INNOCARE
诺诚健华

InnoCare Pharma (9969.HK, 688428.SH)
2022 Annual Results NDR

March 2023

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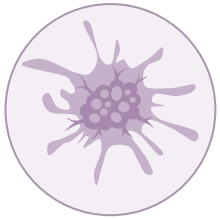
Our Vision

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

Oncology   **Autoimmune**

Our Therapeutic Focus

Transforming from Biotech to Biopharma

Strategy Execution Delivered Strong Growth in 2022

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Commercialization

- Total revenue reached **RMB 625.4mn**,with a **163.6% yoy growth** in product sales
- Rapid market penetration and hospital coverage after NRDL inclusion
- **Tafasitamab**
  - Approved for Urgent Clinical Use in the Hainan Province, 1st patients reached CR after 2 cycles treatment
  - Approved in Hong Kong
  - Eligible for Urgent Clinical Use in Big Bay Area
  - Highly experienced and efficient sales team in hematology

Internal R&D Pipeline

- **Orelabrutinib**
  - **MS phase II:** 80mg QD showed **92.1% relative reduction** achieved in cumulative number of new Gd+ T1 lesions compared to placebo
  - **SLE phase IIa positive,** Phase IIb ongoing
  - **ITP phase II showed positive result**
  - **r/r MZL** under priority review
  - **r/r MCL** NDA approved in Singapore
  - r/r MCL US registrational trial patients enrollment completed
  - **1L DLBCL-MCD registrational Phase3** ongoing
  - **1L CLL/SLL registrational Phase III** proceeding
- **ICP-332** Phase II commenced in AD
- **ICP-488** Phase I ongoing, psoriasis arms will be included
- **ICP-192** registrational trial processing
- **ICP-723** well positioned for registrational trial
- Pipeline strengthened with **6 NMEs**

License-in/Collaboration

- **In-licensing**: **Tafasitamab**
  - **Tafasitamab+LEN** registrational trial ongoing
  - **Tafa+LEN+Orela** exploring trial ongoing
- **Collaboration with KeyMed**
  - **CD3*CD20** dose escalation trial ongoing
  - **CCR8** 1st patient was dosed and enrollment is continuing

Platform

- Internal production capability: Orelabrutinib in GZ facility
- Biologics drug R&D facility in Beijing
- Commercial team in expansion

STAR board listing, >RMB 9 billion total cash, cost sensitive & efficient culture

[1] ***POC**: Proof of concept*

Commercialization Review

Increasing Sales Momentum in Orelabrutinib

Significant Growth of Net Sales

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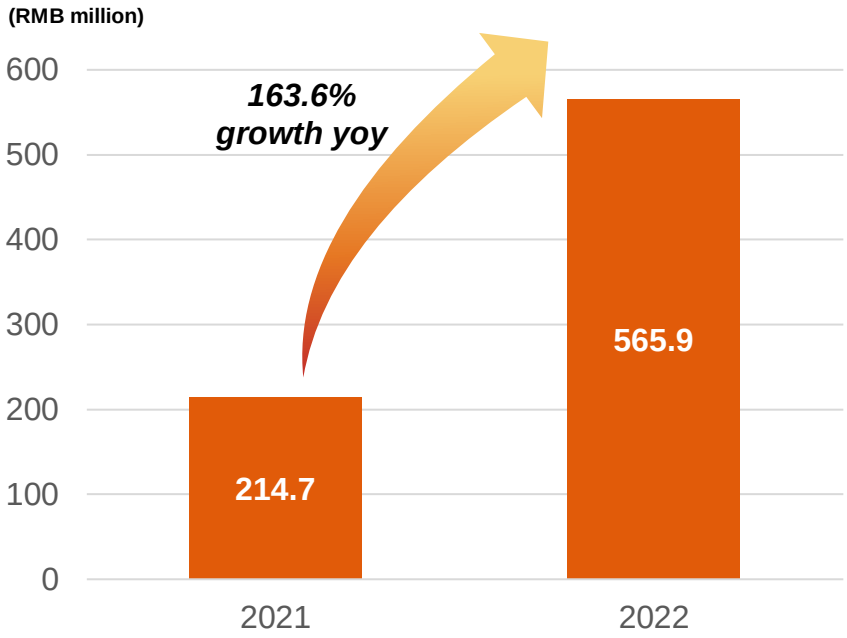
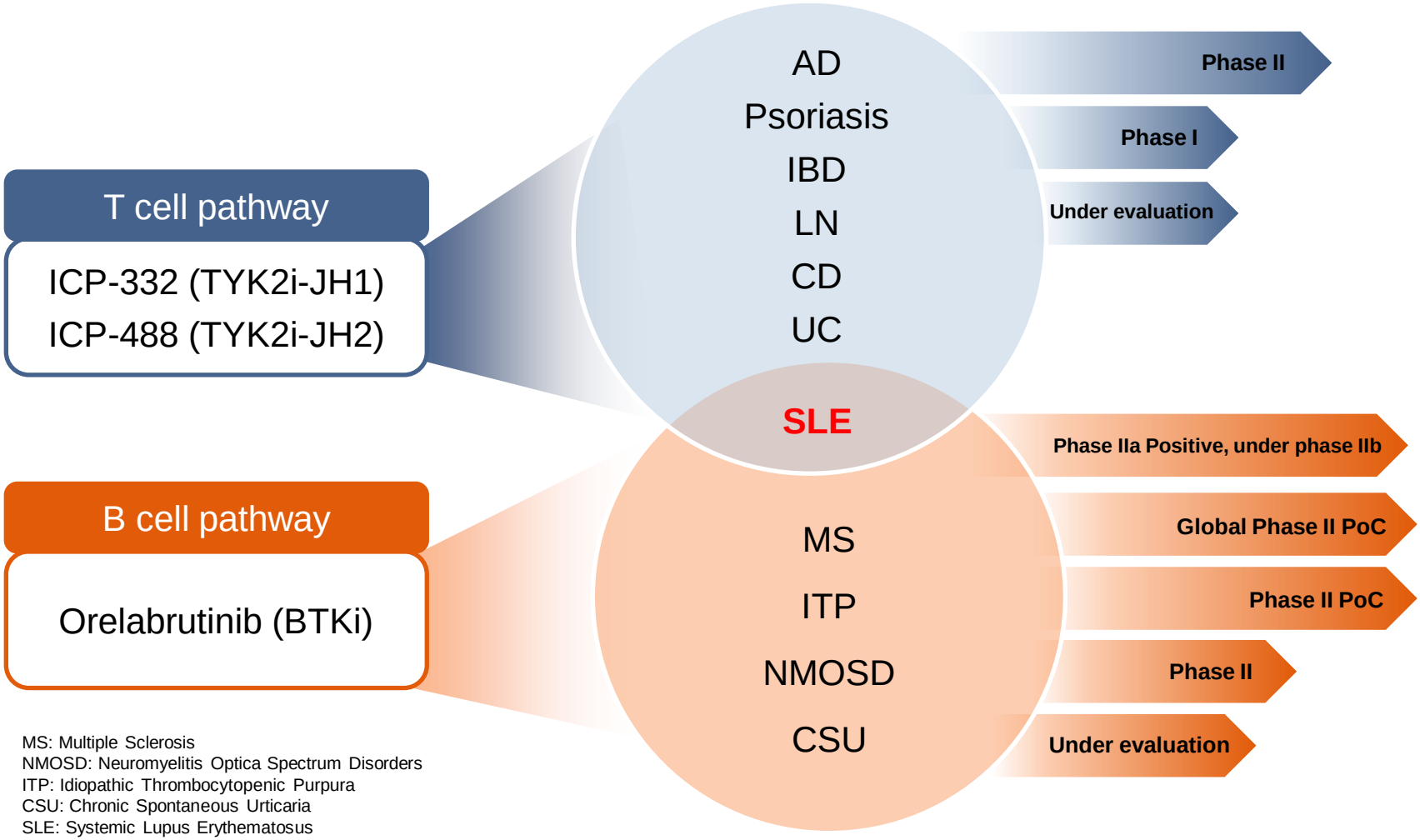


Successful Commercialization Strategy

- Net sales achieved **RMB 565.9mn** in 2022
- Swift implementation of NRDL[1] at local level
- Experienced and effective in-house commercial team
- Rapid coverage of Hemato-oncology market in China:
  - Penetrated **300+** Cities
  - Covered **1,500+** Hospitals
  - Educated **6,000+** Doctors
- **CSCO Diagnosis and Treatment Guidelines** recommended broad use: r/r CLL/SLL, r/r MCL, r/r DLBCL and PCNSL
- Substantial future growth potential:
  - Indication expansion with differentiated strategy
  - DOT enhancement
  - Extensive post market clinical studies to strengthen best-in-class profile
  - Tailored-access at different tiered cities

[1] ***Indications included in NRDL**: r/r Mantle Cell Lymphoma ("**MCL**") and r/r Chronic Lymphocytic Leukemia/Small Cell leukemia ("**CLL/SLL**")*
FPI to NDA took 1.5 years while FPI to launch to the market took 2.5 years

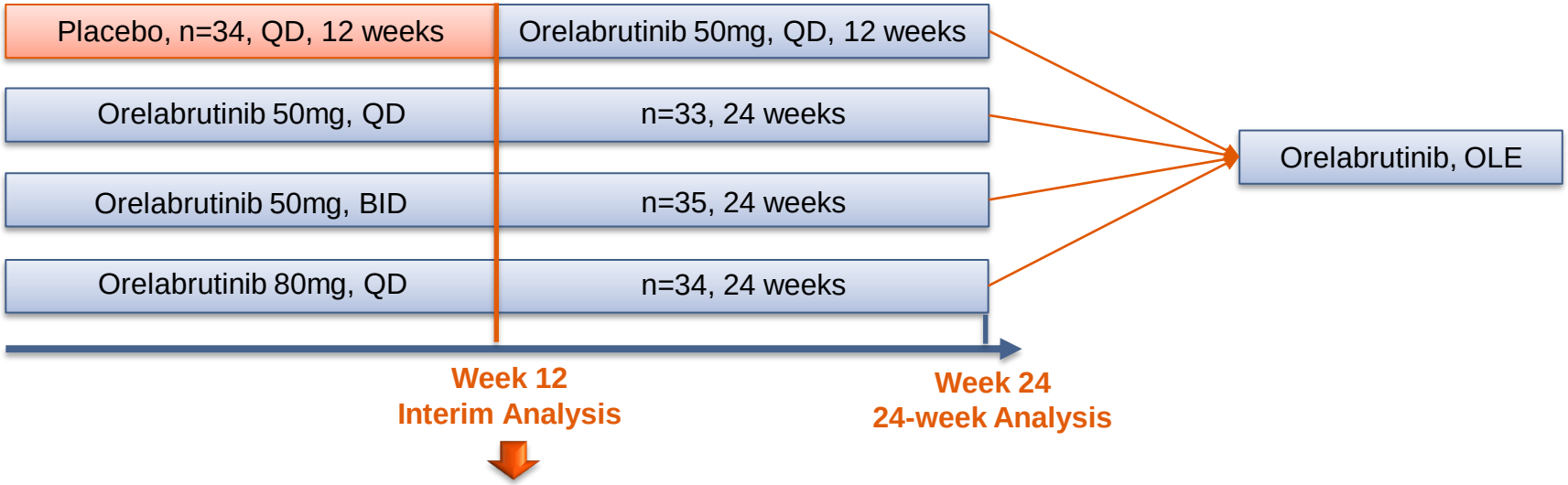
Autoimmune Disease Strategy



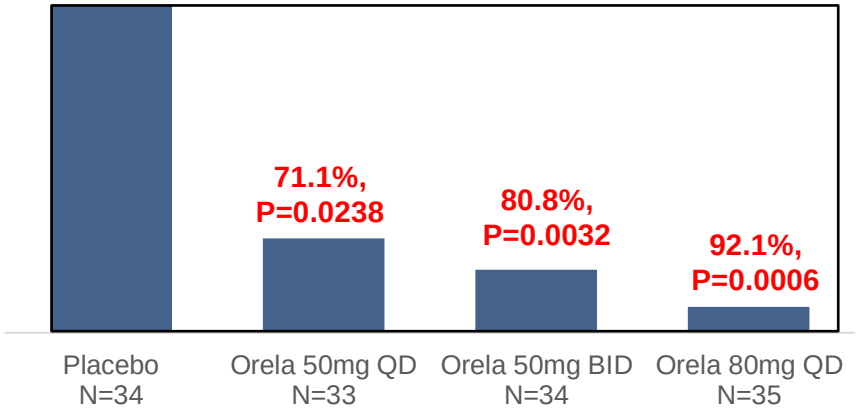
MS: Multiple Sclerosis
NMOSD: Neuromyelitis Optica Spectrum Disorders
ITP: Idiopathic Thrombocytopenic Purpura
CSU: Chronic Spontaneous Urticaria
SLE: Systemic Lupus Erythematosus
AD: Atopic Dermatitis
IBD: Inflammatory Bowel Disease
LN: Lupus Nephritis
CD: Crohn's disease
UC: Ulcerative Colitis

1 Major Program Update : MS Phase II Interim Analysis

Orelabrutinib (ICP-022): Potential Best-in-class BTKi for Multiple Sclerosis



Relative reduction% achieved in cumulative number of new Gd+ T1 lesions compare to placebo



- The primary objective were met dose-dependently(C_{max} driven) in all three active treatment groups
- **92.1%** relative reduction achieved in cumulative number of new Gd+ T1 lesions compared to placebo at 80mg QD
- **Best-in-class** profile

1 Different Therapies for RMS in Phase II Studies

Therapy	Design, Duration[1]	Primary endpoint	Relative Reduction in T1 lesions vs. PBO	Dose	Company
Orelabrutinib BTKi	Placebo-controlled(N = 136), 24Wk + ext	Cumulative Gd+lesionsat Wk12	92.1%	80mg QD	InnoCare
Tolebrutinib BTKi	Placebo-controlled for 4Wk, with 12Wk cross-over (N=130), 16Wk + ext	Dose-response for Gd+ lesions at Wk 12	85%(2)	60mg QD	Sanofi
Evobrutinib BTKi	Placebo-controlled + open label DMF (N = 267),24Wk + ext	Cumulative Gd+ lesions at Wk12, 16, 20, and 24	70%(3)	75mg qd (56% at 75mg bid)	Merck KGaA
Ocrelizumab Anti-CD20	Placebo-controlled + Inf-b1a reference arm (N=218), 24Wk + ext	Cumulative Gd+ lesions at Wk 12, 16, 20, and 24	89%(4)	600mg q6mo	Roche
Ofatumumab Anti-CD20	Placebo-controlled (N=231), 24Wk + ext	Cumulative Gd+ lesions at Wk 12	65% (5)(6) 91%(7)	60mg q12w	Novartis
Siponimod S1PR	Placebo-controlled, adaptive, doseranging (N = 297), 6m + ext	Dose-response for CUAL at 3 mo	72%(8)	2mg qd	Novartis
Dimethyl Fumarate	Placebo-controlled(N = 257),24Wk + ext	Cumulative Gd+ lesions at Wk12, 16, 20, and 24	69%(9)	240mg tid	Biogen
Fingolimod S1PR	Placebo-controlled (N = 281), 6m + ext	Cumulative Gd+ lesions monthly for 6 months	61%(10) 88% at mo. 6	5mg qd	Novartis
Teriflunomide	Placebo-controlled (N = 179), 36Wk + ext	# of CUAL per MRI scan	61%(11)	14mg qd	Sanofi

[1] www.clinicaltrials.gov; (2)Sanofi's R&D held on April 23, 2020;(3) MontalbanX, et al. N Engl J Med 2019; 380:2406-2417;(4) KapposL, et al. Lancet 2011;378:1779-87 (5) Bar-Or A. et al, Neurology 2018;90:e1805-e1814; (6)Endpoint with full data (0-12 Wks) (7) Post hoc data (4-12 wks);(8) Selmaj K, et al Lancet Neurol 2013;12:756-767;(9) Kappos L, et al. Lancet 2008;372(9648):1463-72;(10) Kappos L, et al. N Engl J Med 2006; 355:1124-40;(11) O'Connor P, et al. Neurology 2006;66(6)

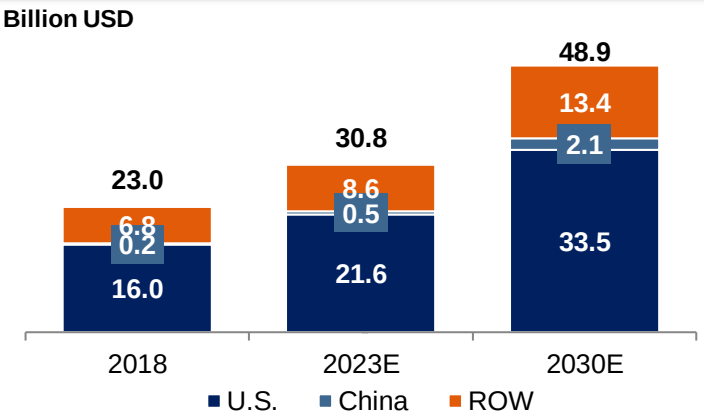
1 Major Program Update

Orelabrutinib (ICP-022): Potential Best-in-class BTKi for Multiple Sclerosis

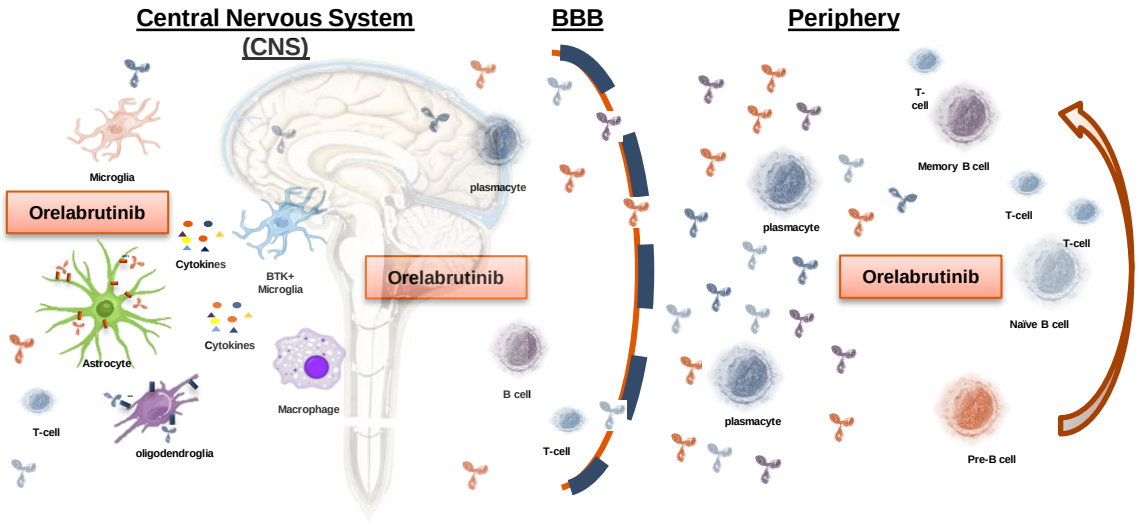
Orelabrutinib has the potential to act in both CNS and periphery for demyelinating diseases. Its high target selectivity, good PK profile and BBB penetration capability presents a promising option for treating MS

BTKi	Company	Dose (mg)	CSF Conc. ~2h (ng/mL)
Orelabrutinib	InnoCare	150 QD	31.3
Evobrutinib	Merck KGaA	75 BID	3.21[2]
Tolebrutinib	Sanofi	120 QD	1.87[1]

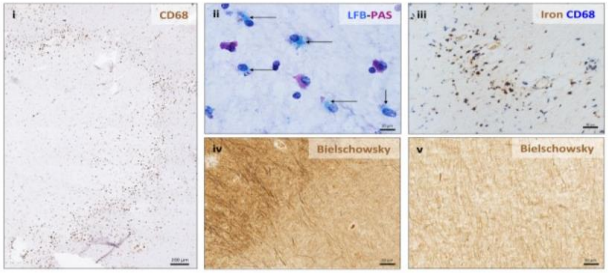
Substantial MS Market Size



Source: Frost & Sullivan Analysis



Microglia are increased in the MS lesion rim[3]



[1] *doi: 10.1016/j.msard.2021.103000*
[2] *Multiple Sclerosis and Related Disorders 51 (2021) 103001 Topic: Advances in therapy in MS; doi: 10.1016/j.msard.2021.103001*
[3] *Absinta et al J Clin Invest. 2016 Jul 1; 126(7): 2597–2609*

2 Major Program Update

Orelabrutinib (ICP-022):SLE Phase IIa Positive Results Lead to Further Development

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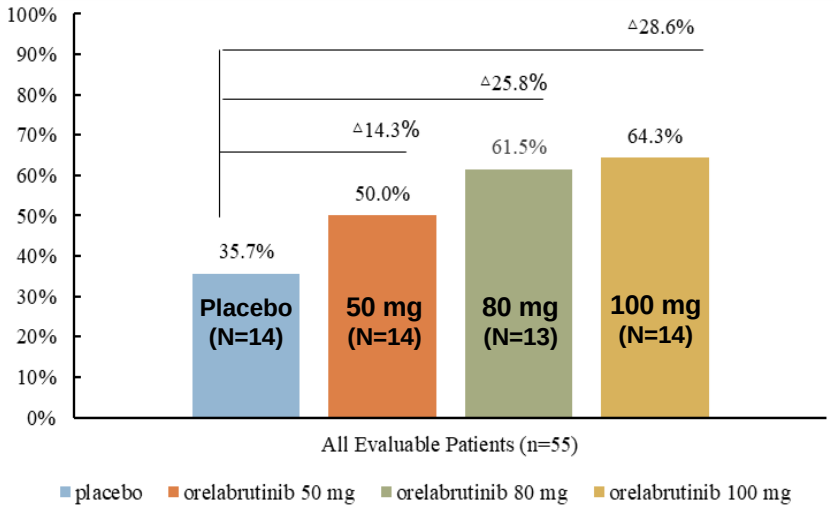
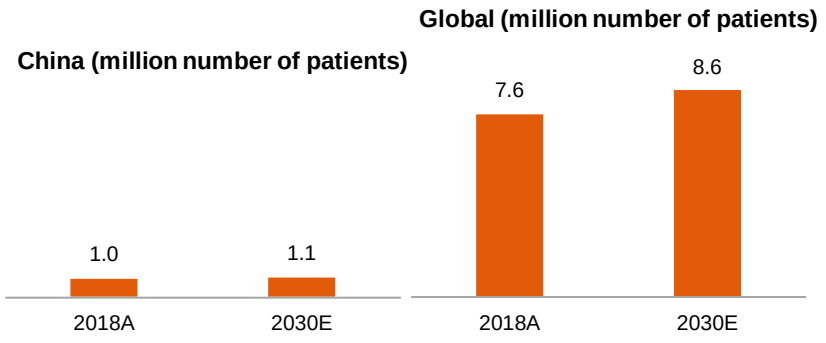
SRI-4 Response Rate at 12 Weeks



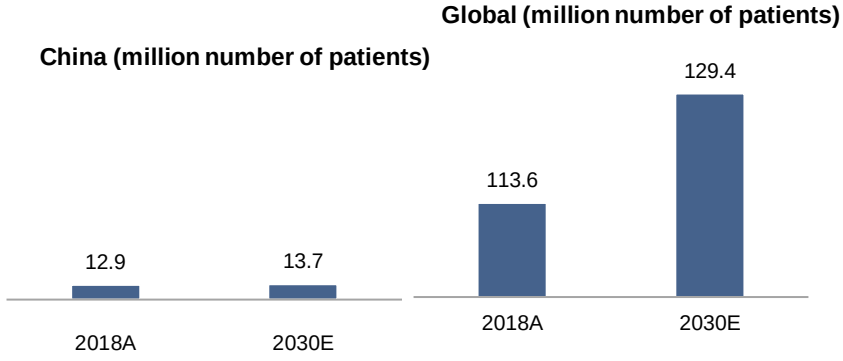
SLE Phase II Study Results[1]

- SLE Responder Index ("SRI")-4 response rates increased in a dose dependent manner
- Trends of reduction in proteinuria level and improvement of immunologic bio-markers[2]
- The only BTKi ever shown efficacy in Phase II SLE trials
- **Phase IIb trial in mainland China is progressing**

SLE Prevalence Rate



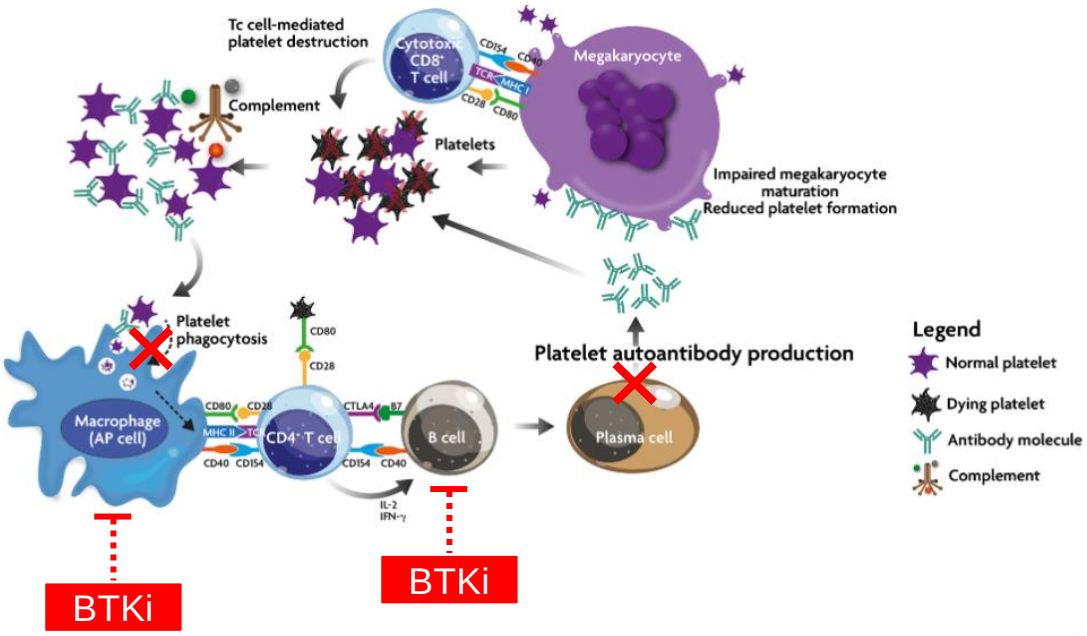
Other Autoimmune Diseases (RA,MS, Psoriasis, LN) Prevalence Rate



*[1] The Phase IIa trial evaluated the safety and efficacy of Orelabrutinib plus standard of care verse placebo plus standard of care ("**SoC**") in patients with mild to moderate SLE*

[2] Reduced immunoglobulin G and increased complements C3 and C4 were observed

Major Program Update
Orelabrutinib (ICP-022): ITP phase II results



BTKi's advantage in ITP

- Decreased macrophage (Fcγ receptor)–mediated platelet destruction
- Reduced production of pathogenic autoantibodies

Phase II data readout, as of cut-off date on 6 February 2023:

- The overall 36.4% (12 out of 33) patients met the primary endpoint, while **40% patients met the primary endpoint at the 50mg arm (6 out of 15)**
- The data from 22 patients with previous response to glucocorticoids ("GC") or intravenous immunoglobulin ("IVIG") were analyzed as a sub-group: **75.0% patients at the 50mg arm achieved the primary endpoint (6 out of 8)**

Source: Drew Provan, John W. Semple, DOI:https://doi.org/10.1016/j.ebiom.2022.103820

Major Program Update

ICP-332:TYK2 JH1 inhibitors to Potential Blockbuster Oral Treatments

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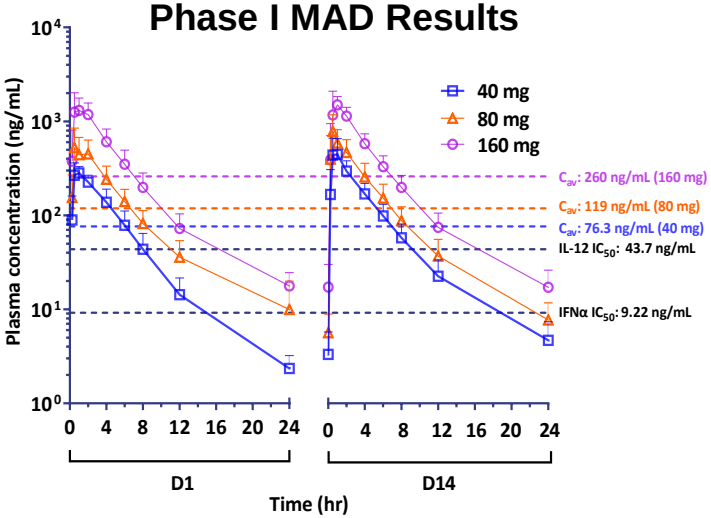
ICP-332 (TYK-2, JH1) Phase I

- Phase I study: SAD, MAD, food effect completed
  - Demonstrated a dose proportional and favorable PK profile, no significant food effect observed
  - Safe and well-tolerated, **no significant decrease of platelet and hemoglobin (JAK2-related AE) observed** and **no DLT observed**
- **Phase II** trial for **atopic dermatitis** ongoing

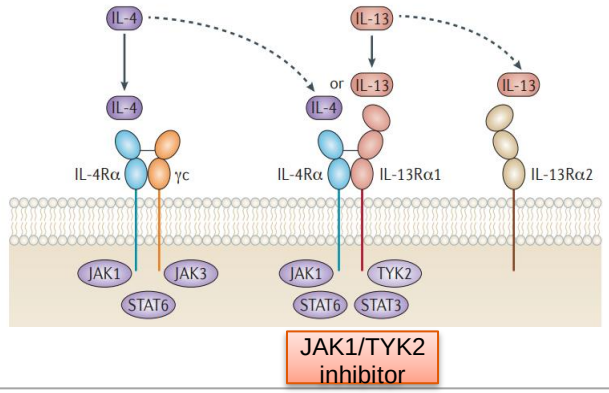


Selectivity

Drug	TYK2 vs. JAK1 (fold)	TYK2 vs. JAK2 (fold)	JAK1 vs. JAK2 (fold)
ICP-332	~40	~400	10

Evaluate JAK1/TYK2 inhibitor for AD and other indications

Strategies: Targeting Type 2 Inflammation by JAK-Inhibitor

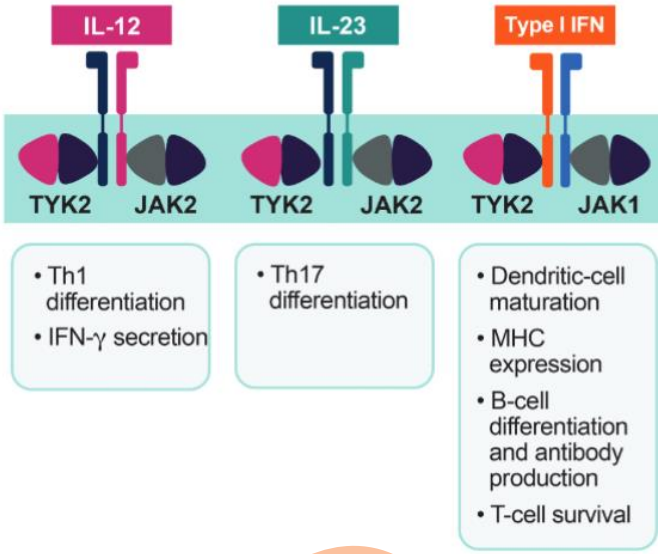


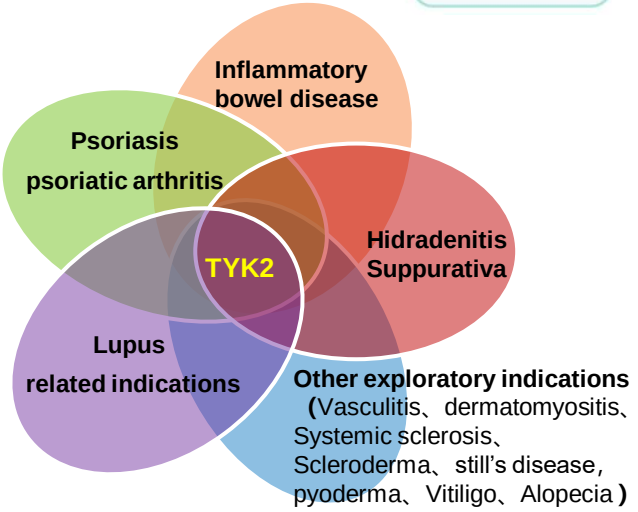
Major Program Update

ICP-488:TYK2 inhibitor: Potential Blockbuster for Oral Treatments

ICP-488 (TYK-2, JH2)

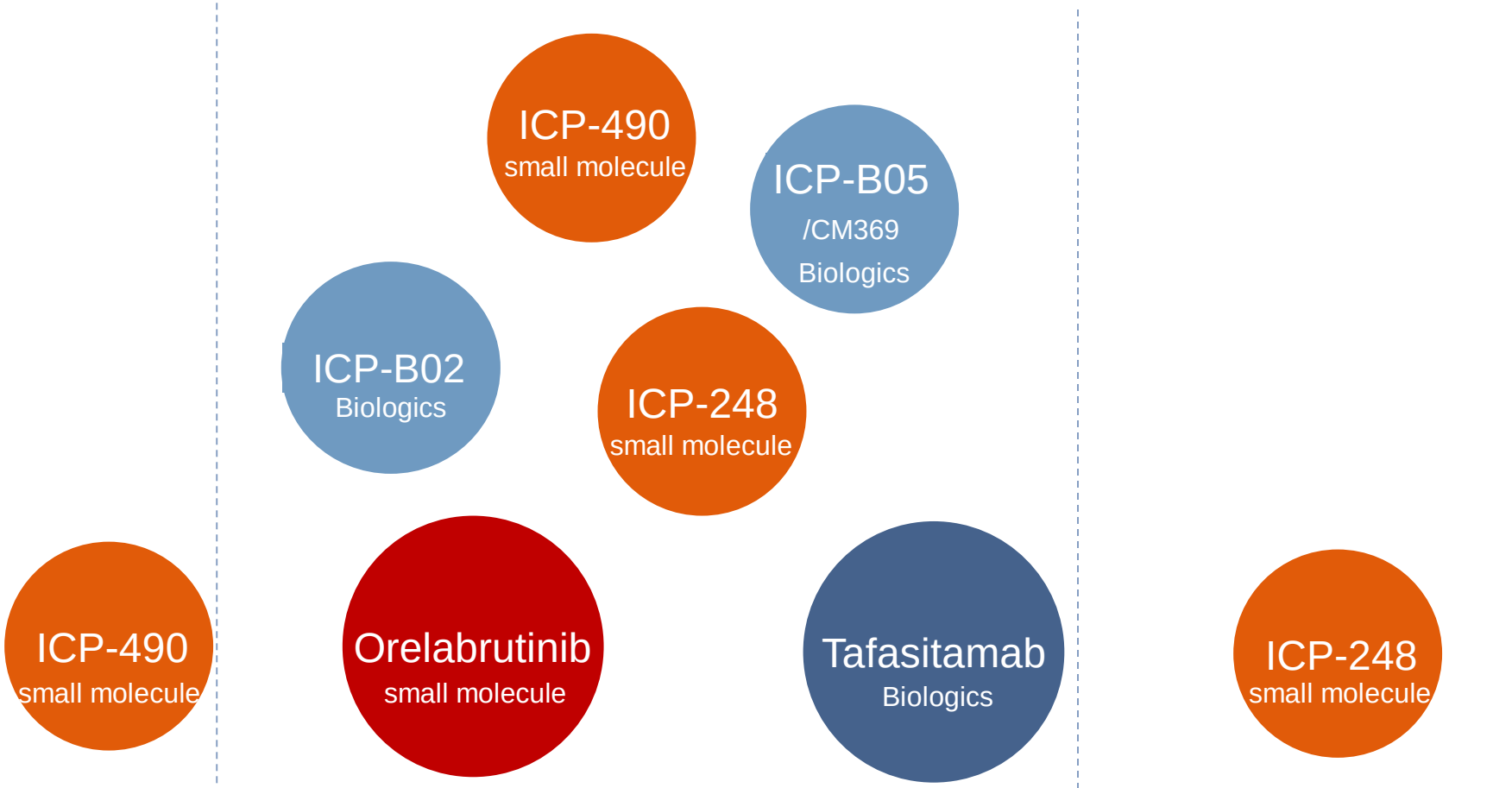
- An oral, potent and allosteric TYK2 inhibitor that selectively binds to the JH2 pseudokinase domain **with no activities on JAK1-3**
- Phase I study
  - Completed SAD (maximum dosage to 36mg), in MAD, **psoriasis** patients arms will be included, no DLT observed so far
  - Potential to show significant advantages in safety profiles verse other JAK family inhibitors





Source: Silvio Danese, MD, PhD, Laurent Peyrin-Biroulet, MD, PhD, Selective Tyrosine Kinase 2 Inhibition for Treatment of Inflammatory Bowel Disease: New Hope on the Rise, Inflammatory Bowel Diseases, Volume 27, Issue 12, December 2021, Pages 2023–2030

Differentiated Strategy in Hemato-oncology



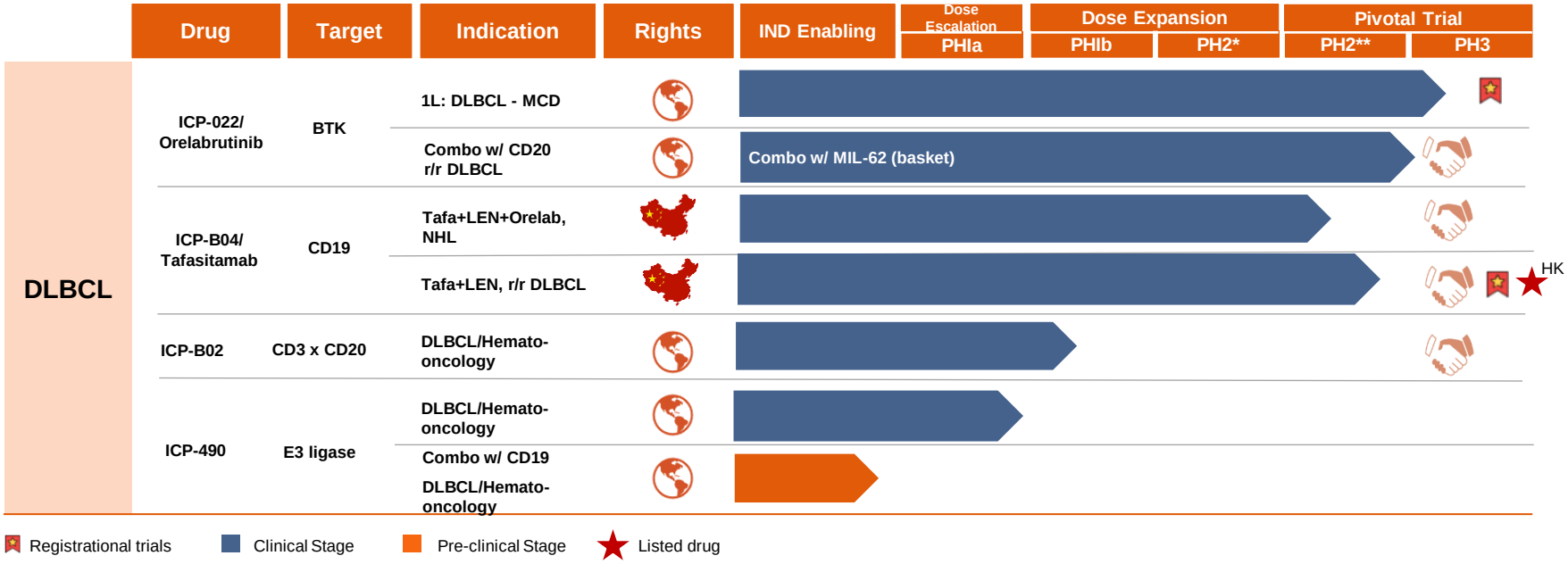
Differentiated Strategy in DLBCL

Orelabrutinib
excellent safety profile for combo therapy

Tafasitamab
CD19 Ab with improved ADCC/ADCP

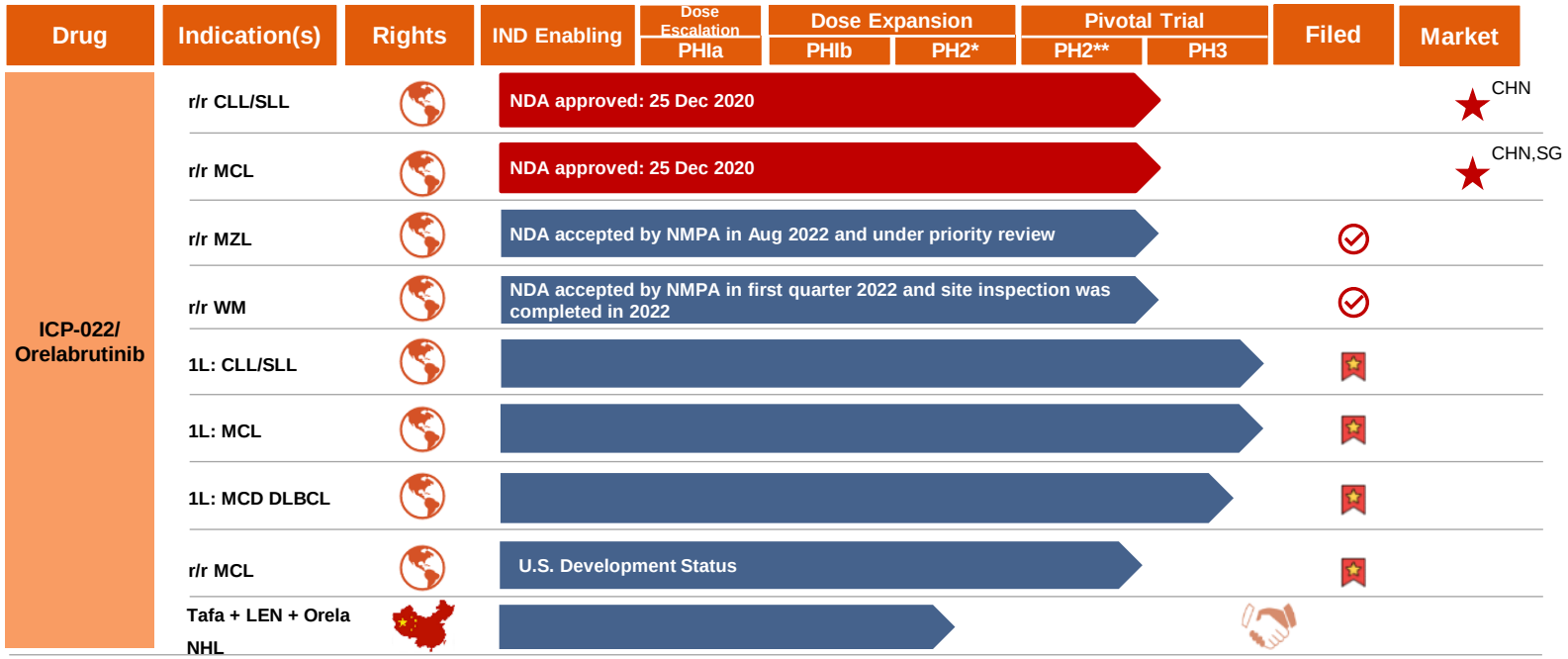
ICP-490
E3 ligase modulator
High selectivity/affinity
Lenalidomide resistant

CD3xCD20
Highly potent, convenient w/ subQ
Safety and convenient for late line patients



Major Program Update

Orelabrutinib (ICP-022): Pipeline in Hemato-oncology



New data:

- **r/r MZL**: **First BTKi for MZL in China**. **ORR was 58.9%** assessed by independent review committee ("**IRC**"). The median duration of response ("DOR") was **34.3 months** (95% CI). The estimated **12-month PFS and OS were 82.8% and 91%**
- **1L MCD DLBCL**: **Differentiated orelabrutinib for 1L DLBCL worldwide**
- **r/r WM**: With a median duration of treatment of 24.9 months, **MRR was 80.9%**. **ORR was 91.5%**. The estimated **12-month DOR was 84.9%.** The estimated **12-month PFS was 81.2%.** The median PFS has not been reached. There was **no reported Grade 3 or higher atrial fibrillation and/or atrial flutter**, or Grade 3 diarrhea

Cao XX, Jin J, Fu CC, Yi SH, Zhao WL, Sun ZM, Yang W, Li DJ, Cui GH, Hu JD, Liu T, Song YP, Xu B, Zhu ZM, Xu W, Zhang MZ, Tian YM, Zhang B, Zhao RB, Zhou DB. Evaluation of orelabrutinib monotherapy in patients with relapsed or refractory Waldenström's macroglobulinemia in a single-arm, multicenter, open-label, phase 2 study. EClinicalMedicine. 2022 Oct 4;52:101682. doi: 10.1016/j.eclinm.2022.101682. PMID: 36313145; PMCID: PMC9596308.

Major Program Update

Tafasitamab: Potential Best Therapy for r/r DLBCL

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Current Status and Further Development

- **Registrational trial for r/r DLBCL is ongoing to support approval in mainland China**
- **Approved for Urgent Clinical Use in the Hainan Province, 1st patients reached CR after 2 cycles treatment**
- **BLA was approved in Hong Kong** and will followed by pilot use in GBA
- Potential combination therapy with Orelabrutinib

Competitive Landscape: 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	BCL2	Venetoclax+R+Pola	II	65	31	5.8	4.4	11

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

Major Program Update

ICP-490: Highly Potent Next Generation CRBN Modulator

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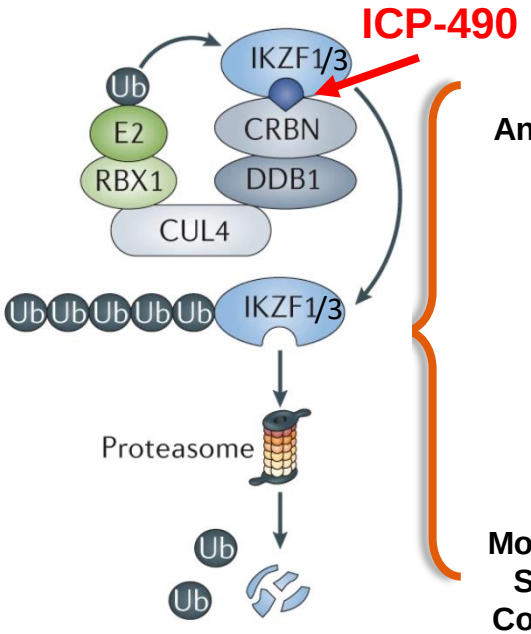
Blockbuster Potential for Multi-indications

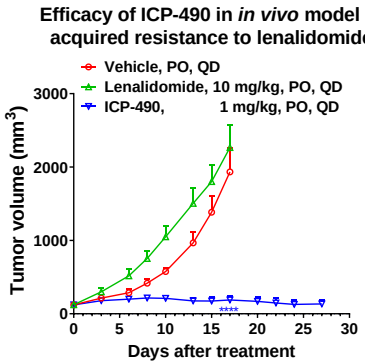
- **Much more potent** than Iberdomide and overcomes acquired resistance against earlier-generations of CRBN modulators
- **Synergizes and enhances efficacy** of mAbs, such as anti-CD38, anti-CD20, anti-CD19 mAbs etc., and provides strong rationale of synergistic combinations in clinic
- **Revolutionary treatment of MM**
- **Immense potential in heme-oncology field, including MM, NHL as a mono therapy or in combo with others**



Direct Anti-Myeloma Effects

Immune Modulation for Synergistic Combinations

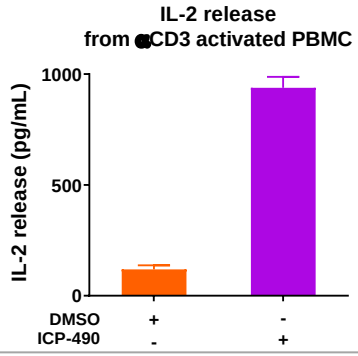
• **Overcomes acquired resistance**



MM

r/r MM
1L MM

• **Increases IL-2 modulates immune**



MM
NHL

MM
NHL
(CLL/SLL, MCL, MZL, WM, FL, DLBCL, etc.)

Source a: Reference: a: Jan, M., Sperling, A. S., and Ebert, B. L. (2021). Cancer therapies based on targeted protein degradation — lessons learned with lenalidomide. Nature Reviews Clinical Oncology 18, 401-417.

Other Valuable Clinical Assets Update

Continuous Strong Flow of Early Stage Projects

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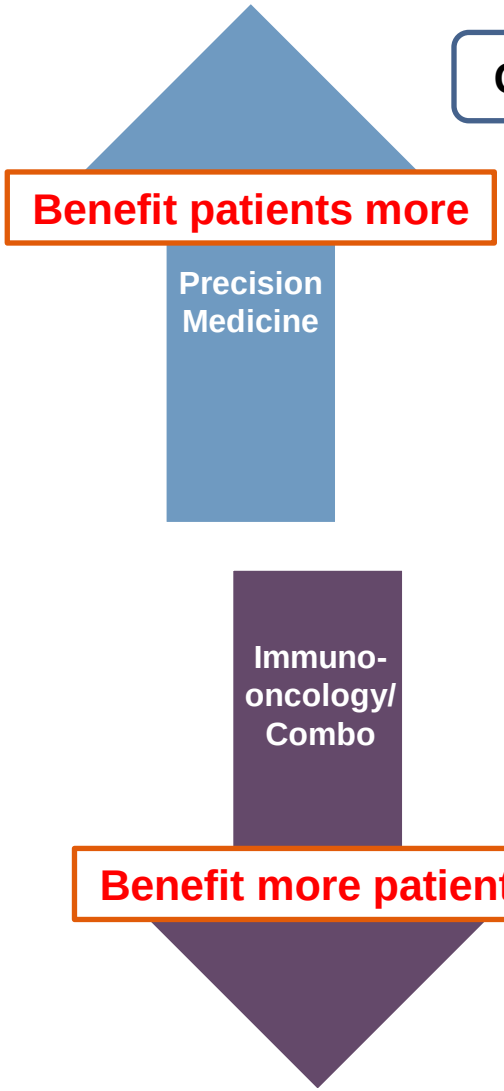
Liquid Tumor Phase I

- **ICP-B02 / CM355 (CD3 x CD20)**
  - Phase I/II trial ongoing in China
  - Dose escalation is progressing with the 4th cohort being completed, **no dose-limiting toxicity observed**
  - **T cell activation and almost complete B cell depletion was observed in patients treated with low dose**
  - IND of Subcutaneous ("SC") formulation was approved in 2023Q1

- **ICP-248 (BCL-2)**
  - IND was approved by CDE in September 2022 and **first patient dosed** in March 2023
  - The study result would **support combo therapy with Orelabrutinib in 1L CLL/SLL treatment**

Solid Tumor Strategy



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

- **ICP-192 (Gunagratinib)**
  20 mg showed **efficacy in cholangiocarcinoma patients** with **52.9% ORR, 94.1% DCR**
- **ICP-723 (Zurletrectinib)**
  75% ORR observed in various types of solid tumors carrying **NTRK fusion** at dosages of **8 mg and above**

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

ICP-189
SHP-2

ICP-B05
CCR8

Cornerstone of Combination Therapy

1 Major Program Update

ICP-192: Promising Safety and Efficacy Seen in Phase II trials

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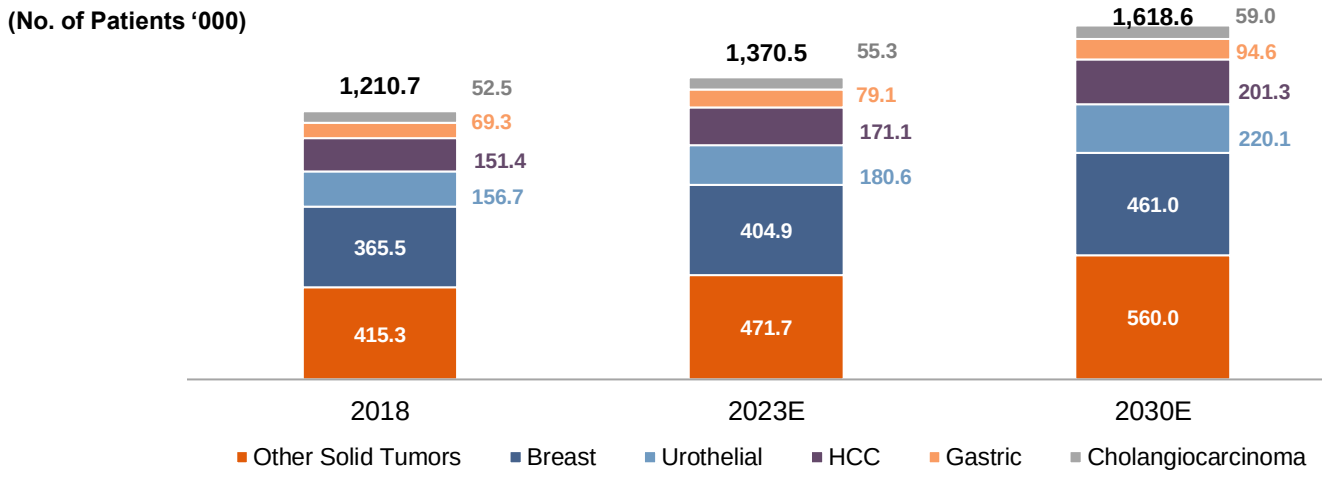
ICP-192 (Gunagratinib, FGFRi)

- Finished dose-escalation ranging from **2 mg to 26 mg** and **no DLT observed**
- Safe and well-tolerated in patients with advanced solid tumors
- **20 mg** showed **efficacy in cholangiocarcinoma patients who have completed at least one tumor assessment** with **52.9% ORR, 94.1% DCR, and mPFS 6.93 months, posted at ASCO GI**
- **Initiated registrational trial in cholangiocarcinoma**
- Exploring urothelial cancer **in China**
- Progressing basket trial, including gastric and head & neck cancer in multiple countries

A Glance at FGFR Mutation by Solid Tumor Types Worldwide



Source: Frost & Sullivan Analysis

Major Program Update

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

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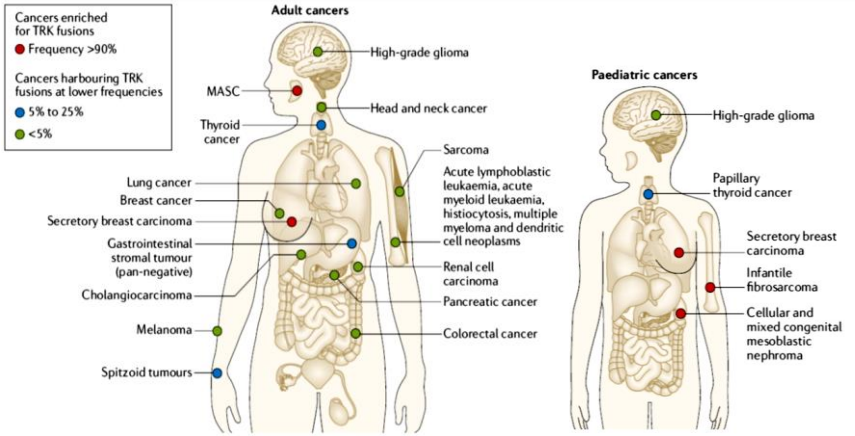
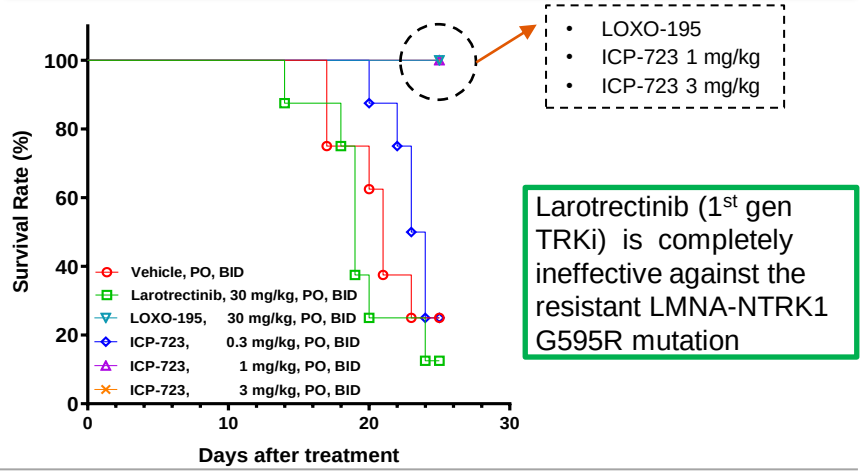
ICP-723 (Zurletrectinib,TRKi)

- **2nd generation TRKi overcomes acquired resistance to 1st generation TRKi**
- **No DLTs** observed in Phase I dose escalation study (1-20 mg)
- Phase I study demonstrated favorable PK profile and anti-tumor activity
- **Phase II does expansion study is going with RP2D at 8 mg, 75% ORR** observed in various types of solid tumors carrying NTRK fusion in different dosage
- Well positioned for registrational trial in China
- IND application of **pediatric patients** was accepted in 2023Q1

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



BaF3 Survial Model Harboring Mutation (LMNA-NTRK1 G595R) that Confer Resistance to 1st Gen TRKi



Larotrectinib (1st gen TRKi) is completely ineffective against the resistant LMNA-NTRK1 G595R mutation

3 Other Clinical Assets Update

Continuous Strong Flow of Early Stage Projects

Solid Tumor Phase I

- **ICP-189 (SHP2)**
  - First patient enrolled in June 2022 and Phase I trial ongoing in China
  - 1 patient with cervical cancer in **20 mg dose cohort achieved PR**
  - Phase Ia dosage escalated to **40 mg with no DLT observed** as of February 2023
  - No ≥ G3 TRAEs and SAEs and preliminary efficacy was observed in monotherapy
  - Demonstrated favorable PK profile and long half-life
  - Potential initiation of Phase Ib trial for the **multiple combination** ie. EGFRi in lung cancer, PD-1 in multiple cancer types
  - **IND approval** was granted by the **FDA** in March 2023

- **ICP-B05 / CM369 (CCR8)**
  - IND was approved by CDE in August 2022 and **first patient was dosed in 2023Q1**

- **ICP-033 (DDR1, VEGFR)**
  - Phase I trial ongoing in China

Anticipated Milestones & Catalysts in Next 12 Months

Leverage Innovation to Drive Next Growth Chapter

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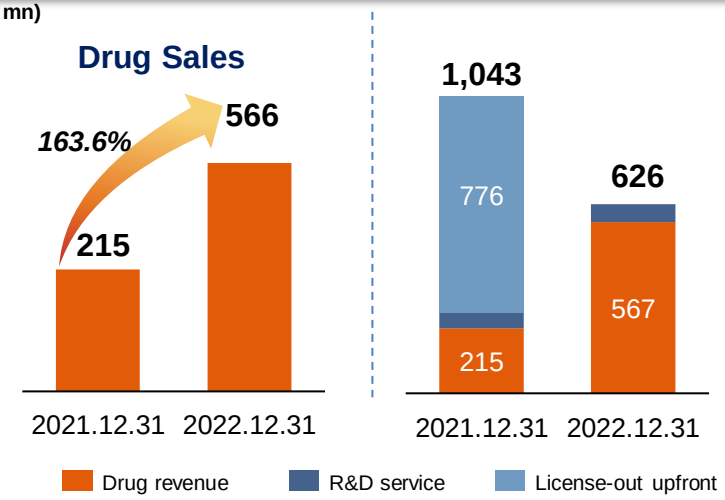
Liquid Cancer	■ **Orelabrutinib** ❑ **r/r MZL NDA approval** ❑ **r/r MCL NDA filing in U.S.** ❑ Complete 1L DLBCL-MCD enrollment ❑ Complete 1L CLL/SLL enrollment	■ **Tafasitamab (CD19)** ❑ **NDA submission in mainland CN** ❑ **Commence pilot use in GBA** ❑ NDA approval in Macau
Auto-immune Diseases	■ **Orelabrutinib** ❑ **MS Phase II full data readout & Phase III study plan** ❑ **ITP Phase II preliminary result** ❑ Complete Phase IIb SLE patients enrollment	■ **ICP-332 (TYK2 - JH1)** ❑ **Phase II data readout** ■ **ICP-488 (TYK2 - JH2)** ❑ **Complete Phase I trial** ❑ **PoC in psoriasis**
Solid Tumors	■ **ICP-192 (FGFR)** ❑ **Complete patients enrollment of iCCA registrational trial** ■ **ICP-723 (TRK)** ❑ **Complete patients enrollment of registrational trial**	■ **ICP-189 (SHP2)** ❑ Phase I trial result, confirm RP2D ❑ **B05 (CCR8)** ❑ Phase I trial result
■ **Commercialization** ❑ Significantly increase total revenue, with orelabrutinib and Tafasitamab ❑ Keep orelabrutinib ramp-up momentum, increase market share		■ **Strategic Collaboration** ❑ Continue to broaden global partnership of internal assets ❑ Expanding platform and pipeline by M&A and in-licensing synergistic products

Financial Review
Key Financials for Fiscal Year 2022

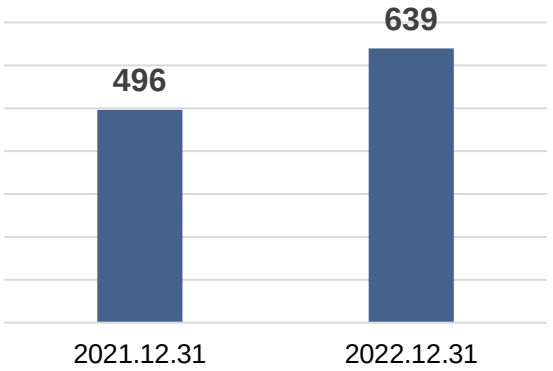
Revenue

(RMB mn)



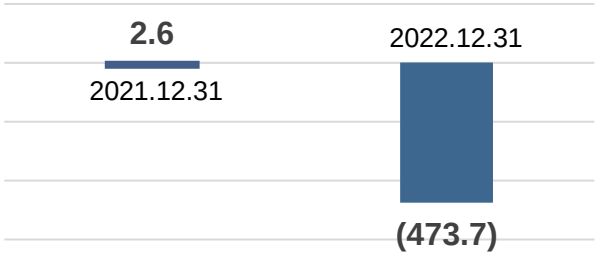
R&D Costs (Exclude licensing costs)

(RMB mn)



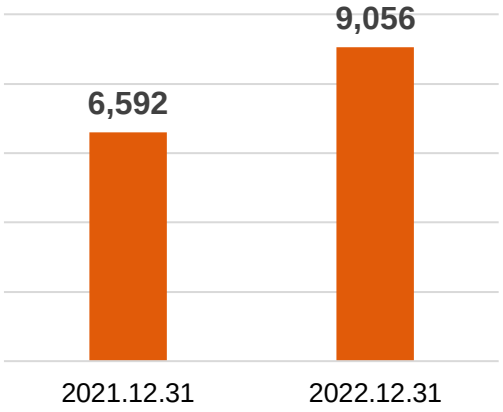
Loss for the Period (Non-HKFRS[1])

(RMB mn)



Cash and Cash Equivalents[2]

(RMB mn)

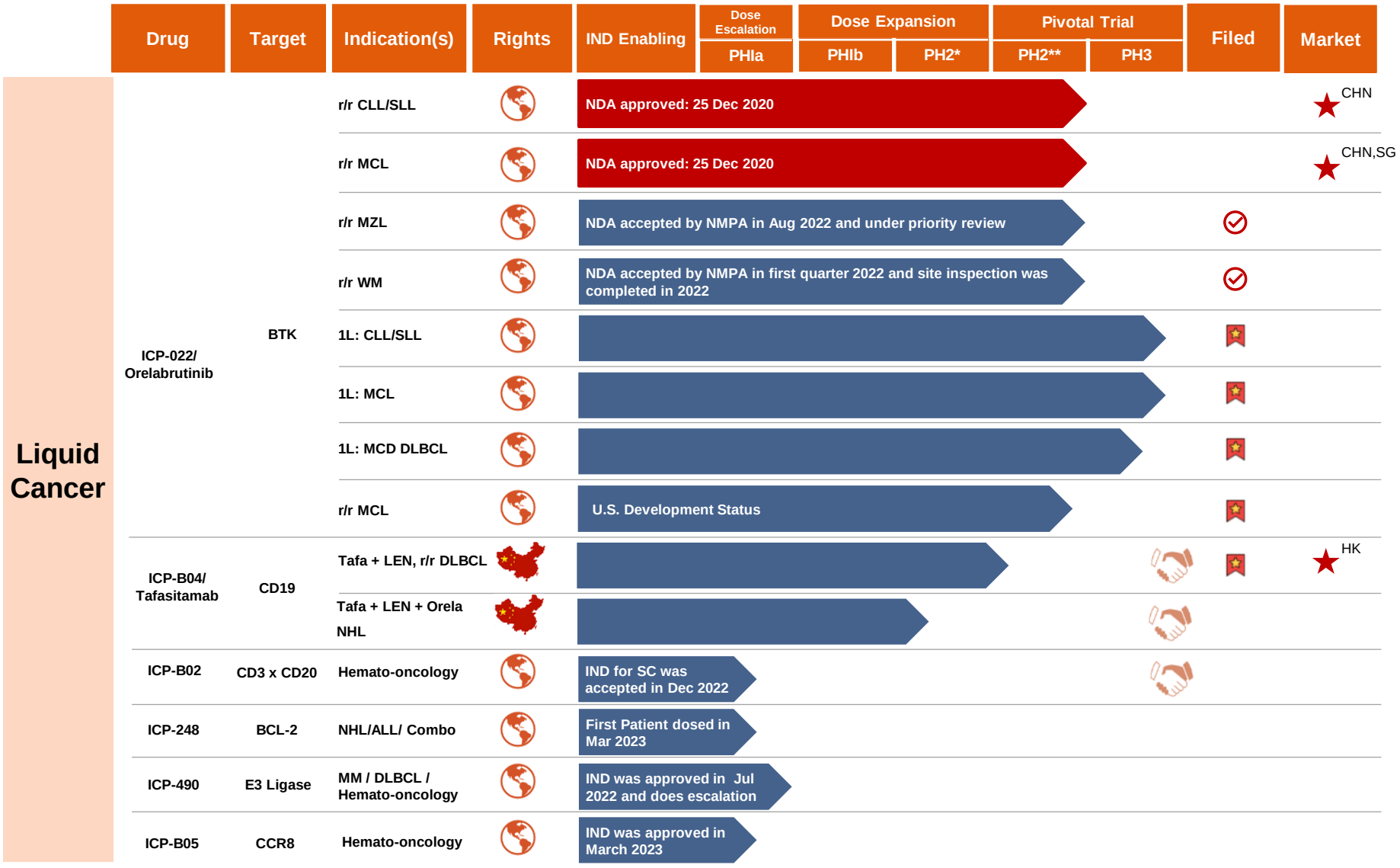


[1] Non-HKFRS: excluding foreign exchange and share-based compensation impact

[2] Cash and cash equivalents = investments measured at fair value investments, cash and bank balance, interest receivable

Research & Development

Product Pipeline – Liquid Cancer



Listed drug | Registrational Trial | NDA | Commercial Product

Research & Development

Product Pipeline – Autoimmune & Solid Tumor

Listed drug | Registrational Trial | NDA | Commercial Product

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Science Drives Innovation for the Benefit of Patients