 months)
- Efficacy observed in adolescents and pediatric patients
- Finished dose escalation for pediatric patients, EOP2 meeting request submitted to CDE to start the registrational trial
- Efficacy observed in TRKi-resistant patient

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



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





ICP-189 SHP2 Inhibitor



Furmonertinib EGFR Inhibitor

#### **Mono-therapy Progress**

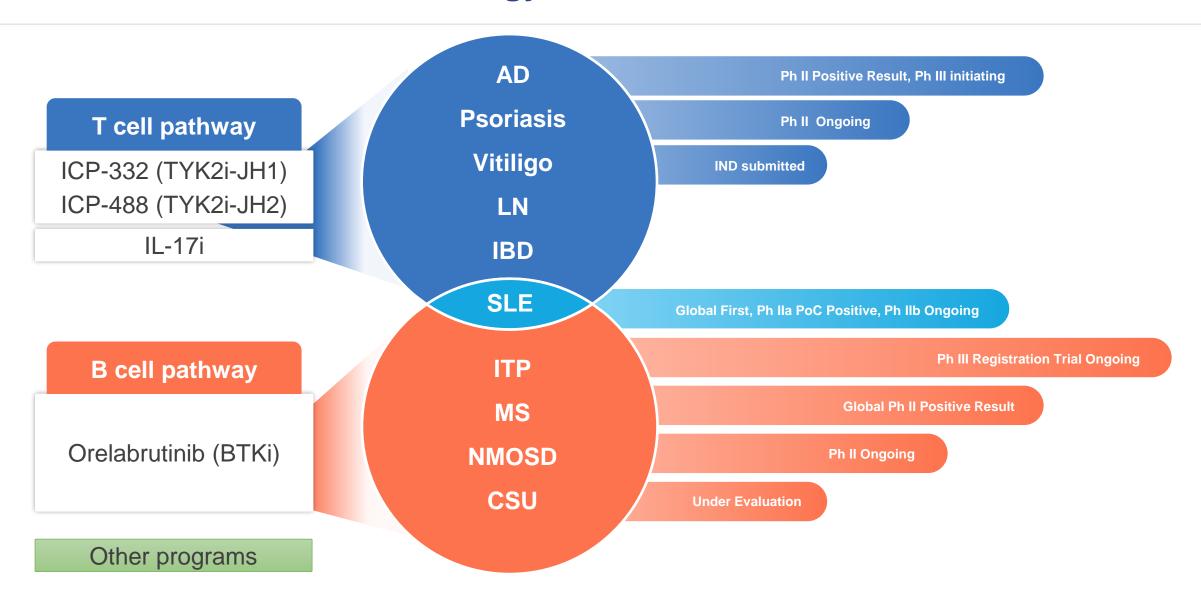
- First-in-Class
- SHP2 inhibitor for NSCLC & others
- Excellent PK and tolerability demonstrated in Ph I dose escalation
- Single agent efficacy observed
- Class-leading safety profile: No grade 3 or higher TRAEs observed up to 120 mg

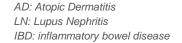
#### **Combo-therapy Strategy**

- 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, escalated to 2 dose
  - ✓ Promising results observed in combo with furmonertinib (EGFRi) in 3rd EGFRi-resistant NSCLC



#### **Autoimmune Disease Strategy**

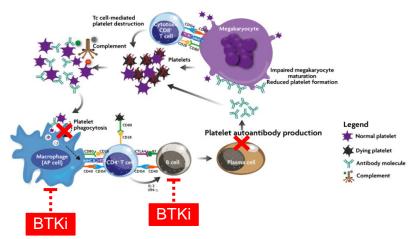




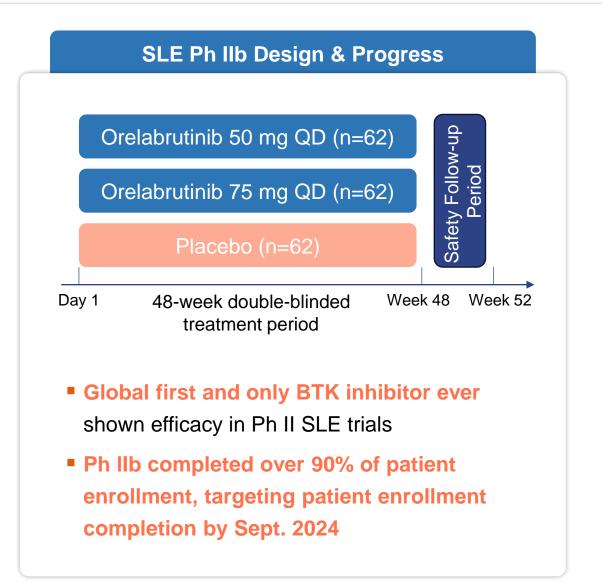
#### Orelabrutinib: Targeting to Extend Life Cycle Management & Expand Market Space

#### **ITP Ph III Registrational Trial**

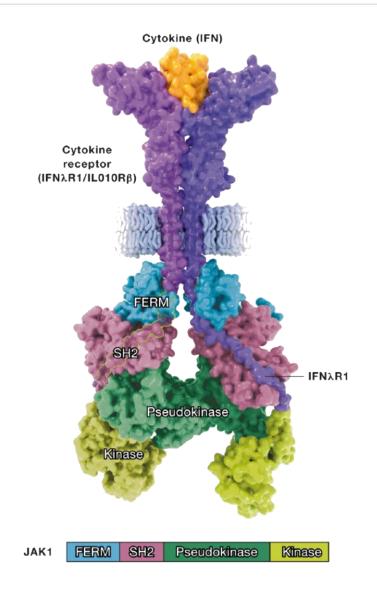
- Ph II result:
  - √ 40% patients met the primary endpoint at 50mg QD
  - ✓ 83.3% achieved durable response among patients who met the primary endpoints
  - √ 75% of patients, who previous responded to GC or IVIG, met the primary endpoint
- Ph III: registrational trial ongoing in China, targeting enrollment completion in 6 months

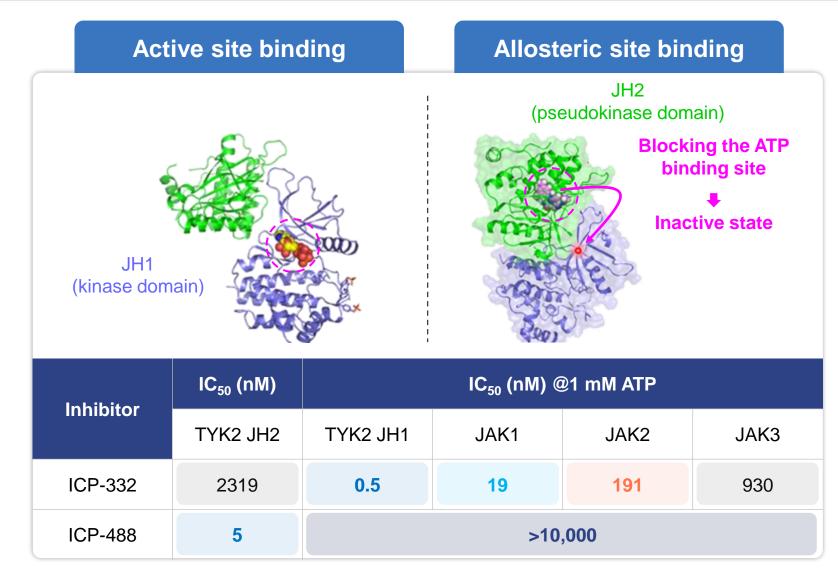


- Decreased macrophage (Fcy receptor)-mediated platelet destruction
- · Reduced production of pathogenic autoantibodies



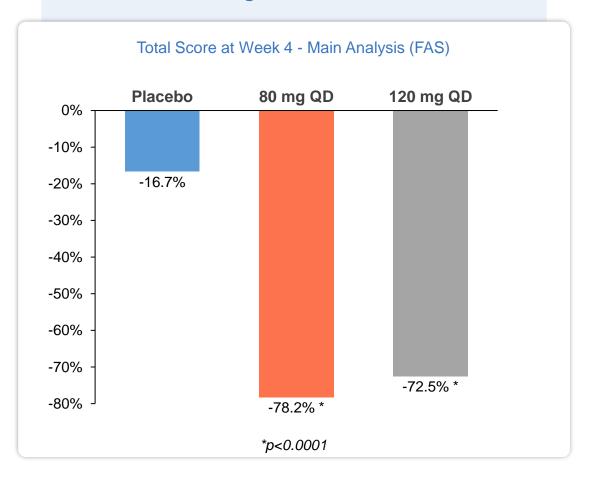
#### ICP-332, ICP-488: TYK2 Inhibitors with Different Selectivity Profiles



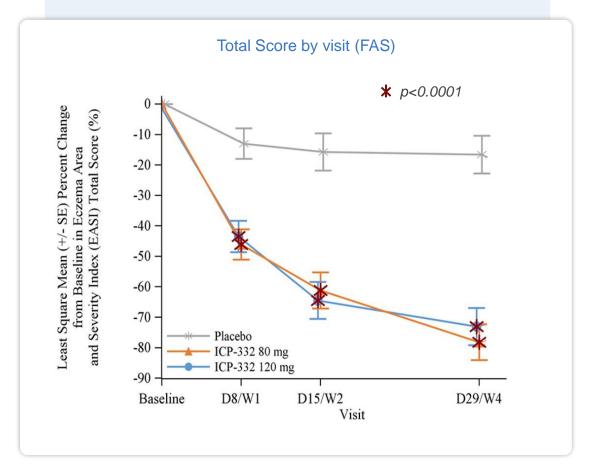


## ICP-332 Significantly Improved EASI Scores from Baseline in Phase II for the Treatment of AD Patients

#### **Percent Change from Baseline in EASI**



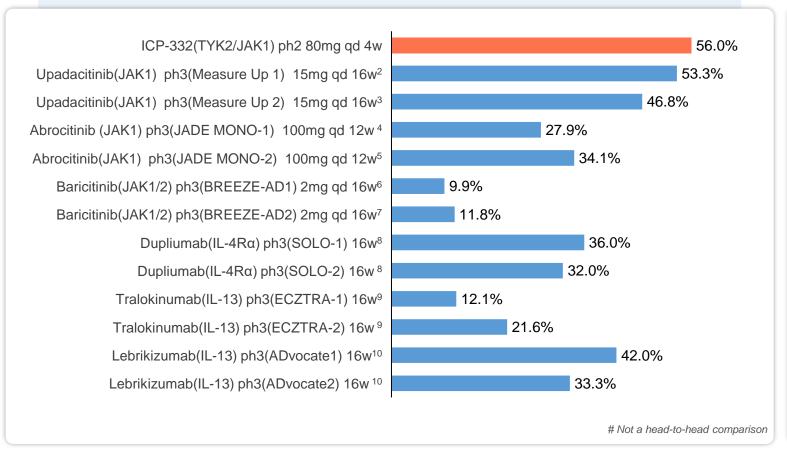
#### **Percent Change from Baseline in EASI**



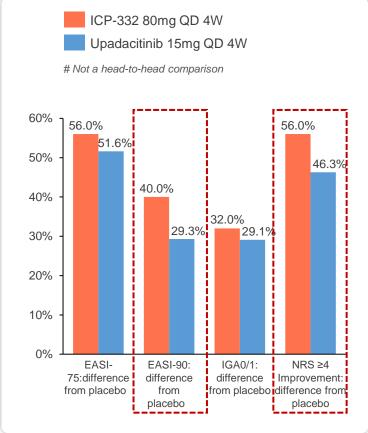
EASI: Eczema Area and Severity Index; FAS: Full Analysis Set

## ICP-332 Demonstrated Top Efficacy in PII Across Different MoAs for the Treatment of Atopic Dermatitis

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



### Efficacy Comparison of ICP-332 with Upadacitinib at Week 4<sup>1</sup>



Source: 1. Simpson EL, et al. JAMA Dermatol. 2022;158(4):404–413. doi:10.1001/jamadermatol.2022.0029;

<sup>2,3,4,5,6,7:</sup> data from ClinicalTrials.gov <a href="https://www.clinicaltrials.gov/">https://www.clinicaltrials.gov/</a>

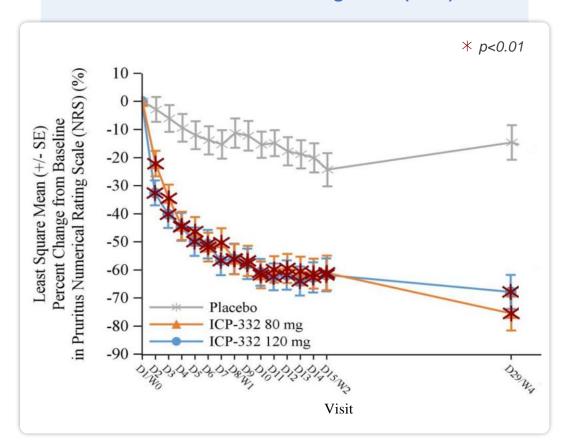
<sup>8.</sup> DUPIXENT® (dupilumab) injection label.

<sup>9.</sup> A. Wollenberg, et al. Br J Dermatol 2021; 184:386–387 DOI 10.1111/bjd.19574. 10. Silverberg JI, et al. N Engl J Med . 2023 Mar 23;388(12):1080-1091. doi: 10.1056/NEJMoa2206714.

#### ICP-332: Quick Response in Improving Patient Quality of Life

## **Quick and Statistically Significant Response from Day 2**

#### **Pruritus Numerical Rating Scale (NRS)**

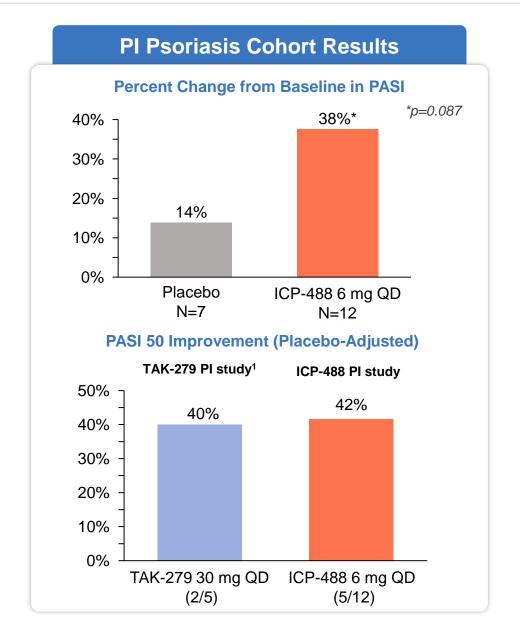


#### **Improvement of Patient Quality of Life**

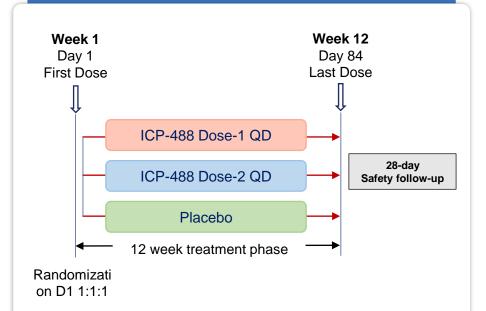
Dermatology Life Quality Index (DLQI) Score Change from Baseline by Visits (Full Analysis Set)

	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

## ICP-488: PoC Study in Psoriasis Patients Achieved Positive Results, and PII Study Completed Patient Enrollment

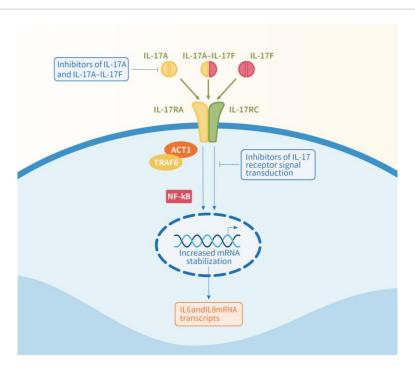


#### **Psoriasis PII Study Design & Progress**

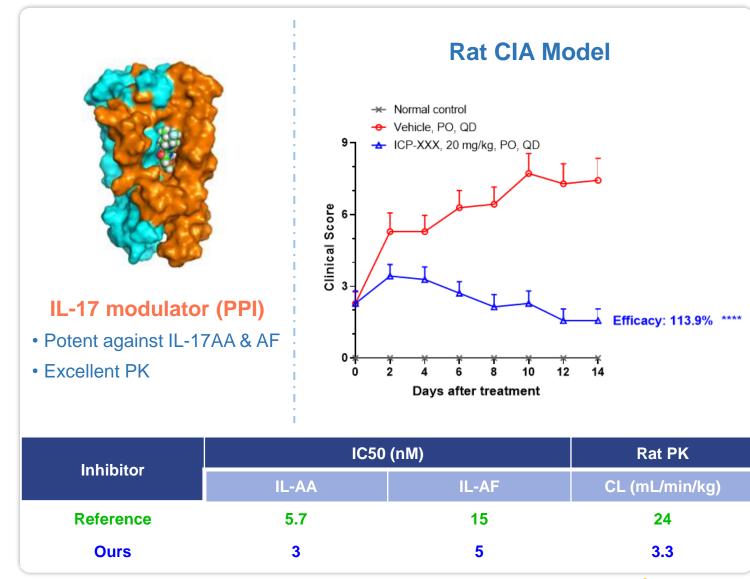


- ✓ Psoriasis PII trial completed patient enrollment in China in May 2024. A total of 129 patients were enrolled.
- ✓ Study readout by end of 2024.

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

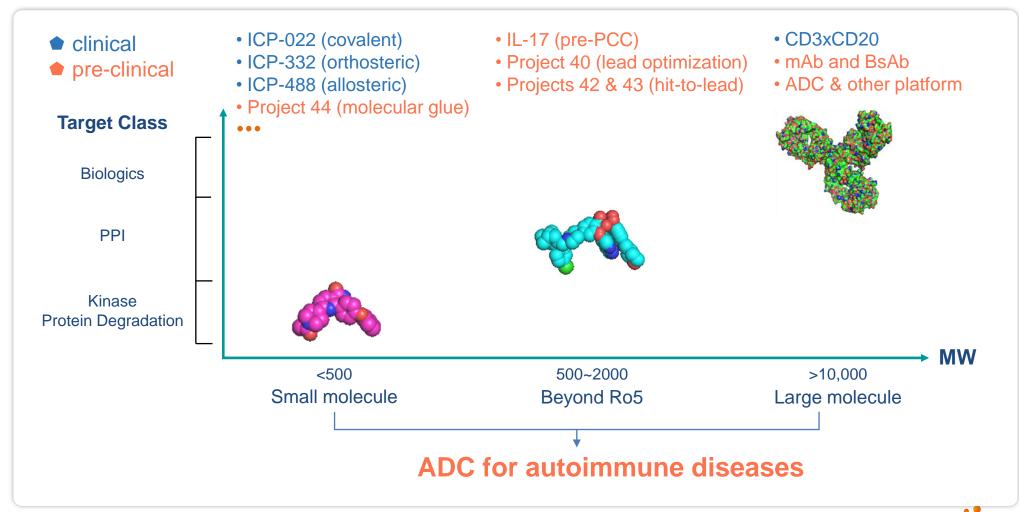


- Broad market demand
- ➤ Well validated target
- Small molecules for patient convenience
- Our molecular targeted profile: better efficacy & PK



#### **Preclinic:** Innovative Platform Broadly Targeting Autoimmune Diseases

- Covering different autoimmune disease mechanisms of action
- A variety of modalities

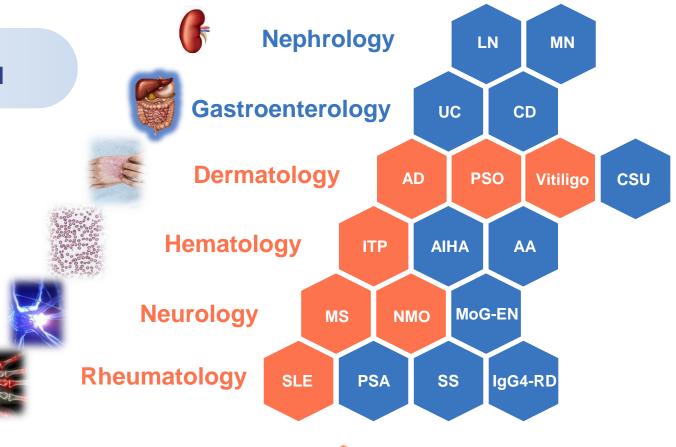


#### **Tapping into Enormous Unmet Medical Needs Exist in Autoimmune Diseases**



>500 M patients world wide

>40 M patients in China

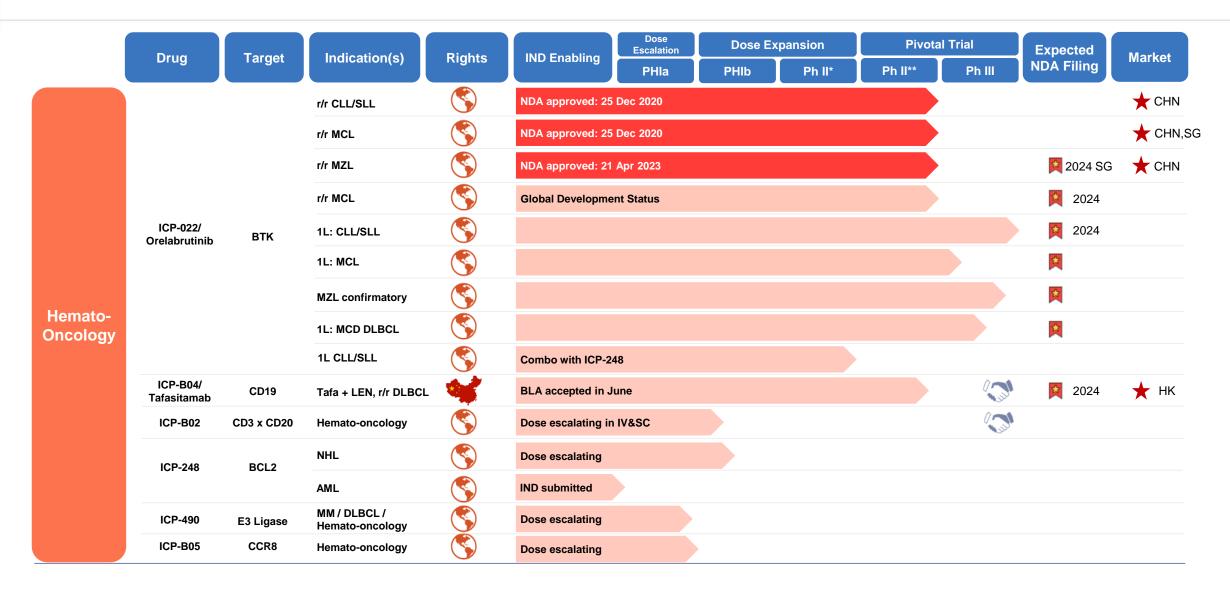


InnoCare current coverage

SS: Sjogren syndrome



#### **Product Pipeline – Hemato-oncology**





#### **Product Pipeline – Solid Tumors and Autoimmune Diseases**



