INNOCARE

InnoCare Pharma
Q3 2024 Results

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Financial/Commercial Highlight

Business Highlight in Q3 2024: Outstanding Performance Underpins Foundations for Future Sustained Growth

Increasing Commercial Growth

- Orelabrutinib achieved **75.5%** yoy growth in Q3 2024, **45.0%** yoy growth in Q1-Q3 2024 with revenue of **RMB693M**
- Expect Orelabrutinib revenue will continue to grow with:
  - ✓ Further **r/r MZL market penetration, 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**
  - ✓ **2.0 commercial team has clear marketing strategy and strong execution capability**

Strong Financial Result

- Total loss of Q1-Q3 2024 decreased by **47.1%** compared to the same period of last year
- Gross profit margin of total revenue increased to **86.0%** in Q1-Q3 2024
- Cash and related balance* is **RMB7.8B** as of Sept. 30 2024, providing strong bases for future development and flexibility

Significant Progress of Clinical Trials

Orelabrutinib
- Accelerated 1st 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, clinical site inspection completed

ICP-248 (BCL-2)
- Combo with orelabrutinib in 1L CLL/SLL
- Dose expansion in BTKi failure NHL is on going
- US clinical trial initiated
- AML clinical trial started in CN & AU

Orelabrutinib
- Global Ph III of PPMS initiation
- Global Ph III of SPMS will start in 2025H1
- ITP Ph III targeting enrollment completion in 2025Q1
- SLE Ph IIb enrollment completed

ICP-332 (TYK-2 JH1)
- Ph III in AD initiated
- IND for Ph II/III trial in Vitiligo accepted
- Finished Ph I US clinical trial

ICP-488 (TYK-2 JH2)
- Ph II results on plaque psoriasis showed best-in-class potential
- Ph III in psoriasis will be started early next year

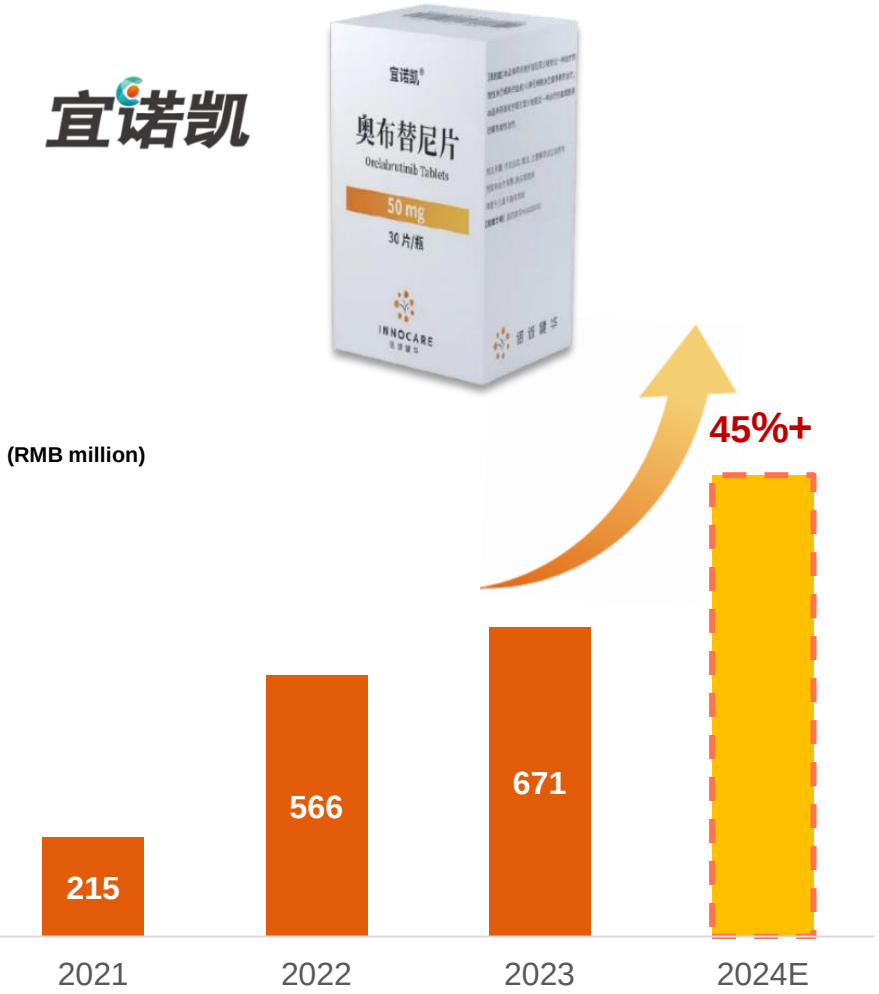
ICP-723 (NTRK)
- Pre-NDA package submitted, targeting NDA submission in 2025Q1

ICP-189 (SHP2)
- Combo with 3rd gen EGFRi**, promising results observed

* Cash and Related balance included cash and bank balance, other financial assets balance and interest receivable
** combo with furmonertinib

Orelabrutinib Commercialization: Anticipate ＞45% Sales Revenue Growth in 2024

Full year drug sales guidance raised to ＞45%



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

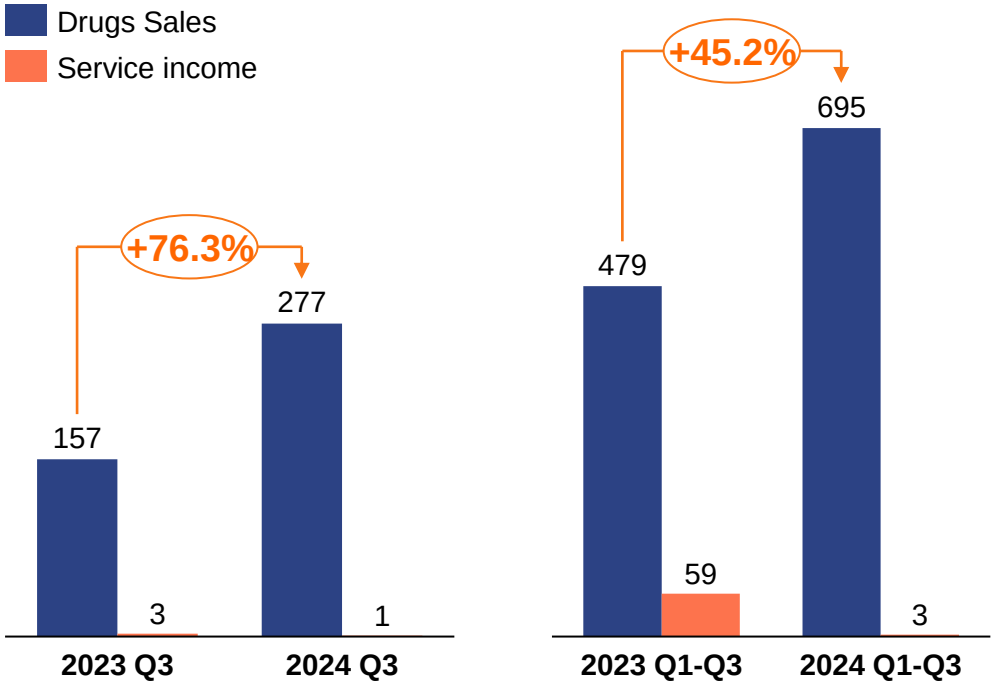
- ✓ **Experienced commercial leadership team** in hemato-oncology
- ✓ **Optimized strategy and quick deployment**
- ✓ Enhanced productivity and **cost efficiency**

[1]***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 MCL), and adult patients with marginal zone lymphoma who have received at least one prior therapy (r/r MZL)*

Drug Sales Achieved 76.3% yoy Growth in Q3 2024, 45.2% yoy Growth in Q1-Q3 2024, Total Loss Narrowed Down by 47.1% in Q1-Q3 2024

Revenue

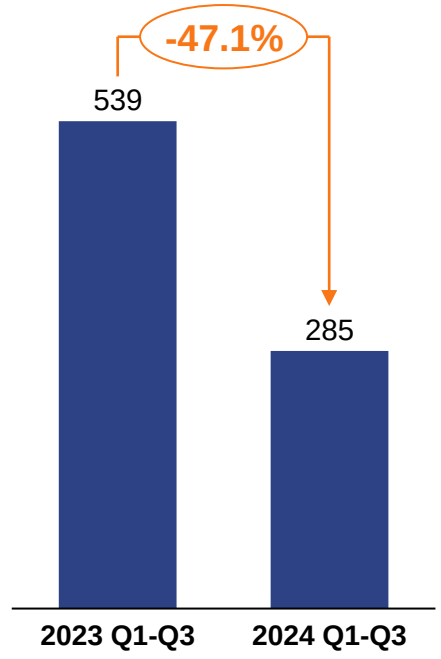
In RMB millions



Drug sales growth increased in Q3, full year drug sales guidance raised to ＞45%

Loss for the Period

In RMB millions



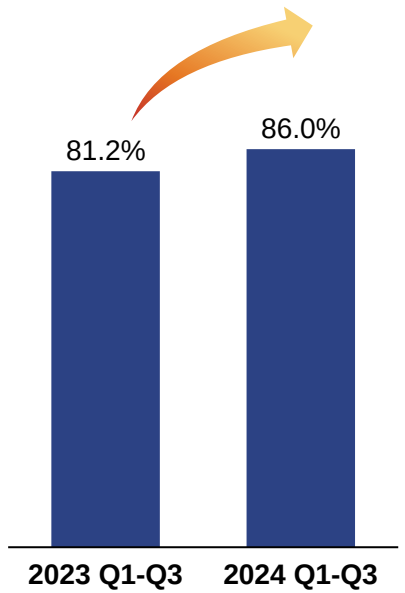
Loss of the period narrowed down by RMB 254M / 47.1% yoy attributed to drug sales growth, cost efficiency improvement and favorable impact of unrealized foreign exchange gain

Note: The above financials is based on CAS (China Accounting Standards for Business Enterprises)
Drug Sales include products revenue of Orelabrutinib(RMB693m), tafasitamab and other sales

Driving for Sustained Growth and Strong Cash Position Provides Flexibility

Gross Margin % *

In RMB millions

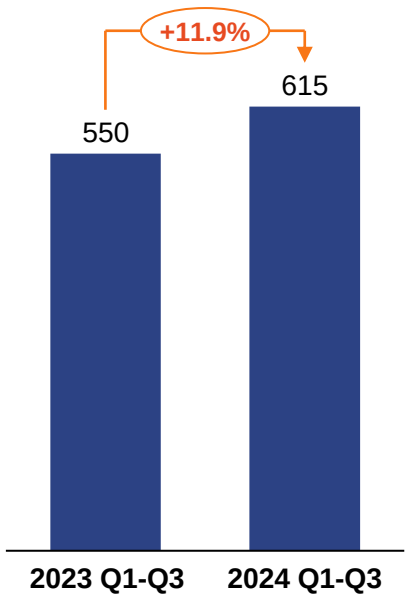


Gross margin %=1-Cost of Revenue/Total Revenue

YTD Gross profit margin keeps increasing to 86.0%, attributing to the orelabrutinib revenue increase and changes in revenue composition

R&D Expense

In RMB millions



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

Cash and cash related balance*

In RMB millions

Robust cash and cash related balance of RMB 7.8B (~US$1.1B) provides flexibility to expedite the clinical development and to invest in a competitive pipeline

Note: The above financials is based on CAS (China Accounting Standards for Business Enterprises) .
Cash and cash related balance includes cash and bank balances, other financial assets and interest receivables balance

Progresses of Clinical Trials

Progress of Orelabrutinib for Multiple Sclerosis(MS): Enormous Market Potential

Significant progress in MS global study

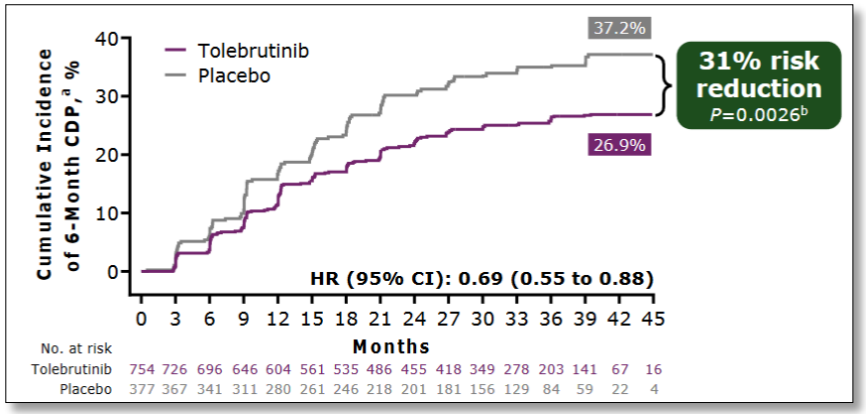
- ✓ We have reached agreement with FDA to initiate **global Phase 3 study in PPMS**
- ✓ FDA encouraged us also start a **Phase 3 study in SPMS**

PMS: Urgent and Unmet Medical Needs

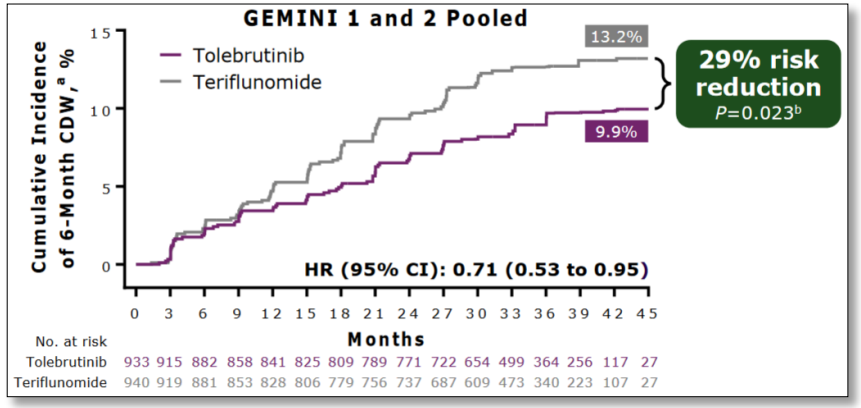
- ✓ **2.8 million**[1] people globally living with MS.
- ✓ Patients diagnosed with **PPMS** account for **10%-20%**[2] of MS cases.
- ✓ **Majority**[3] **of patients** diagnosed with RRMS will **eventually develop into SPMS.**
- ✓ **MS market** is expected to reach **$38.94 billion**[4] by 2032.
- ✓ **PPMS and SPMS** lack sufficient treatment options, presenting **significant market potential!**

BTK Inhibitor Slows Disability Progression in MS

Tolebrutinib Phase 3 Trial in nrSPMS - Primary Endpoint: Time to 6-Month CDP



Tolebrutinib Phase 3 Trials in RMS-Key Secondary Endpoint: Time to 6-Month CDW



1 The Multiple Sclerosis International Federation (MSIF)S 2020. Atlas of MS 3rd edition. Mult Scler Int Fed (MSIF), Sept 2020. 2020;(September):1-37
2 Klineova S, Lublin FD. Clinical course of m ultiple sclerosis. Cold Spring Harb Perspect Med. 2018;8(9):1-12.
3 Weinshenker BG, Bass B, Rice GP, et al. The natural history of multiple sclerosis: a geographically based study. I. Clinical course and disability. Brain. 1989;112 (Pt 1:133-146.
4 Source: https://www.fortunebusinessinsights.com/industry-reports/multiple-sclerosis-drugs-market-100386
Source of the picture：Sanofi website

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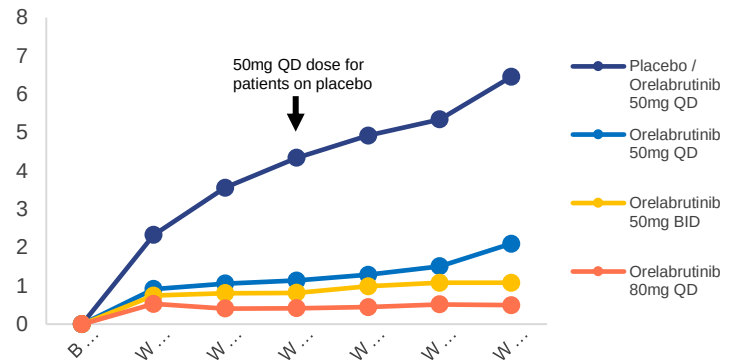
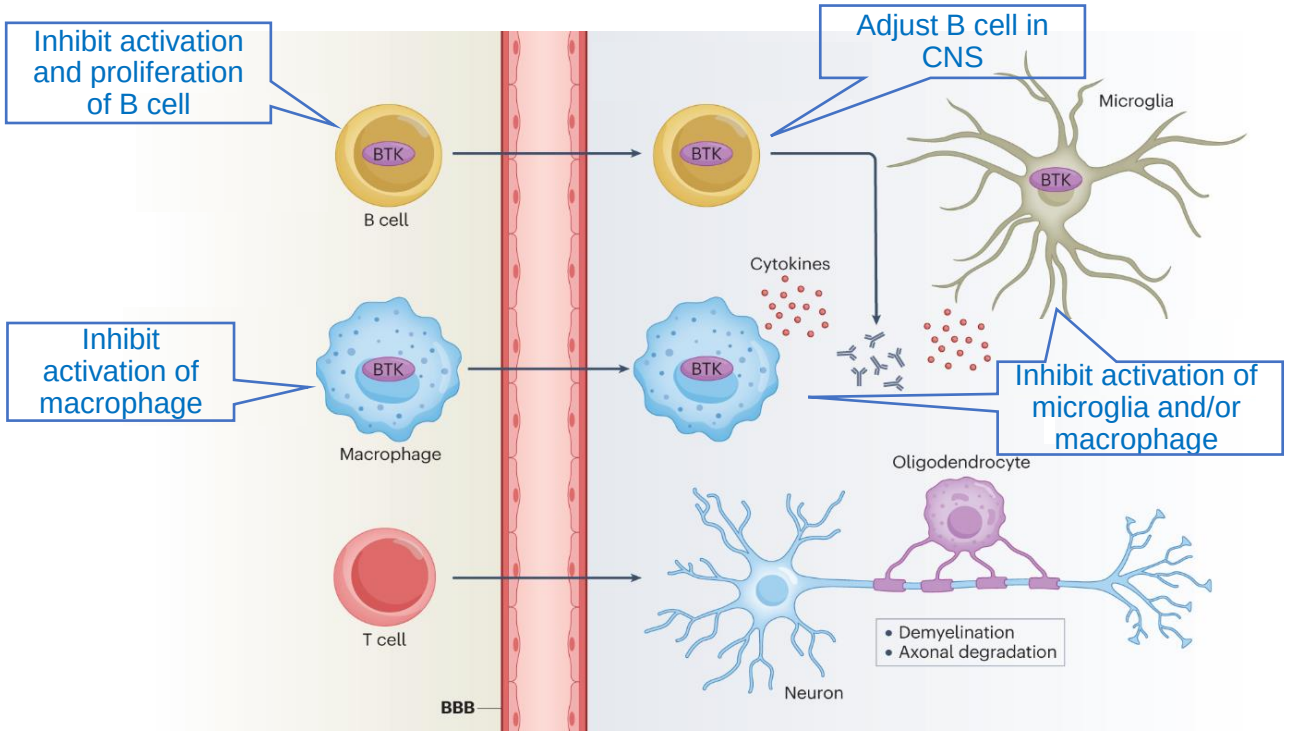
Orelabrutinib: Best-in-Class Potential for the Treatment of PMS

New Gd+ T1 Brain Lesions (N=115)

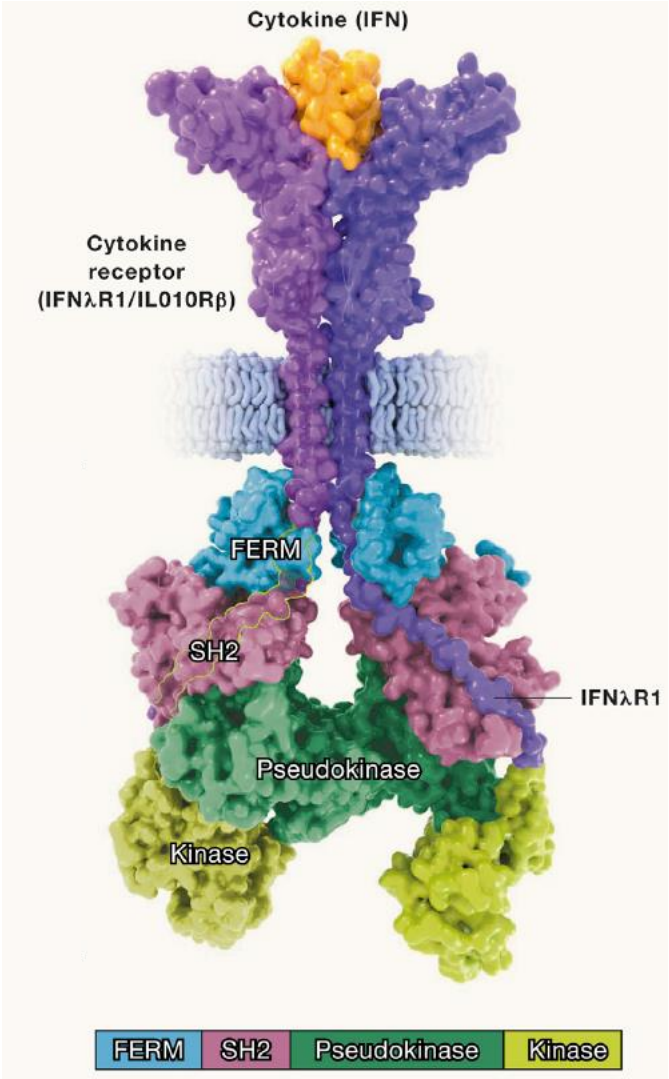


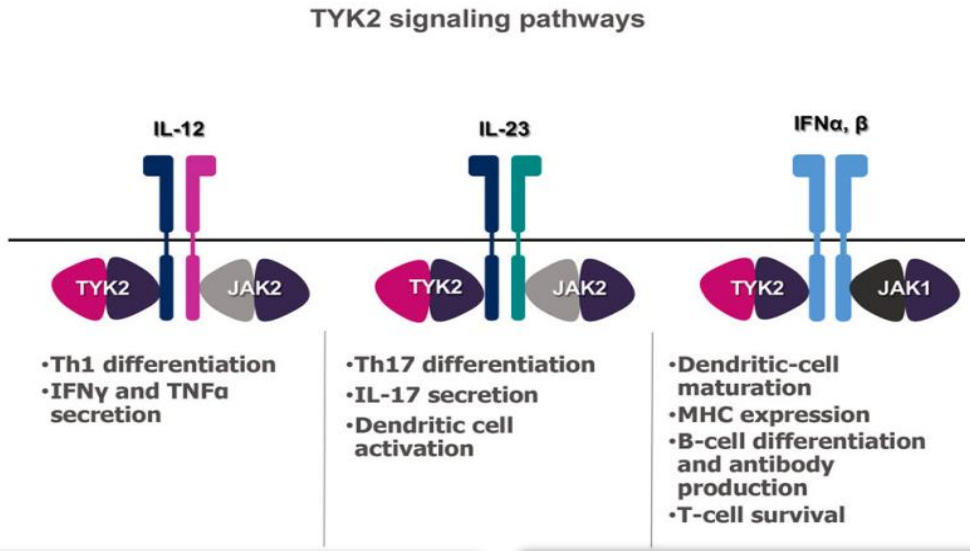
- **92.3% relative reduction achieved in cumulative number of new Gd + T1 lesions at 80mg QD compared to placebo arm**
- **Best-in-class profile**

BTKi	Free Peripheral Plasma Conc.(ng/mL)	CSF Conc. (ng/mL)	CSF Conc./ BTK IC50	Dosing Regimen
Orelabrutinib	**64.4**	**31.3**	**44.7X**	**150 mg QD**
Tolebrutinib	0.83	1.87	6.23X	120 mg QD

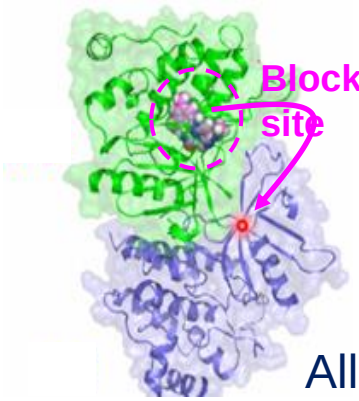


ICP-488: Highly Selective Allosteric Inhibitor of TYK2





Active site binding



Potent *in vitro* kinase inhibitory activity

Kinase		ICP-488
IC_{50} (nM)	TYK2 JH2	5
IC_{50} (nM) @1 mM ATP	TYK2 JH1	>10,000
	JAK1	>10,000
	JAK2	>10,000
	JAK3	>10,000

Note: The picture adopted from Cell 2022, 185, 3857-3876. & Lombardo, SAPA Symposium 2020 & Dermatology and Therapy, 2023, 13(2):417-435.

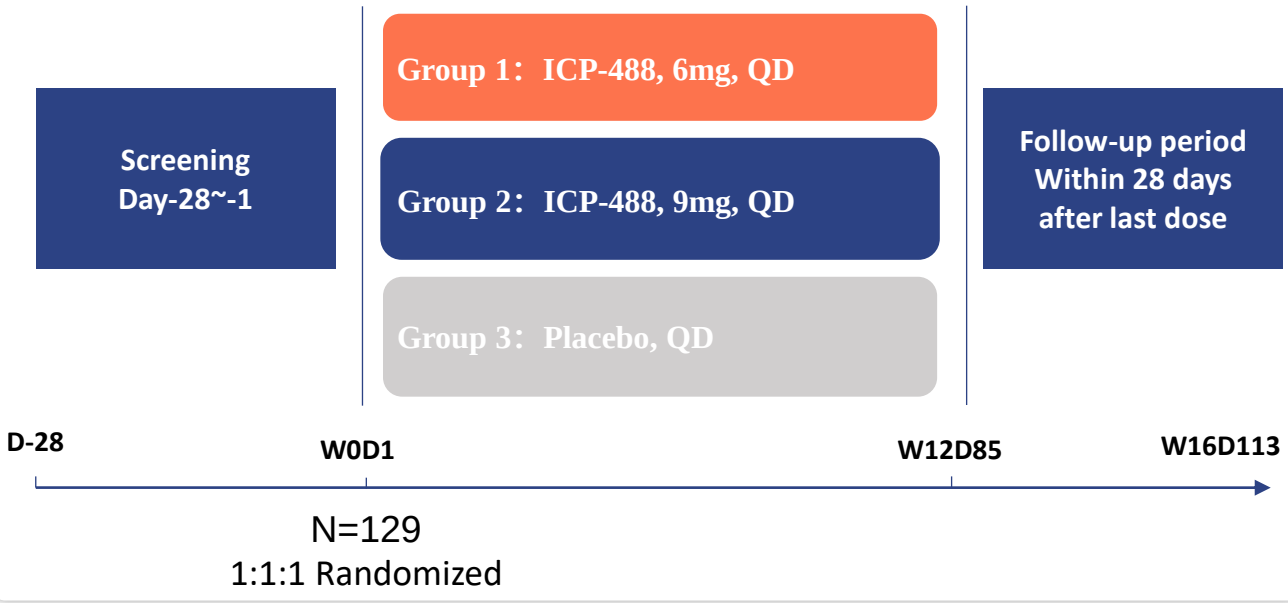
ICP-488 Phase II Study Design in Plaque Psoriasis

Objectives

The phase II, randomized, double-blind, placebo-controlled study aimed to evaluate efficacy and safety of ICP-488 in patients with moderate-to-severe plaque psoriasis.

Treatment

This study comprises a 28-day screening period, a 12-week double-blind treatment phase, and a 28-day safety follow-up period.



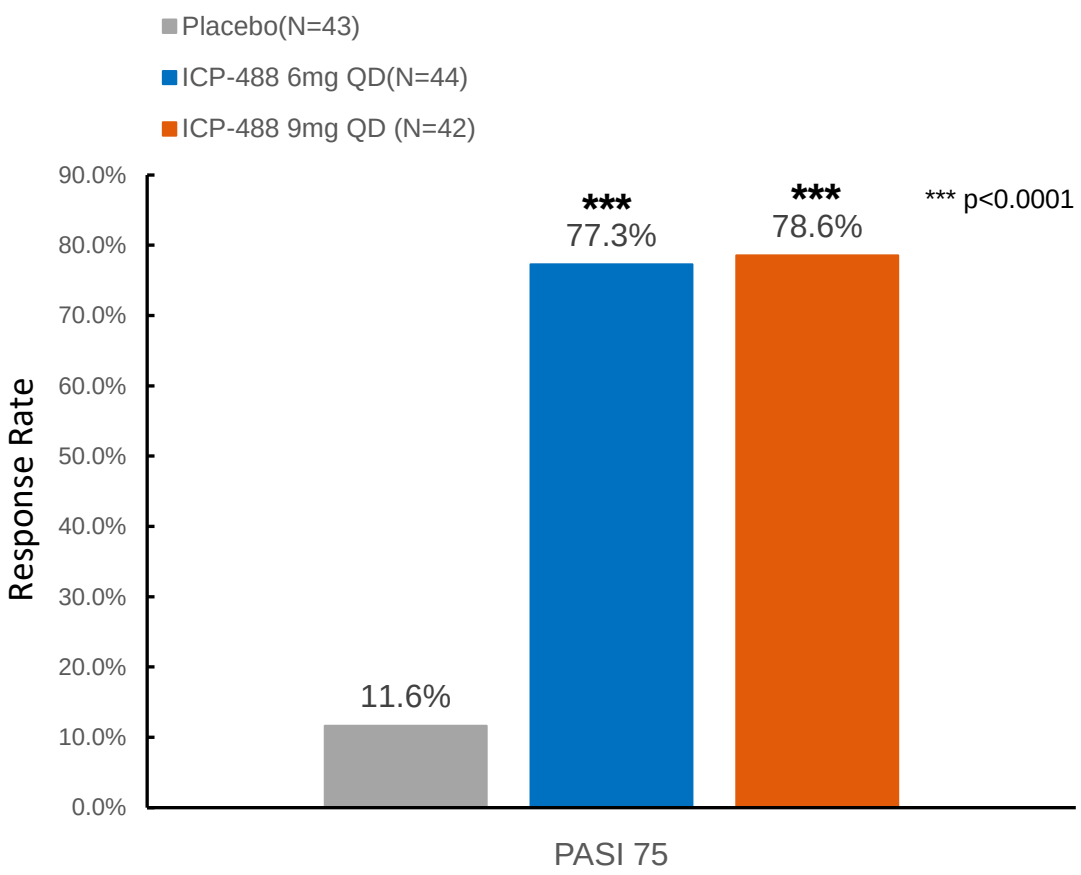
Assessments

- **Primary Endpoints:**
  PASI 75 at Week12
- **Secondary Endpoints:**
  - Safety
  - Other Efficacy endpoint:
    - ✓ PASI 50/75/90/100
    - ✓ PASI changes
    - ✓ sPGA 0/1

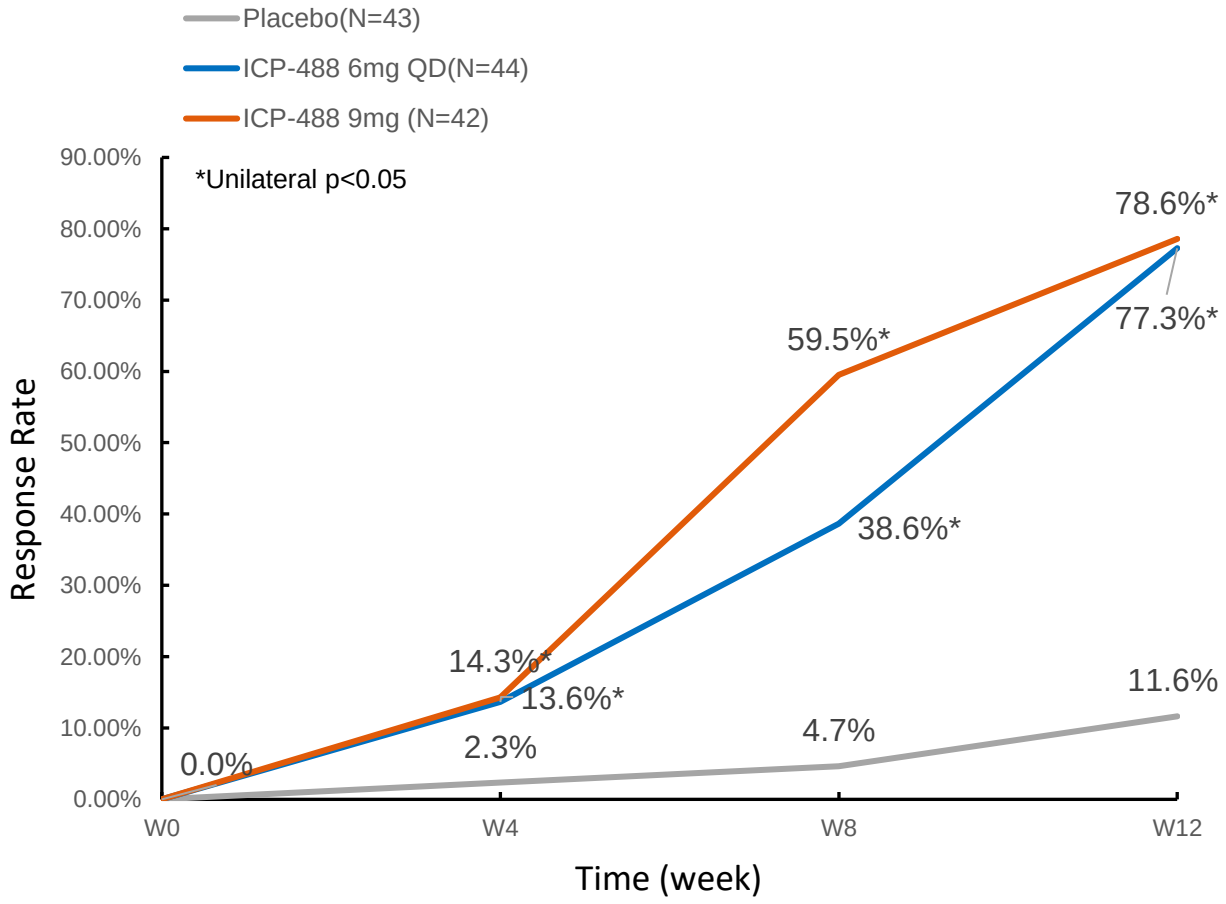
BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; sPGA, Static Physician's Global Assessment; QD, once daily

ICP-488: Best-in-class Potential in Plaque Psoriasis

Patients achieving PASI 75 at Week 12 (FAS)

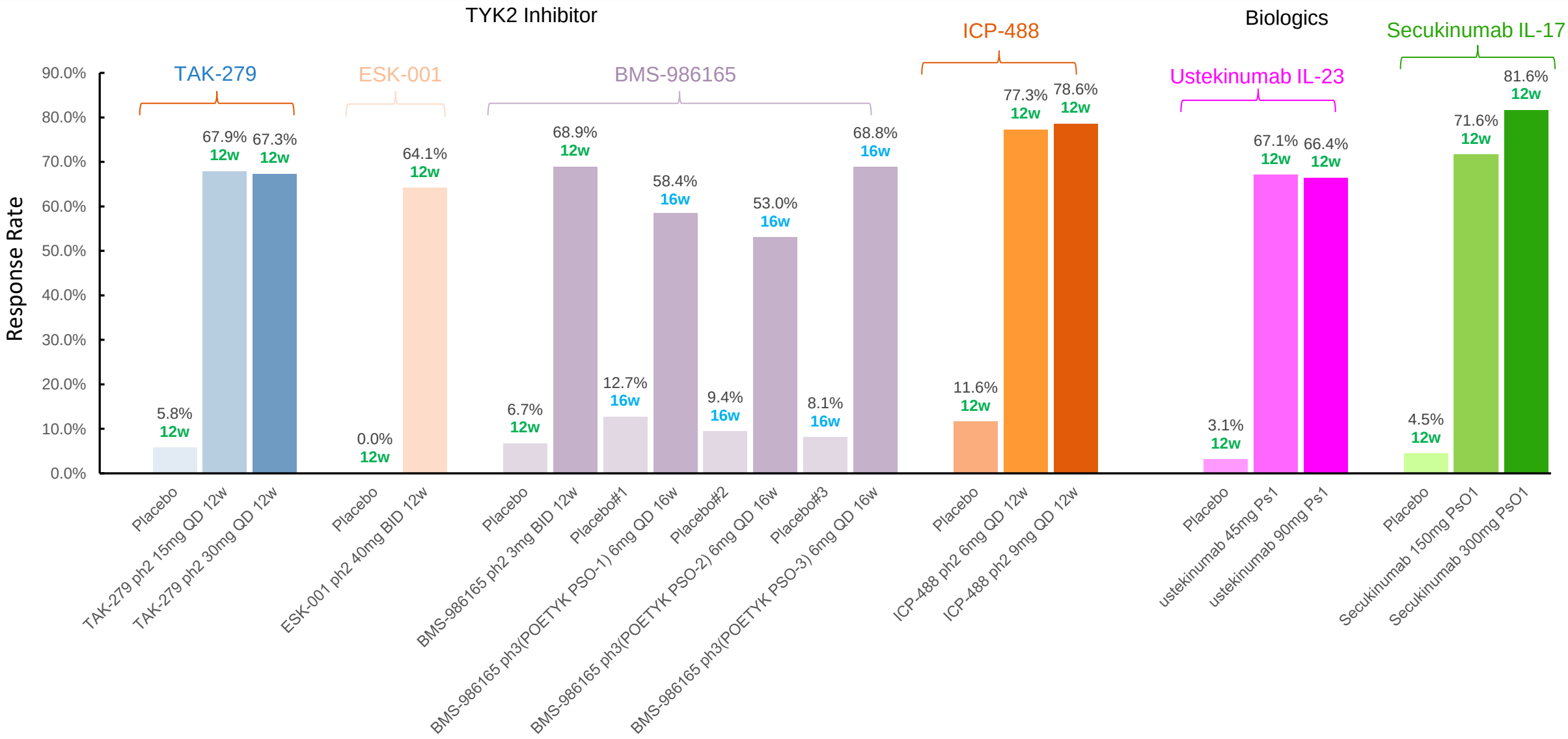


PASI 75 Response Rate by visit (FAS)



All randomized subjects were included in the FAS analysis. p values from a Cochran-Mantel-Haenszel test, with prior biologic treatment included as a stratification factor, comparing the proportion of patients in the treatment group versus placebo.
PASI, Psoriasis Area and Severity Index; QD, once daily; NRI, non-responder imputation

ICP-488: Excellent Efficacy among TYK2 Inhibitors for the Treatment of Plaque Psoriasis on PASI 75



***TAK-279**: from investor call data; **ESK-001**: from EADV 2024 annual meeting data; **BMS-986165**: ph2& PSO-3 from https://clinicaltrials.gov/. PSO-1 from Journal of the American Academy of Dermatology. 2023;88(1):29-39. PSO-2 from Journal of the American Academy of Dermatology. 2023;88(1):40-51. **Ustekinumab**: The Lancet. 2008;371(9625):1665-1674; **Secukinumab**: N Engl J Med. 2014;371(4):326-338.*

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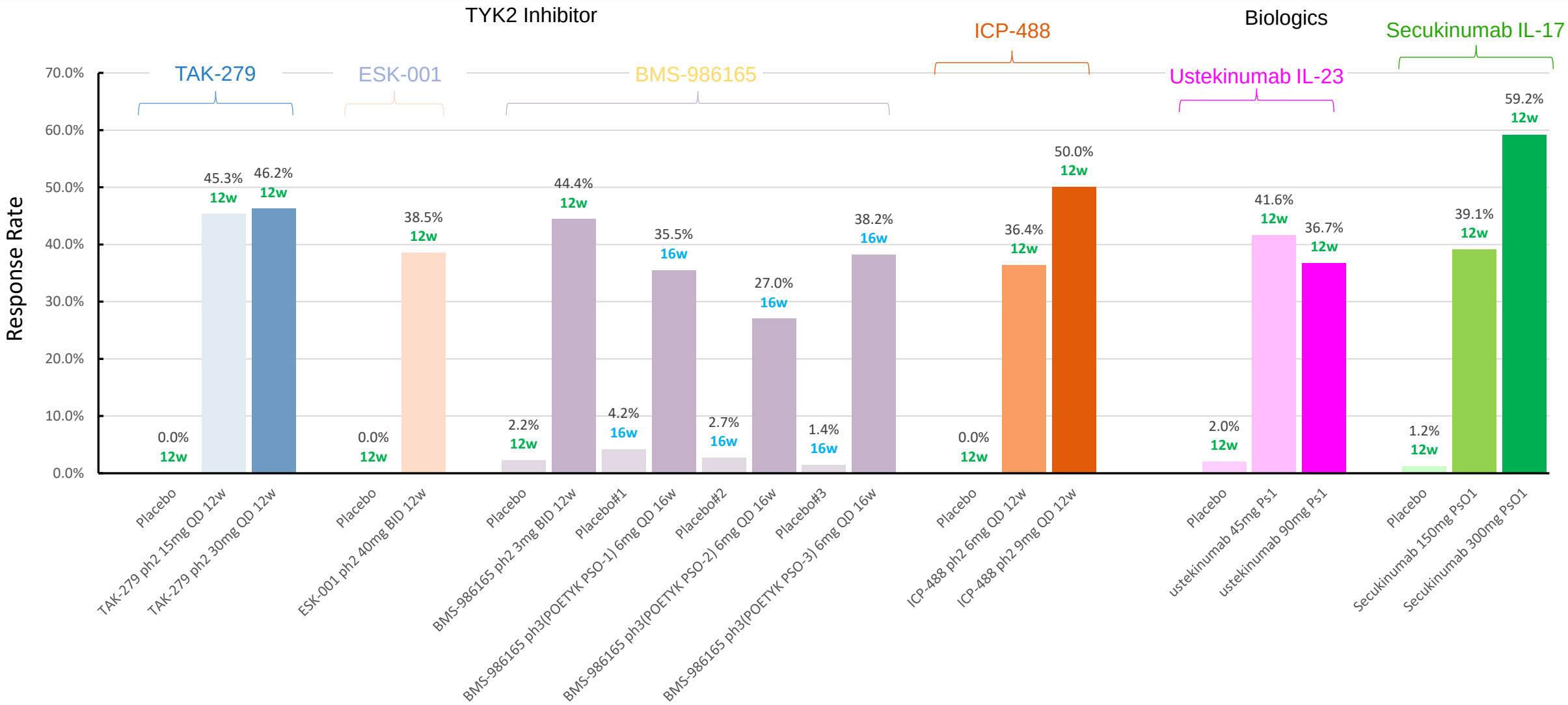
ICP-488: Strong Efficacy among TYK2 Inhibitors for the Treatment of Plaque Psoriasis on PASI 90



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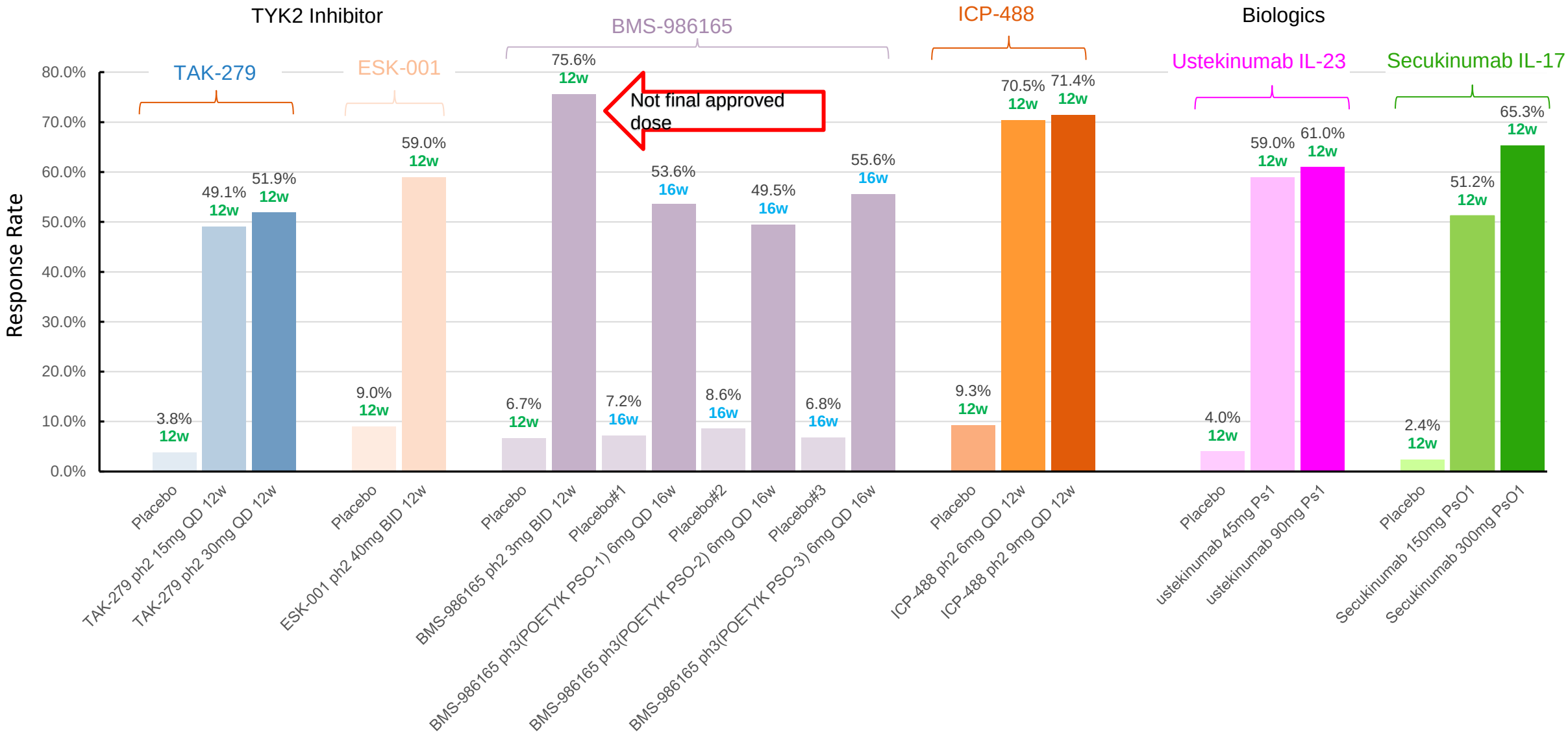
ICP-488: Top Efficacy among TYK2 Inhibitors for the Treatment of Plaque Psoriasis on sPGA Scores of 0/1



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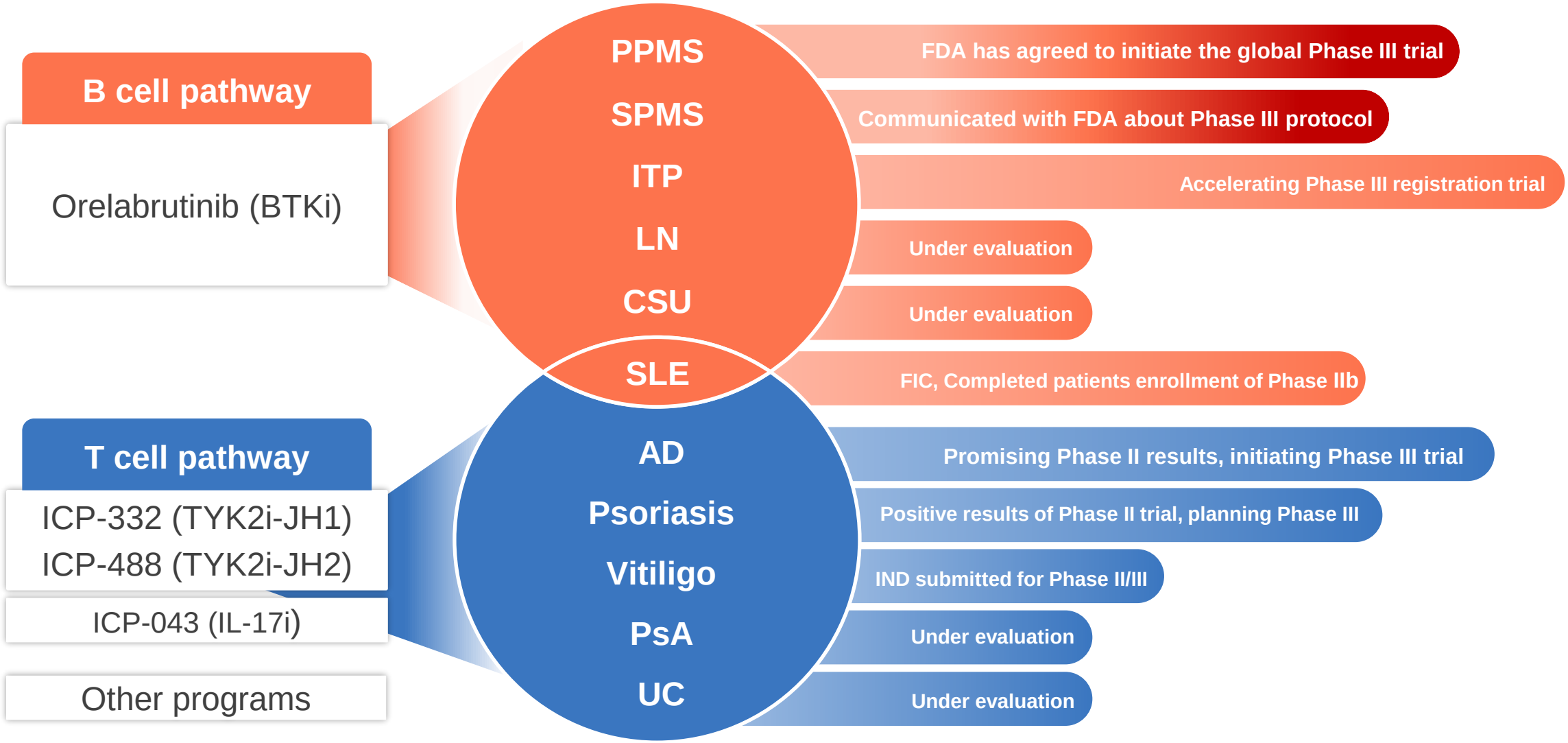
ICP-488: Overall Safety Profile

- Most TEAE are mild to moderate
- Most moderate TEAEs were not related to the treatment of ICP-488
- No severe TEAE, no TEAE leading to drug withdraw or death
- No SAEs were observed that were related to the drug treatment
  - Two unrelated SAE reported: one in placebo arm (kidney stone); another in the ICP-488 9mg QD arm (skin infection, with a history of trauma)

	Placebo (N = 43) n (%)		ICP-488 6mg (N = 44) n (%)		ICP-488 9mg (N = 42) n (%)	
	TEAE	**TRAE**	**TEAE**	**TRAE**	**TEAE**	**TRAE**
All AE	31 (72.1)	14 (32.6)	35 (79.5)	18 (40.9)	32 (76.2)	19 (45.2)
-Mild	26 (60.5)	11 (25.6)	27 (61.4)	14 (31.8)	23 (54.8)	18 (42.9)
-Moderate	5 (11.6)	3 (7.0)	8 (18.2)	4 (9.1)	9 (21.4)	1 (2.4)
-Severe	0	0	0	0	0	0
Serious AE	1 (2.3)	0	0	0	1 (2.4)	0
AEs leading to drug interruption	1 (2.3)	1 (2.3)	1 (2.3)	1 (2.3)	2 (4.8)	0
AEs leading to drug withdrawn	0	0	0	0	0	0
AEs leading to death	0	0	0	0	0	0

Autoimmune Disease Strategy



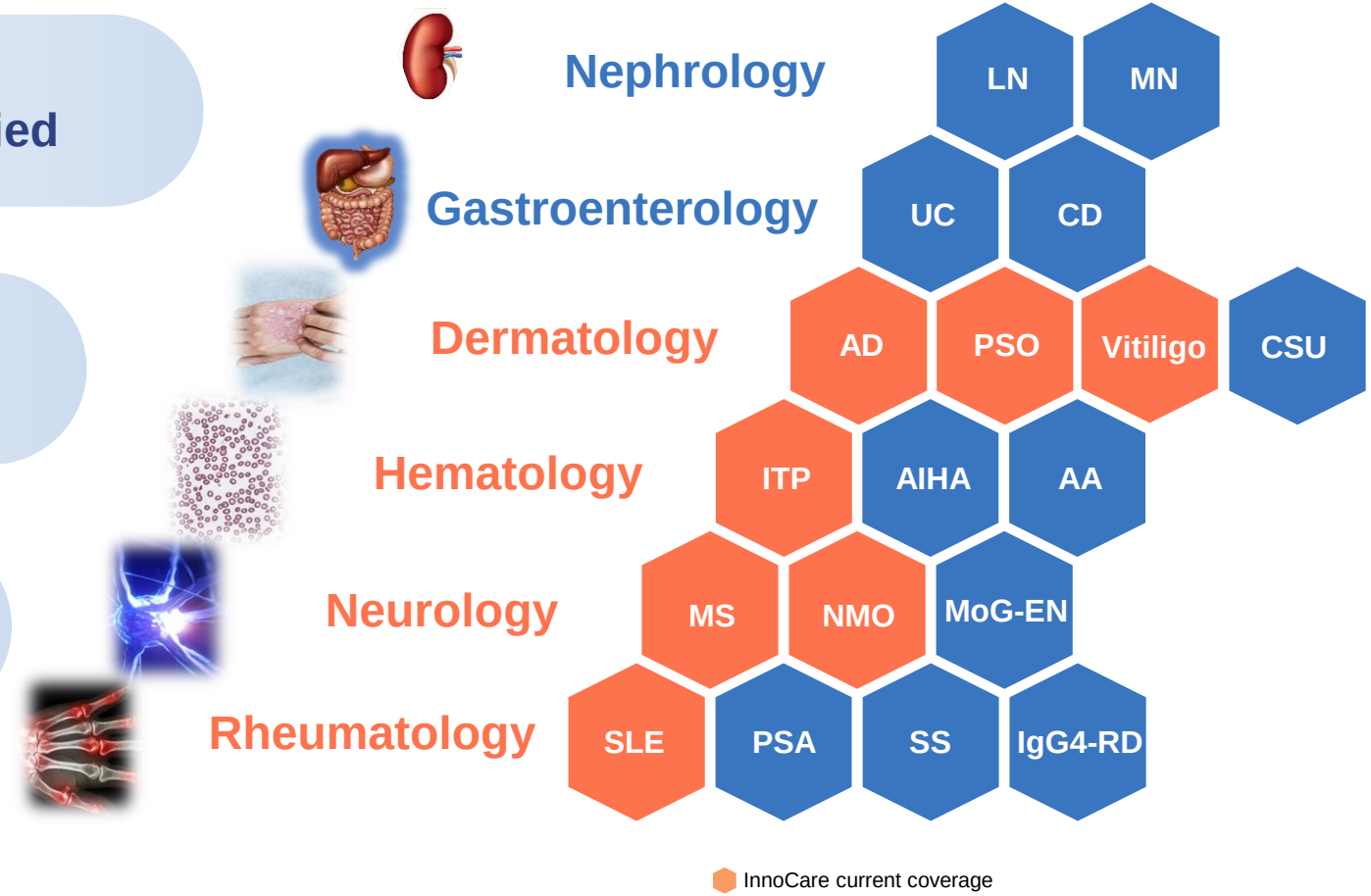
Tapping into Enormous Unmet Medical Needs Exist in Autoimmune Diseases

>150 autoimmune diseases identified

>500 M patients world wide

>15B market potential

(InnoCare products)



Source: Http://autoimmune.org/disease-information, Orient Securities

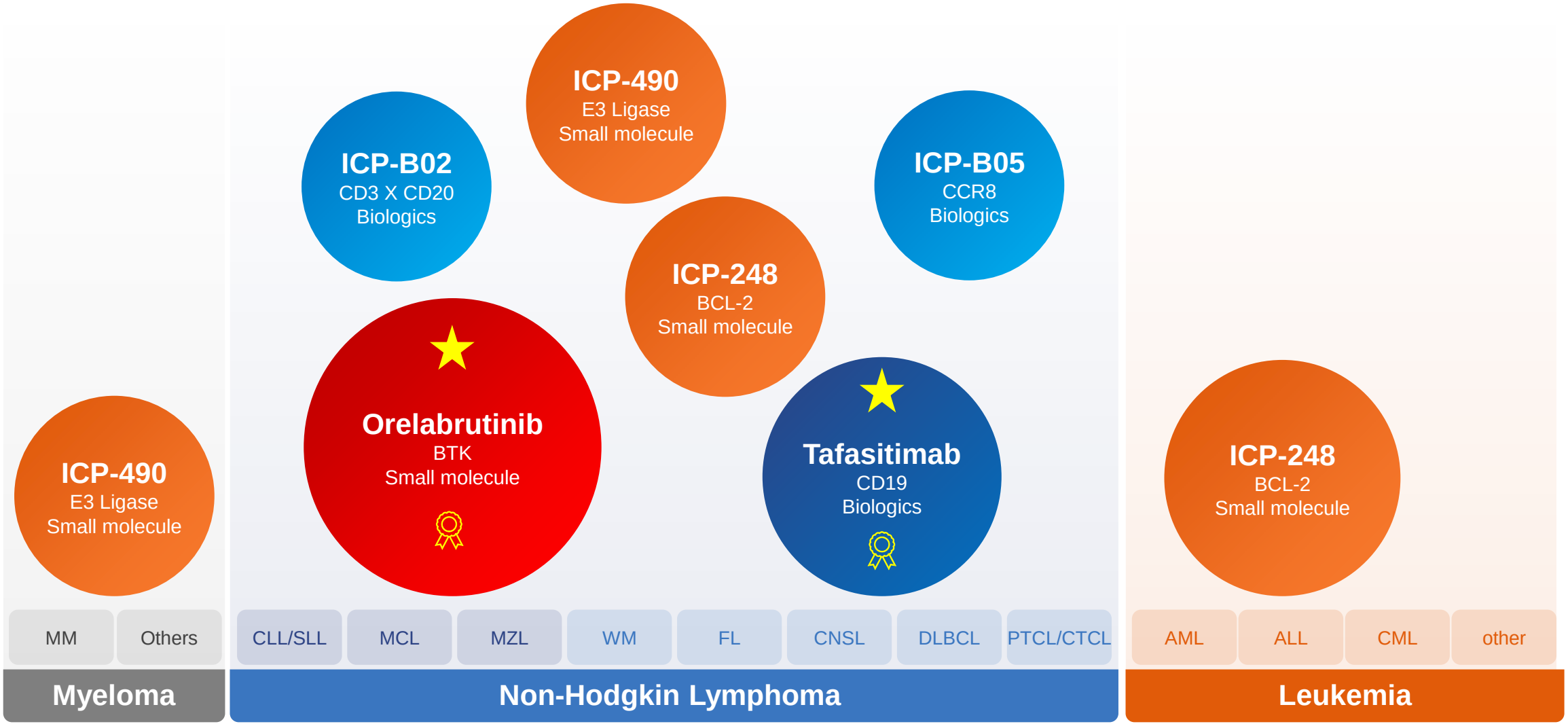
AA: Aplastic Anemia
AIHA: Autoimmunehemolytic Anemia
CD: Crohn's Disease

CLE: Cutaneous Lupus Erythematosus
IgG4 RD: Immunoglobulin G4-related disease
ITP: Immune thrombocytopenic purpura

LN: Lupus Nephritis
MN: Membranous Nephropathy
MoG-EN: MOG encephalomyelitis

PsO: Psoriasis
SLE: Systemic Lupus Erythematosus
SS: Sjogren syndrome

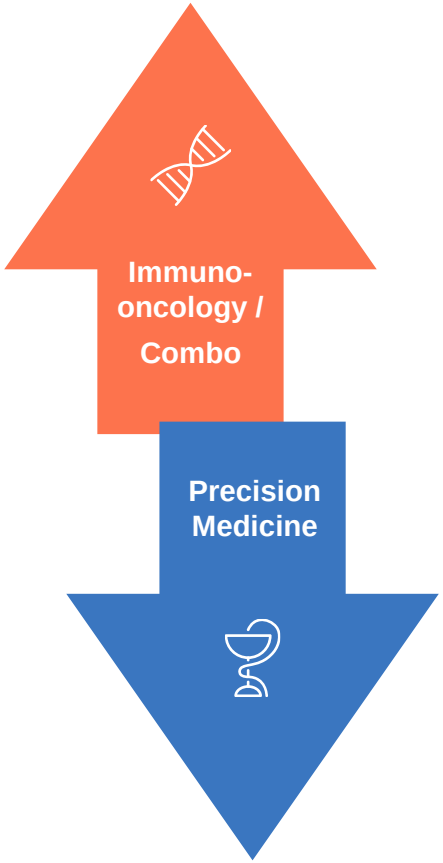
Comprehensive Coverage in Hemato-oncology Indications & MOAs



NDA

Solid Tumors Strategy

Benefit more patients



Benefit patients more

First-in-Class
Cornerstone of combination therapy

ICP-189
SHP-2

ICP-B05
CCR8

RTKi	EGFRi	VEGFi	KRASi	RAFi
MEKi	CDK4/6i	PD-1/PD-L 1	ICI	

ICP-723
NTRK/ ROS1

ICP-192
FGFR

Provide the right medicine, to the right patient, at the right time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Tafasitamab: For the Treatment of r/r DLBCL

Pilot use in Hainan & GBA → Approved in HK → Collaboration with TTY for TW development → BLA accepted in June 2024

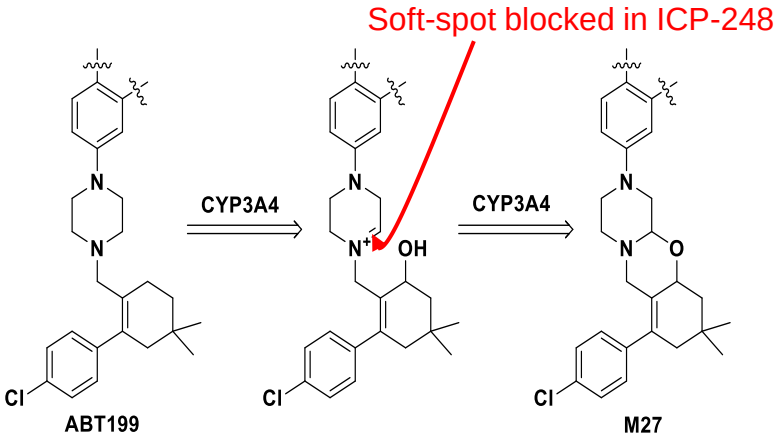
Comparison of Selected Novel Therapy in r/r DLBCL

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

Non-head-to-head comparison

Source: Frost & Sullivan Analysis as of the end of 2022; Insight; Pharma Intelligence

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

- **Combo with Orelabrutinib** (1L CLL/SLL)
- **Dose expansion in r/r NHL**
- **US trial in NHL**
- **1L AML IND started**

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

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

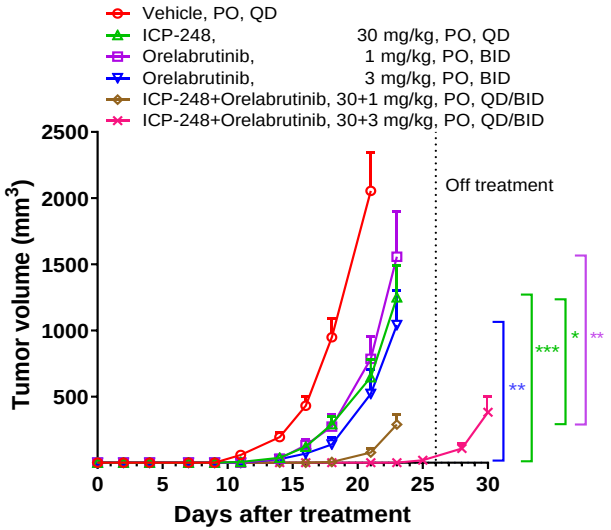
Best-in-class in both efficacy and safety

Asset	ICP-248 100 mg QD	APG-2575[1]	BGB-11417[2]	LP-108[3]	Venetoclax[4]
Sample Size	14	11	NA	21	81
Indication	BTKi failure B-NHL				
ORR	71.4%	Not reported		48%	40%

- Best-in-class for patients with BTKi failure B-NHL
- Most tolerable safety profile
- Consecutive with Orela in NHL

Expanding and Evolving ICP-248 Portfolio

Significant Synergy with Orelabrutinib



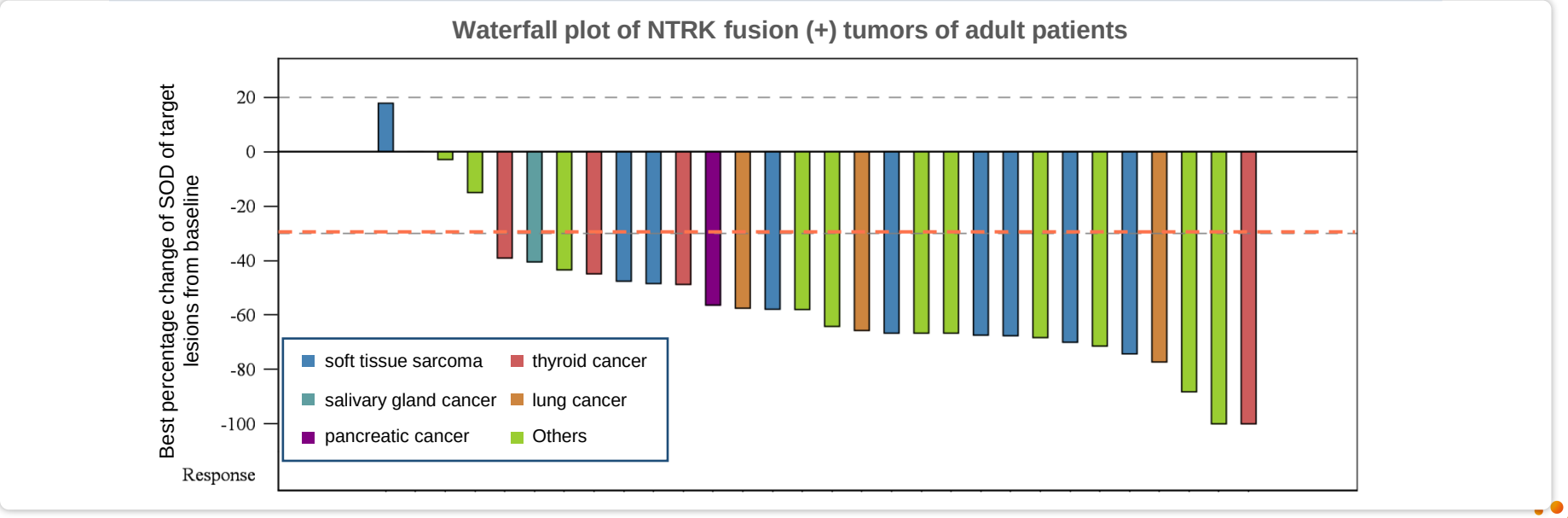
- **1L CLL/SLL combo with Orela fixed duration therapy**
  - Safety run-in enrollment completion (42 pts) ahead of 2 months in timeline due to excellent compound and study profile

Source: 1. Matthew S. Davids et al. 2022 ASH; 2. Caixia Li et al. 2023 EHA, 2022 ASH; 3. Xu W et al. 2023 EHA; 4. Yazeed Sawalha et al. Blood Adv. 2023 ;7(13):2983-2993.

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



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

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

INNOCARE 诺诚健华 | ARRIVENT

ICP-189
SHP2 Inhibitor

Furmonertinib
EGFR Inhibitor

Mono-therapy Progress

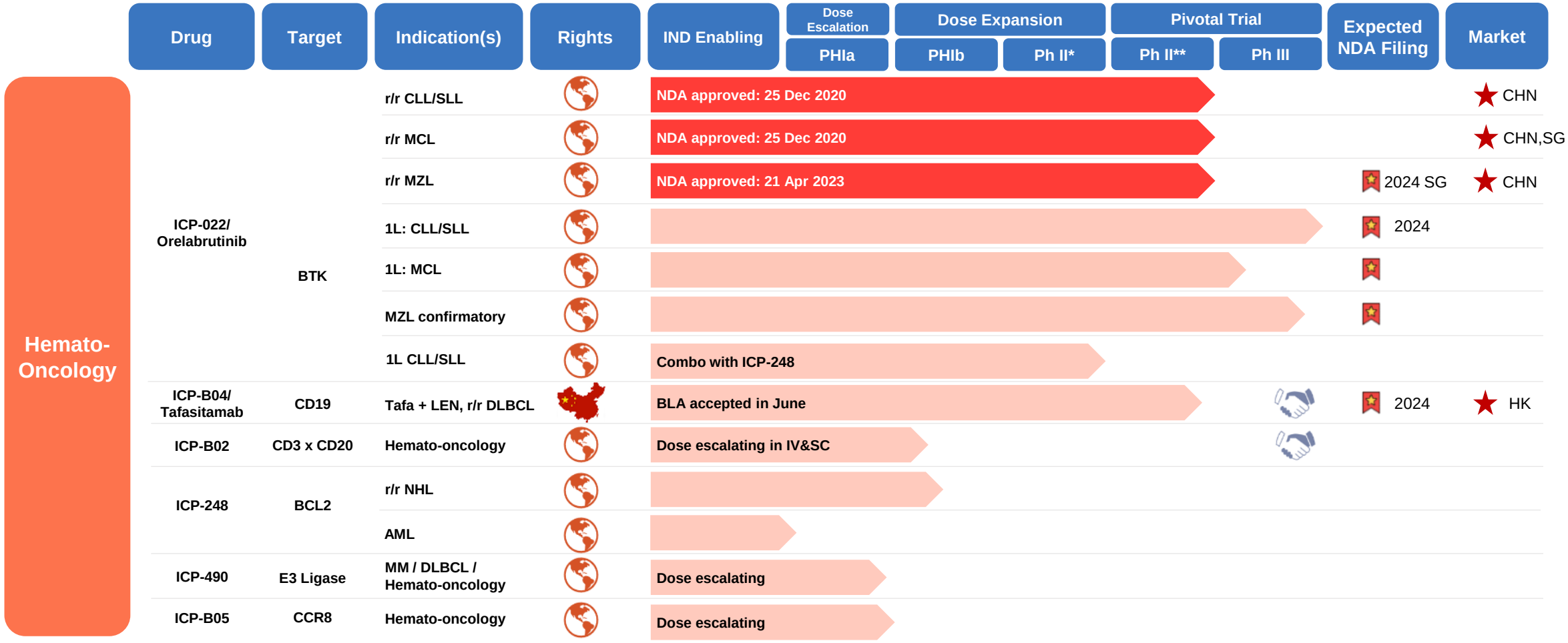
- First-in-Class
- SHP2 inhibitor for NSCLC & others
- **Excellent PK and tolerability demonstrated** in Ph I dose escalation
- **Single agent efficacy** observed
- Class-leading safety profile: **No grade 3 or higher TRAEs** observed up to 120 mg

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**

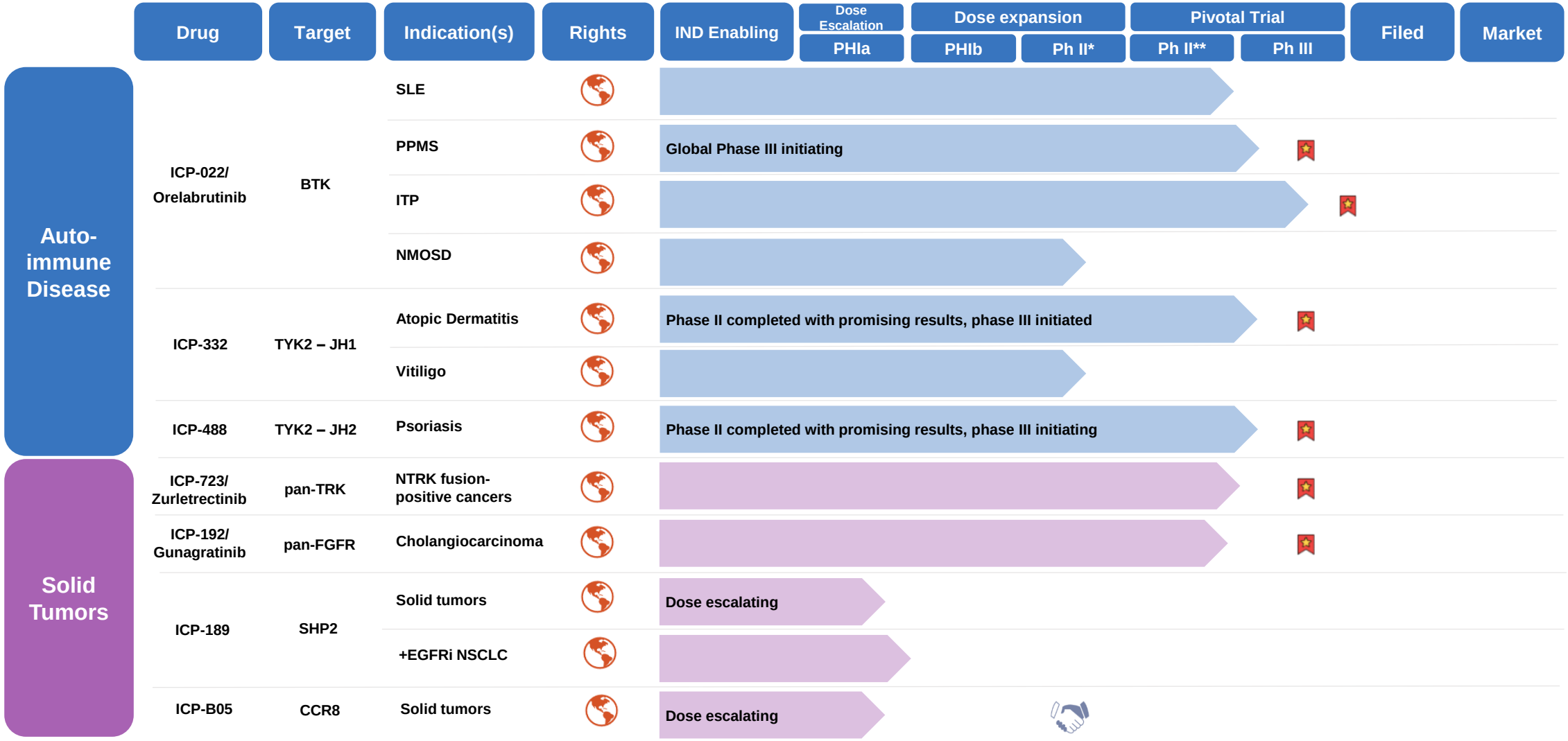
**Combo with furmonertinib, in collaboration with ArriVent*

Product Pipeline – Hemato-oncology



Listed drug Registrational Trial NDA

Product Pipeline – Solid Tumors and Autoimmune Diseases



Listed drug Registrational Trial NDA