

InnoCare Pharma (9969.HK, 688428.SH)

January 11, 2023



These materials are for information purposes only and do not constitute or form part of an offer or invitation to sell or issue or the solicitation of an offer or invitation to buy or subscribe for securities of InnoCare Pharma Limited (the "Company") or any of its holding company or subsidiaries in any jurisdiction. No part of these materials shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.

The information or opinions contained in these materials has not been independently verified. No representation or warranty, whether expressed or implied, is made as to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of such information or opinions contained herein. The information and opinions contained in these materials are provided as of the date of the presentation, are subject to change without notice and will not be updated or otherwise revised to reflect any developments, which may occur after the date of the presentation. The Company, any of its affiliates, directors, supervisors, senior managers, officers, employees, advisers and their respective representatives shall not have any liability whatsoever (in negligence or otherwise) for any loss howsoever arising from or in reliance upon any information contained or presented in or derived from these materials or otherwise arising in connection with these materials.

These materials contain statements that reflect the Company's current beliefs and expectations about the future as of the respective dates indicated herein. These forward-looking statements are based on a number of assumptions about the Company's operations and businesses and on factors beyond the Company's control, and are subject to significant risks and uncertainties, and, accordingly, the actual results may differ materially from these forward-looking statements. You should not place undue reliance on any of such forward-looking information. The Company assumes no obligation to update or otherwise revise these forward-looking statements for new information, events or circumstances that emerge subsequent to such dates.

**Our Vision** 



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



**Our Therapeutic Focus** 

## Transforming from Biotech to Biopharma Snapshot of Achievements in 2022 Q1-Q3



#### **Accelerated Commercialization**

- Total revenue reached RMB 442mn, including RMB 400mn of Orelabrutinib 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 HK, eligible for urgent clinical use in Great Bay Area

#### Solid Financial Position

- STAR Board listing
- Over RMB 7.7bn net cash in hand
- Cost sensitive and cost efficient culture

#### Rapidly Maturing Pipeline

- **13** clinical assets in total
- Orelabrutinib
- r/r WM & r/r MZL NDA accepted, r/r MZL under priority review
- r/r MCL NDA approved in Singapore
- IL DLBCL-MCD registrational Phase III trial commenced
- SLE moves to further clinical trial in China
- ICP-332 Phase II trials initiated in AD
- ICP-488 Phase I initiated and plan to enroll psoriasis patients
- ICP-192 entered registrational trial
- ICP-723 well positioned for registrational trial
- 6 NMEs entered clinical stage

#### Business Development Progressing

- Out-licensing
- Orelabrutinib collaboration with Biogen
- In-licensing:
- Tafa+LEN registrational trial in China is recruiting patients
- Exploring synergistic combination to target NHL/DLBCL with Tafa+LEN+Orela trial
- Collaboration with KeyMed
- CD3\*CD20 dose escalation trial ongoing
- CCR8 pts enrollment initiated

### Enhancing Integrated Platform

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

## **Commercialization Update** Strong Sales Ramp-up with Orelabrutinib

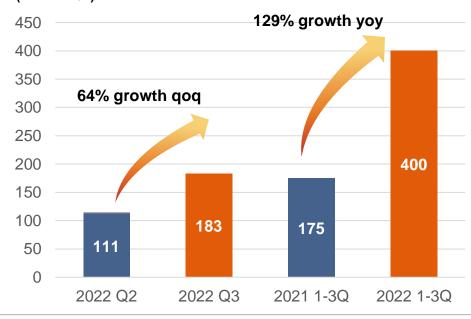


#### **Robust Net Sales Growth<sup>1</sup>**



#### (RMB million)

官语凯



#### Successful Commercialization Strategy

- Net sales achieved RMB 400mn in 2022Q1-Q3
- Swift implementation of NRDL at local level
- Experienced and effective in-house commercial team
- Rapid coverage of hematology market in China:
  - Penetrated 260+ Cities
  - Covered 1,000+ Hospitals
  - □ Educated **5,000+** 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
  - DOT enhancement
  - Extensive post market clinical studies to strengthen best-in-class profile
  - Tailored-access at different tiered cities

## **Research & Development** *Product Pipeline – Liquid Cancer*

36

	Drug	Target	Indication(s)	Rights	IND Enabling	Dose Escalation PHIa	Dose Ex PHIb	pansion PH2*	Pivot PH2**	al Trial PH3	Filed	Market
			r/r CLL/SLL	3	NDA approved: 2	5 Dec 2020						+ CHN
			r/r MCL	3	NDA approved: 2	5 Dec 2020				•		CHN, SG
			r/r MZL	3	NDA accepted by	NMPA in Aug 2	022 and under p	priority review		•	$\oslash$	
			r/r WM	3	NDA accepted by completed in 202	NMPA in first q 2	uarter 2022 and	site inspection	n was	•	$\oslash$	
	ICP-022/		1L: CLL/SLL	3							2	
	Orelabrutinib	BTK	1L: MCL	3							<b>A</b>	
			1L: MCD DLBCL	3							*	
Liquid			1L: WM	3							2	
Cancer			r/r MCL	3	U.S. Developmer	t Status					<b>\$</b>	
			r/r CNSL	3								
			r/r non-GCB DLBCL (double mutation)									
			Combo w/ MIL-62 (basket)									
	ICP-B04/ Tafasitamab	CD19	Tafa + LEN, r/r DLBCL	-							2	★нк
			Tafa + LEN + Orela NHL	*								
	ICP-B02	CD3 x CD20	Hematology	3								
	ICP-248	BCL-2	NHL/ALL	3	IND was approved Sep 2022	d in						
	ICP-490	E3 Ligase	Hematology	3	IND was approved Jul 2022	i in						

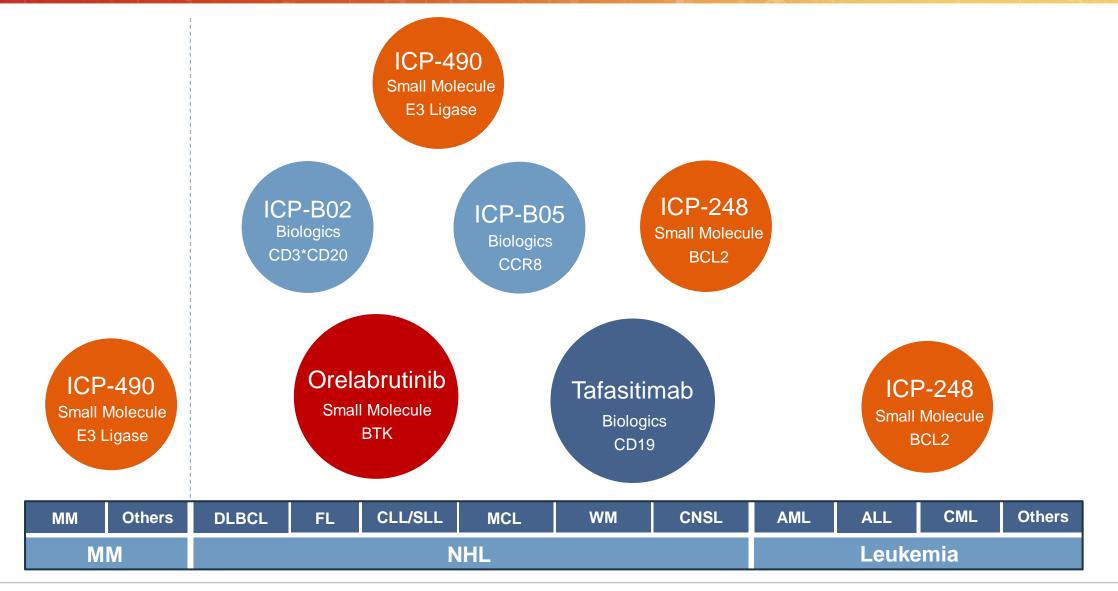
## **Research & Development** *Product Pipeline – Solid Tumor & Autoimmune Disease*

い INNOCARE 密 诚 健 华



# Major Program Update Differentiated strategy to be the leader in Hematology





## Major Program Update Orelabrutinib (ICP-022) : Comprehensive Coverage in Hematology

うで INNOCARE 街 诚 健 华

- Orelabrutinib has been approved for r/r MCL in Singapore
- r/r WM NDA was accepted and the site inspection was completed; r/r MZL NDA was included in priority review by CDE
- IL DLBCL MCD registrational trial enrollment ongoing, promising real world study results presented at ASCO
- 1L CLL/SLL trial in China is more than halfway through patient enrollment; Registrational trial in r/r MCL in West is ongoing
- A comprehensive tool-kit including Orelabrutinib, Tafasitamab, ICP-B02, ICP-490 and ICP-248 offers us a unique position to target NHL with combination therapies

Drug	Target	Indication(s)	Rights	IND Enabling	Dose Escalation PHIa	Dose Ex PHIb	pansion PH2*	Pivota PH2**	l Trial PH3	Filed	Market
		r/r CLL/SLL		NDA approved: 2							★сн
		r/r MCL		NDA approved: 2	5 Dec 2020						<b>*</b> Сні
		r/r MZL		NDA accepted by NMPA in Aug 2022 and under priority review							
		r/r WM		NDA accepted by NMPA in first quarter 2022 and site inspection was completed in 2022							
ICP-022/	DTI/	1L: CLL/SLL									
Drelabrutinib	BTK	1L: MCL									
		1L: MCD DLBCL									
		1L: WM									
		r/r MCL r/r CNSL		U.S. Developmer	nt Status						
		r/r non-GCB DLBCL (double mutation)									
		Combo w/ MIL-62 (basket)									

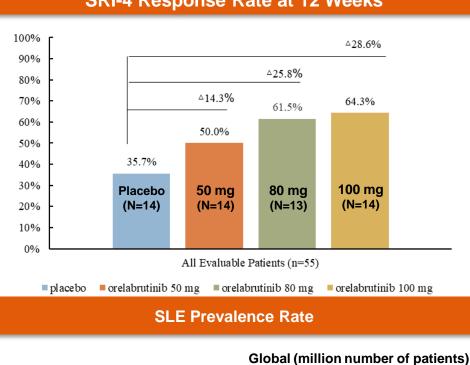




- MCD subtype DLBCL identified as a subgroup with potentially high sensitivity to BTKis
  - MCD subgroup is predominantly enriched with B-cell receptor-dependent NF-κB activation which indicates this patient sub-group might respond well to BTK inhibitors
  - Data from real world analysis of Orelabrutinib in combination with SOC in MCD DLBCL patients was presented at ASCO
    - 1<sup>st</sup> Line MCD-DLBCL (Orela + R-CHOP or R-EPOCH): CR Rate of 75% was observed
    - <sup>o</sup> 2<sup>nd</sup> Line MCD DLBCL (Orela + RICE or R-CHOP or R-Len): CR Rate of 66.67% was observed
- Orelabrutinib may be a superior BTKi when combined with other antibody drugs including CD20 and tafasitamab
  - The preclinical model proved that Orelabrutinib preserves NK-cell-mediated antibody-dependent cell-mediated cytotoxicity ("ADCC") induced by anti-CD20 antibody due to less inducible T cell kinase ("ITK") inhibition
  - Combination trial of Orelabrutinib with tafasitamab and lenalidomide has been initiated
- A comprehensive tool-kit including Orelabrutinib, Tafasitamab, ICP-B02 and ICP-490 offers us a unique position to tackle all stages of DLBCL patients with combination therapies

	Drug	Torgot	Indication	Rights	IND Enabling	Dose Escalation	Dose Expansion		Pivotal Trial	
	Drug	Target	mulcation	Rights		PHIa	PHIb	PH2*	PH2**	PH3
	ICP-022/ Orelabrutinib	ВТК	1L: DLBCL - MCD	3						
			Combo w/ Tafa+LEN r/r DLBCL	3						
			Combo w/ CD20 r/r DLBCL	3	Combo w/ MIL-62 (baske	t)				
DLBCL	ICP-B04/ Tafasitamab	CD19	2L DLBCL/Hematology	-						
	ICP-B02	CD3 x CD20	DLBCL/Hematology	3						
	ICP-490	) E3 ligase	DLBCL/Hematology	3	IND was approved in Jul	2022				
			Combo w/ CD19 DLBCL/Hematology	\$						



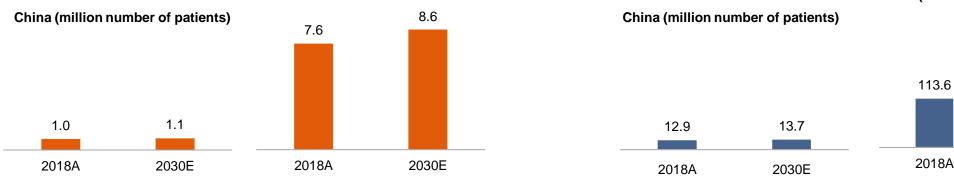


#### SRI-4 Response Rate at 12 Weeks

#### SLE Phase II Study Results<sup>1</sup>

- 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<sup>2</sup>
- The only BTKi ever shown efficacy in Phase II SLE trials
- Phase IIb trial in mainland China is initiated

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



#### Global (million number of patients)

129.4

2030E

<sup>1</sup> The Phase II 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 <sup>2</sup> Reduced immunoalobulin G and increased complements C3 and C4 were observed

## **3** Major Program Tafasitamab: Potential Best Therapy for r/r DLBCL



**Current Status and Further Development** 

- Pivotal 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
- Tafasitamab received marketing authorization in Hong Kong; will be followed by pilot use in GBA

Potential combination therapy \	with Orelabrutinib
---------------------------------	--------------------

	Comp	etitive Landscape	e: Selecte	d Novel	herapy	in r/r DLBC	;L	
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	II	59	41	4.8	5.5	11.6
Roche	CD79b ADC	Polatuzumab vedotin + BR vs BR	II	45 vs 18	40 vs 18	12.6 vs 7.7	9.5 vs 3.7	12.4 vs 4.7
Amgen/ Beigene	CD19/CD3	Blinatumomab	II	43	19	11.6	3.7	5.0
Regeneron/ Zai Lab	CD20/CD3	Mosunetuzumab	lb	35	19	N/A	N/A	N/A
Roche	CD20/CD3	Glofitamab	lb	38	31	N/A	N/A	N/A
Others	BCL2	Venetoclax	Ι	18	12	N/A	1.0	8.0



#### ICP-332 (TYK-2, JH1) Phase I MAD Results Safe and well-tolerated, no significant 104 decrease of platelet and hemoglobin Ĩ 🖶 40 mg ration (ng/r 01 s 🛆 80 mg (JAK2-related AE) observed in 🕂 160 mg Phase I studies Ę 10 Demonstrated a dose proportional and Plasm 10<sup>1</sup> favorable PK profile, no significant food FNα IC<sub>50</sub>: 9.22 ng/mL effect observed 8 12 16 20 8 12 16 Phase II trials initiated in atopic D1 D14 dermatitis Time (hr)

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

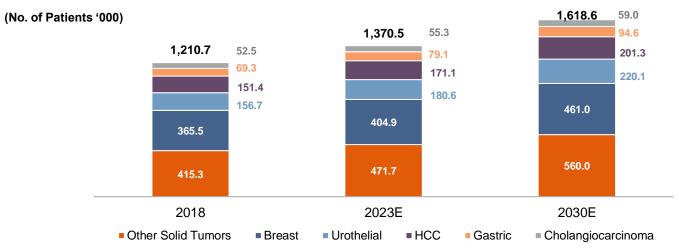
- An oral, potent and allosteric TYK2 inhibitor that selectively binds to the JH2 pseudokinase domain
- Favorable ADME and safety profile with no activities on JAK1-3
- Potential to show significant advantages in safety profiles verse other JAK family inhibitors
- Completed SAD, entered MAD, and plan to include psoriasis patients



でで INNOCARE 诺诚健华

#### ICP-192 (Gunagratinib, FGFR)

- 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 with 64.5% ORR and 100% DCR, data posted at ASCO
- Entered registrational trial in cholangiocarcinoma
- Advance Phase II trial in urothelial cancer in China
- Advance basket trial, including gastric and head & neck cancer in China, Australia and the U.S.



A Glance at FGFR Mutation by Solid Tumor Types Worldwide

## Major Program Update ICP-723: Favorable Clinical Results with Potential Best-in-Class Profile

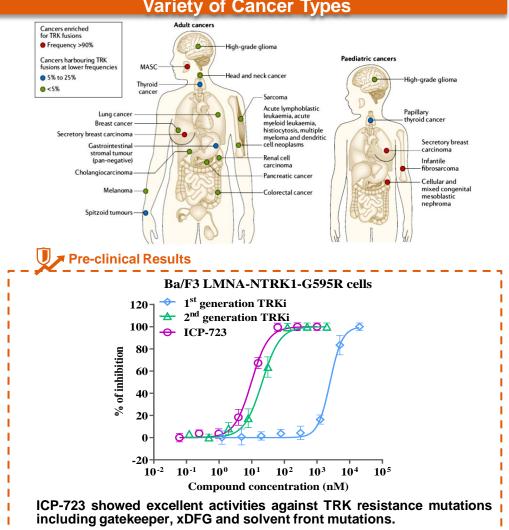


## ICP-723 (TRK)

- 2<sup>nd</sup> generation TRKi overcomes acquired resistance to 1<sup>st</sup> generation TRKi
- No DLTs observed in Phase I (1-16 mg)

6

- Phase I study demonstrated favorable PK profile and anti-tumor activity
- 100% ORR observed in various types of solid tumors carrying NTRK fusion at dosages of 4 mg and above. Initiated adolescent patient enrollment and plan to enroll pediatric patients in 2023Q1
- Well positioned to enter potential registrational trial in China soon
- Further potential study in adolescent and patients in 2023Q1
- Clinical trial initiated in the U.S.



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

## **Other Program Update** Continuous Strong Flow of Early Stage Projects





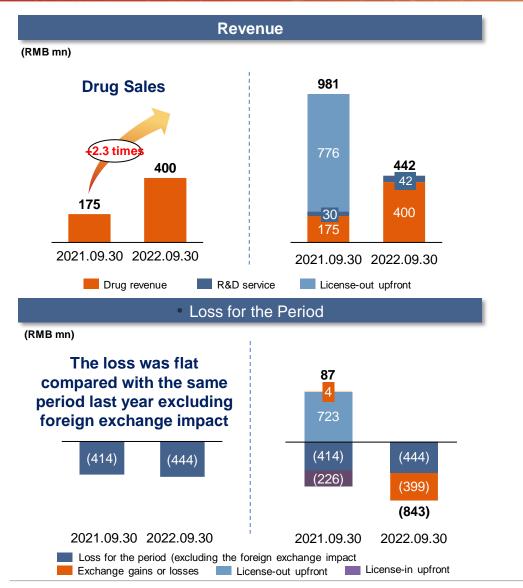
## **Anticipated Milestones & Catalysts in Next 12 Months**

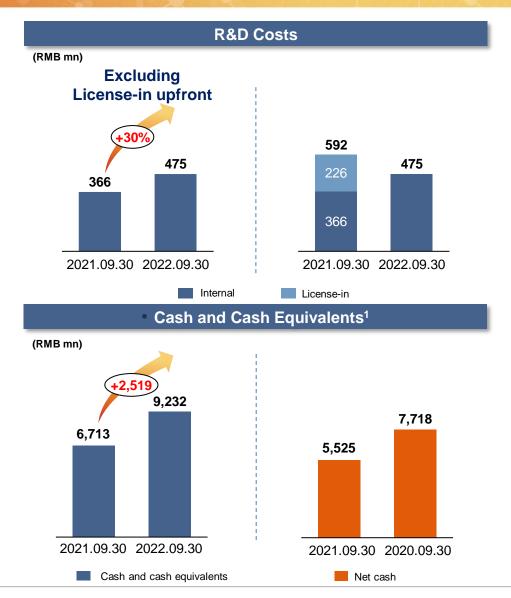


Liquid Cancer	<ul> <li>Orelabrutinib</li> <li>r/r WM NDA approval</li> <li>r/r MZL NDA approval</li> <li>r/r MCL NDA approval in Singapore</li> <li>Complete 1L DLBCL-MCD registrational trial enrollment</li> <li>Complete 1L CLL/SLL trial enrollment</li> <li>Complete r/r MCL registrational trial enrollment in the west</li> </ul>	<ul> <li>Tafasitamab (CD19)</li> <li>NDA approval in Macau</li> <li>Commence pilot use in GBA</li> <li>Submit NDA in Taiwan</li> <li>Complete r/r DLBCL pivotal trial and submit NDA in China</li> <li>Advance combination trial (Tafa +LEN +Orela) to explore potential synergism between CD19 and BTK inhibition</li> </ul>
Solid Tumors	<ul> <li>ICP-192 (FGFR)</li> <li>Advance iCCA registrational trial in China</li> <li>ICP-723 (TRK)</li> <li>Initiate registrational trial in China</li> </ul>	<ul> <li>ICP-189 (SHP2)</li> <li>Phase I trial result, confirm RDH2</li> <li>B05 (CCR8)</li> <li>Phase I trial result</li> </ul>
Auto- immune Diseases	<ul> <li>Orelabrutinib</li> <li>Accelerate SLE patient enrollment in China</li> <li>MS Phase II global trial result</li> <li>ITP Phase II preliminary result</li> </ul>	<ul> <li>ICP-332 (TYK2 - JH1)</li> <li>Phase II in AD efficacy and safety result</li> <li>ICP-488 (TYK2 - JH2)</li> <li>Complete Phase I trial</li> </ul>
Commercial ization	<ul> <li>Orelabrutinib</li> <li>Keep ramp-up momentum, increase market</li> <li>Tafasitamab (CD19)</li> <li>Initiate pilot use in GBA</li> </ul>	<ul> <li>Strategic Collaboration</li> <li>Continue to broaden global partnership of internal assets</li> <li>Expanding platform and pipeline acquiring/licensing synergistic products</li> </ul>

## **Financial Update** *Key Financials for 2022 Q1-Q3*

INNOCARE 诺诚健华





<sup>1</sup>Cash and cash equivalents = investments measured at fair value investments, cash and bank balance, interest receivable  $^{2}$  Net cash = cash balance – convertible loan – loans and borrowings – loans from a related party



# 科学驱动创新 患者所需为本

Science Drives Innovation for the Benefit of Patients