

(Stock Code: 1177.HK)

# 2024年全年业绩发布会 2024 Annual Results Announcement

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Financial Highlights

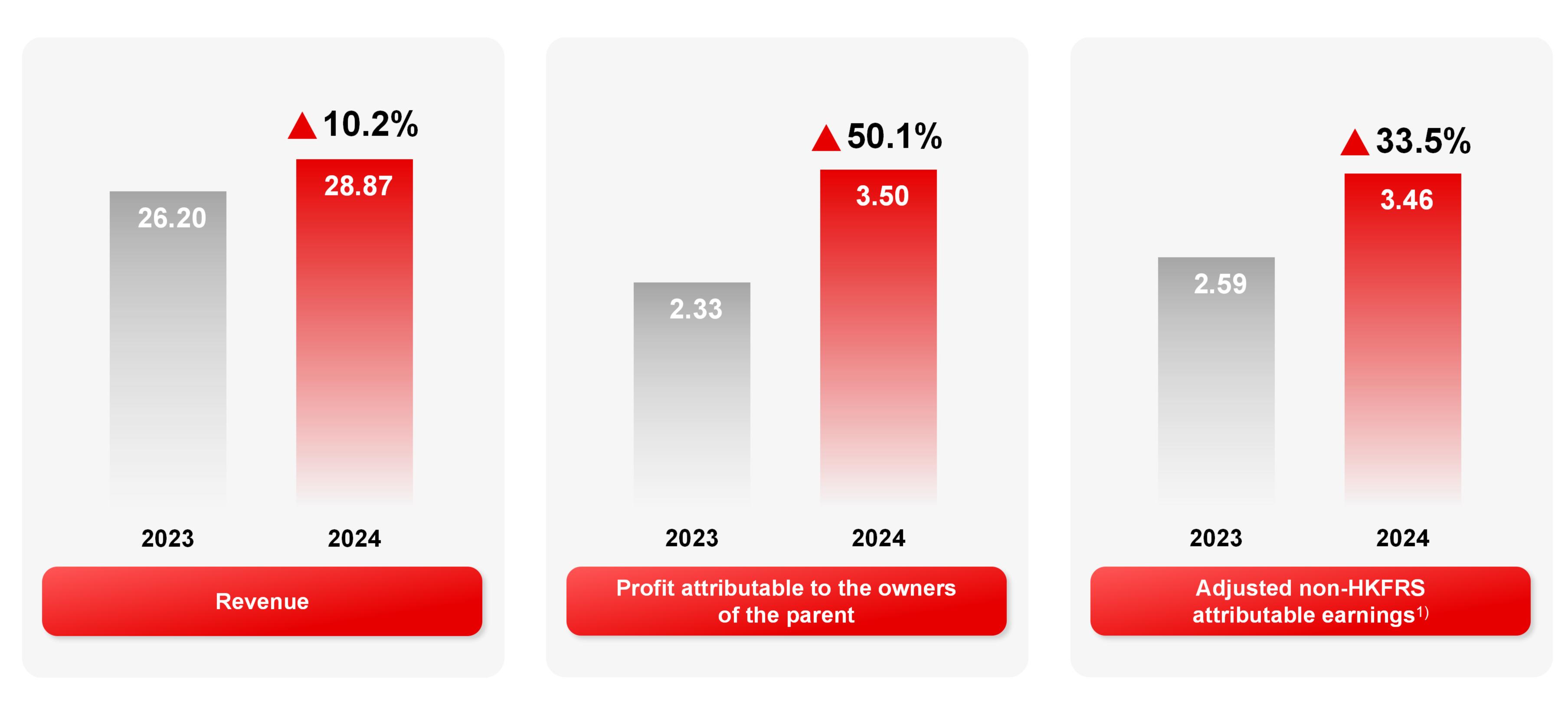


# Financial Highlights

Revenue achieved double-digit growth, with profit growth significantly outpacing revenue



(RMB bn)



Notes: 1) Adjusted non-HKFRS attributable earnings is presented as an additional financial measure to provide supplementary information for better assessment of the performance of Sino Biopharm's core operations. 3 Sino Biopharm is committed to maintaining the stability of this adjustment basis for investors' reference. Please refer to the next page for details.

# Adjusted non-HKFRS attributable earnings



(RMB bn)

	2024	2023	Growth
Profit attributable to the owners of the parent	3.50	2.33	+50.1%
Profit attributable to the owners of the parent from discontinued operations	-1.58	-0.44	
Share of profits and losses of associates and joint ventures <sup>1)</sup>	0.11	0.48	
One-off adjustments for the impairment and fair value changes of certain assets and liabilities1)	1.39	0.10	
Fair value losses/(gains) of current equity investments, net1)	0.00	-0.06	
Share-based payments <sup>1)</sup>	0.04	0.02	
Convertible bond debt component of:			
Effective interest expenses	0.00	0.01	
Exchange (gain)/loss	-0.00	0.08	
Fair value gains of derivative financial instruments in relation to foreign currency forward contracts	_	-0.05	
Loss on extinguishment of partial convertible bond	_	0.12	
Fair value gain of convertible bond embedded derivative component	_	-0.00	
Adjusted non-HKFRS profit attributable to the owners of the parent	3.46	2.59	+33.5%

Notes: 1) Net of related tax and non-controlling interests.

# Manufacturing

Centralized procurement and optimized capacity utilization, driving gross margin growth



(RMB bn)

Centralized procurement to ensure quality and price competitiveness

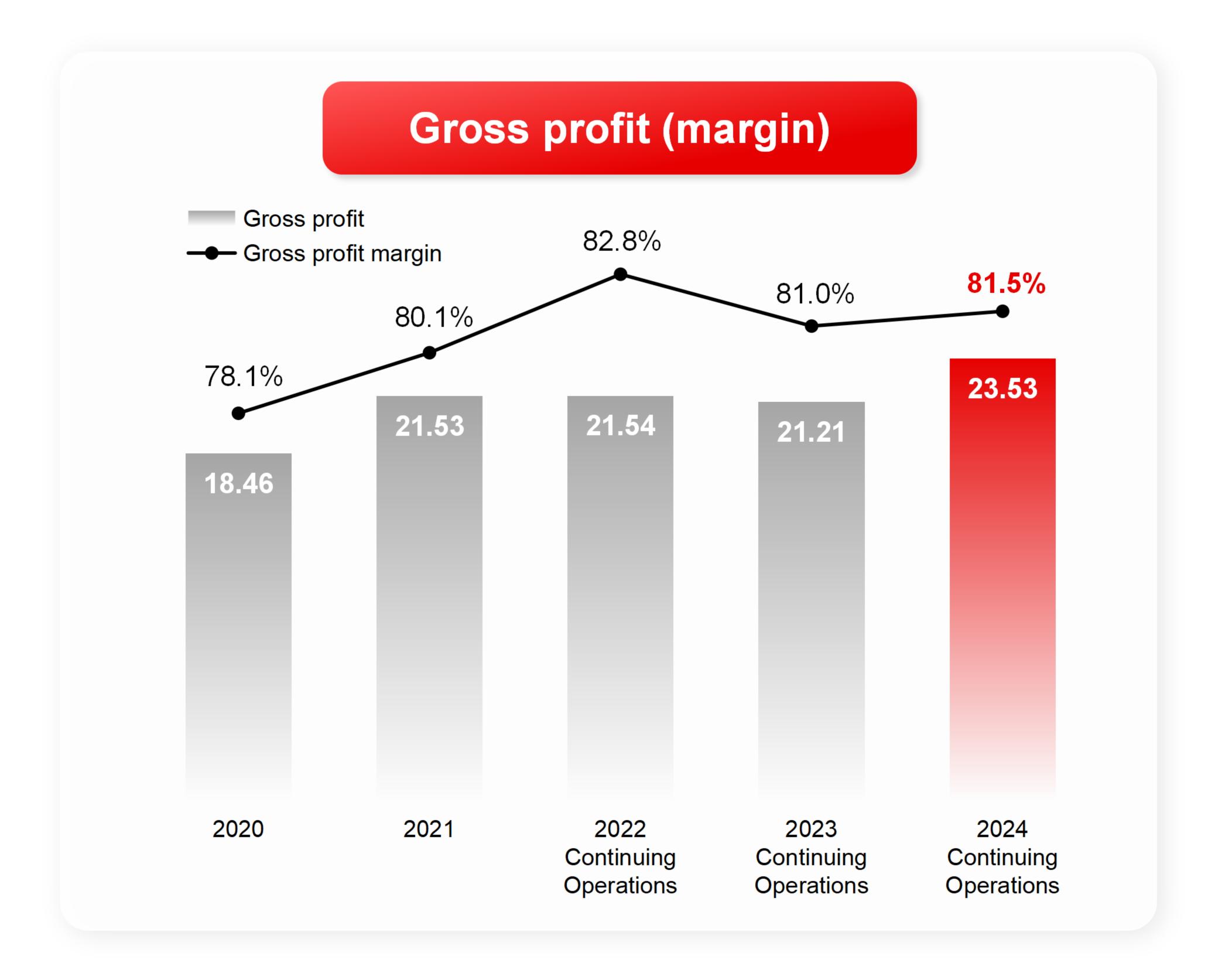
Procurement

Optimize production scheduling to improve capacity utilization

Utilization

One of the first companies to use 10000L bioreactors, scale effect

Scale effect



# R&D

# Increasing investment in innovative R&D, focusing on core areas and core assets



(RMB bn)

Increase investment in R&D, entering the high-yield phase of the innovative pipeline

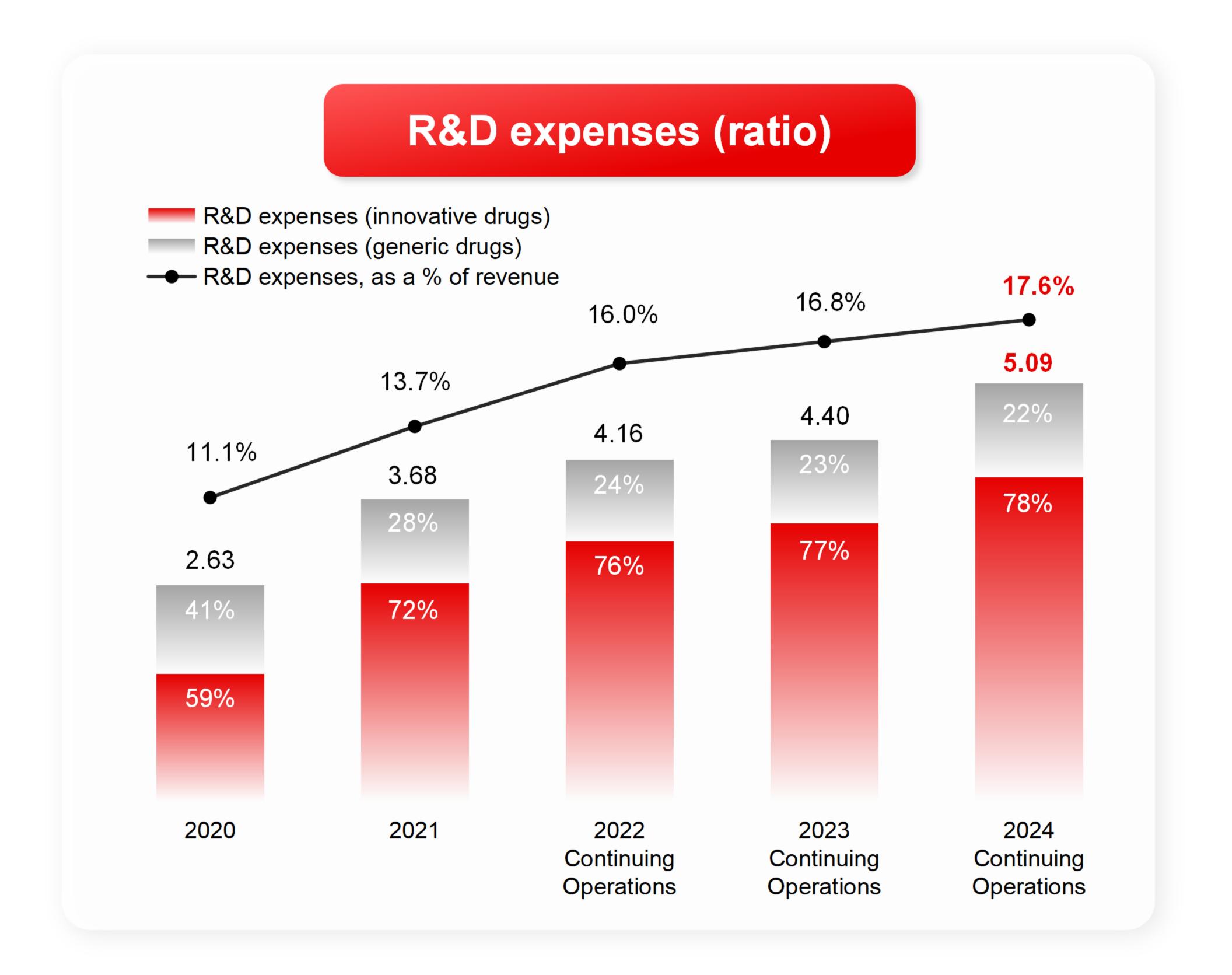
Harvest

Focus on four key TAs to improve R&D efficiency

Efficiency

Focus on core projects with tiered and differentiated resource allocation

Differentiate



# Sales

Digitalized and compliance-driven management, achieving steady improvement in staff efficiency.



(RMB bn)

Focus on efficiency, striving to improve per capita output

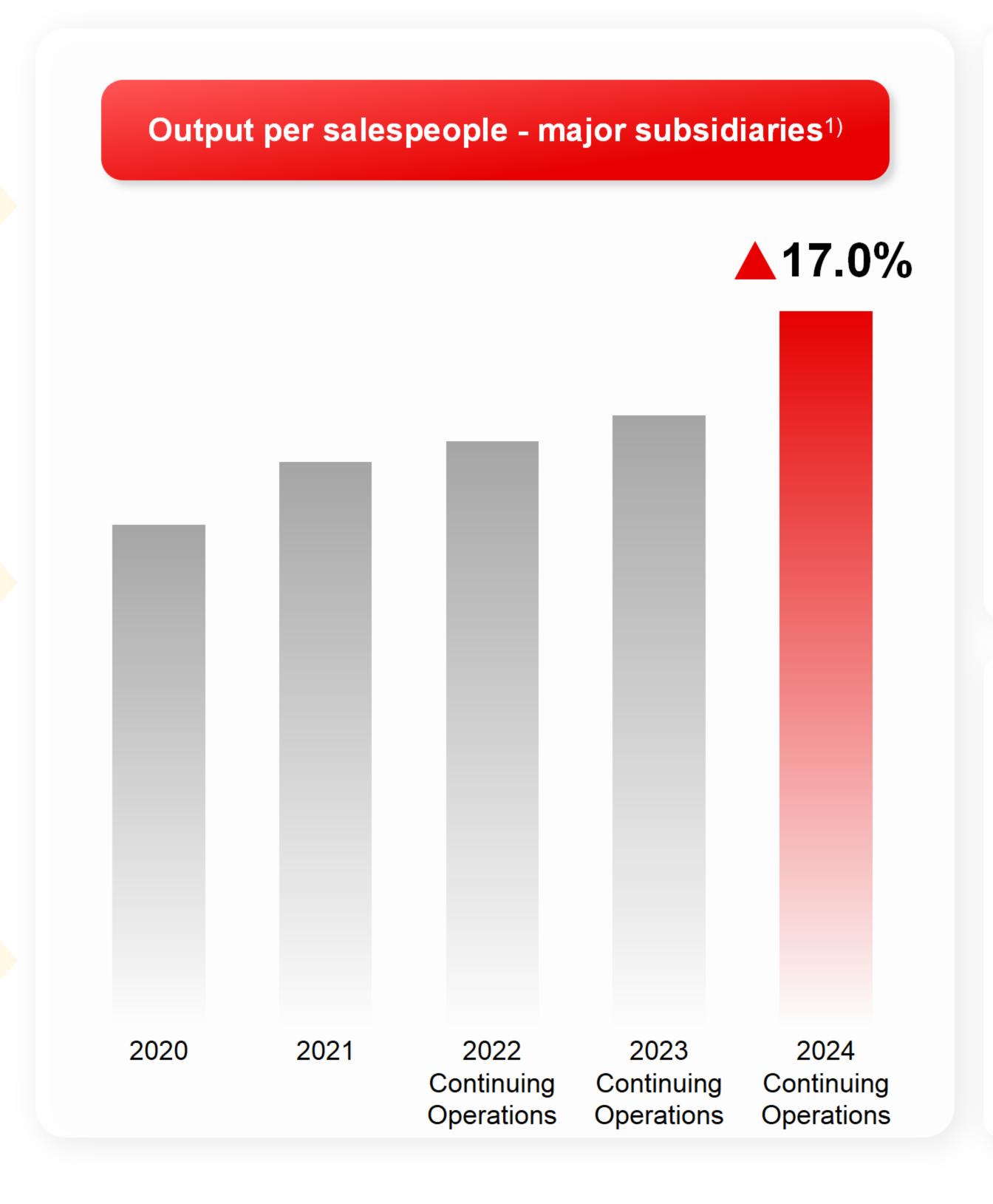
Efficiency

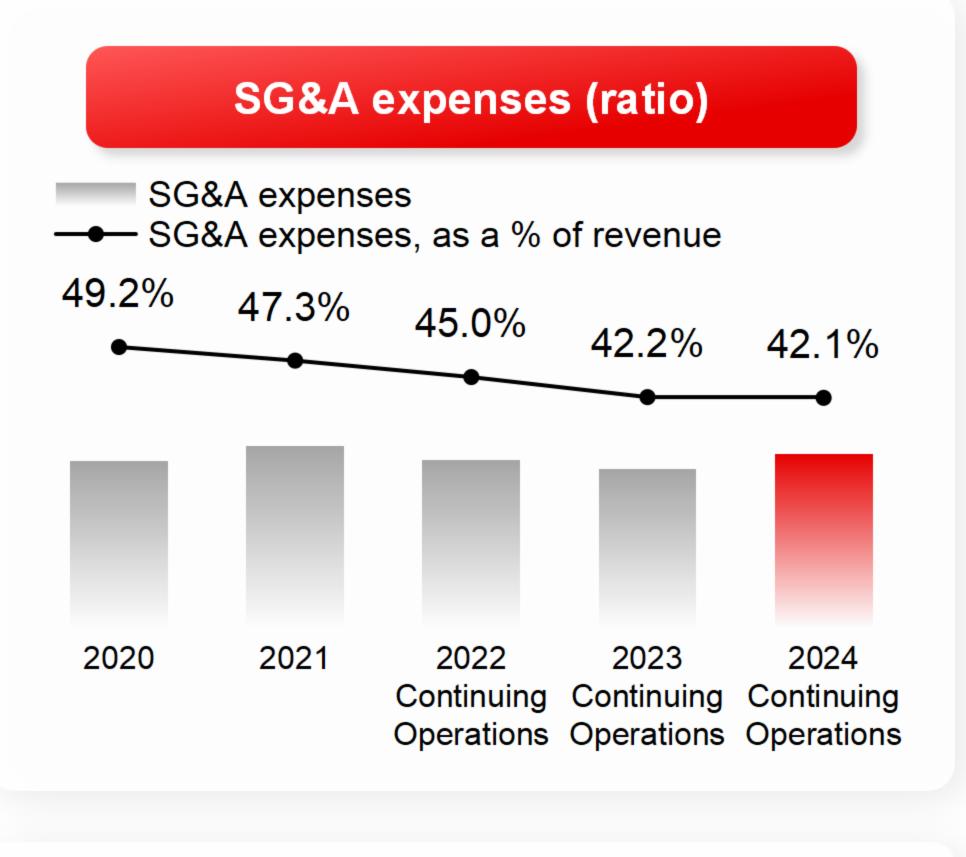
Improve internal control for better transparency and compliance

Compliance

Apply CRM system, an intelligent sales and marketing platform

Digitalization





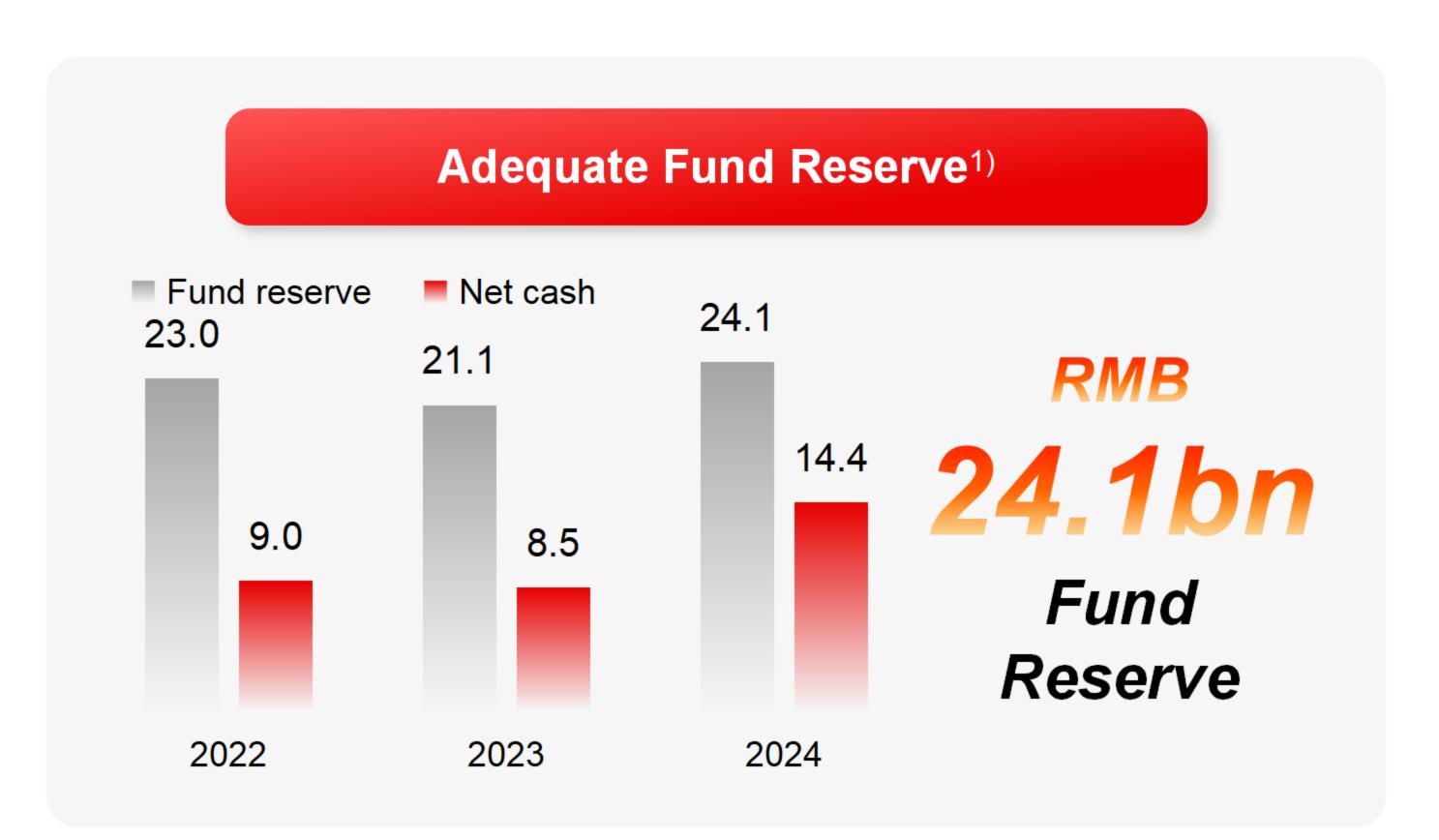


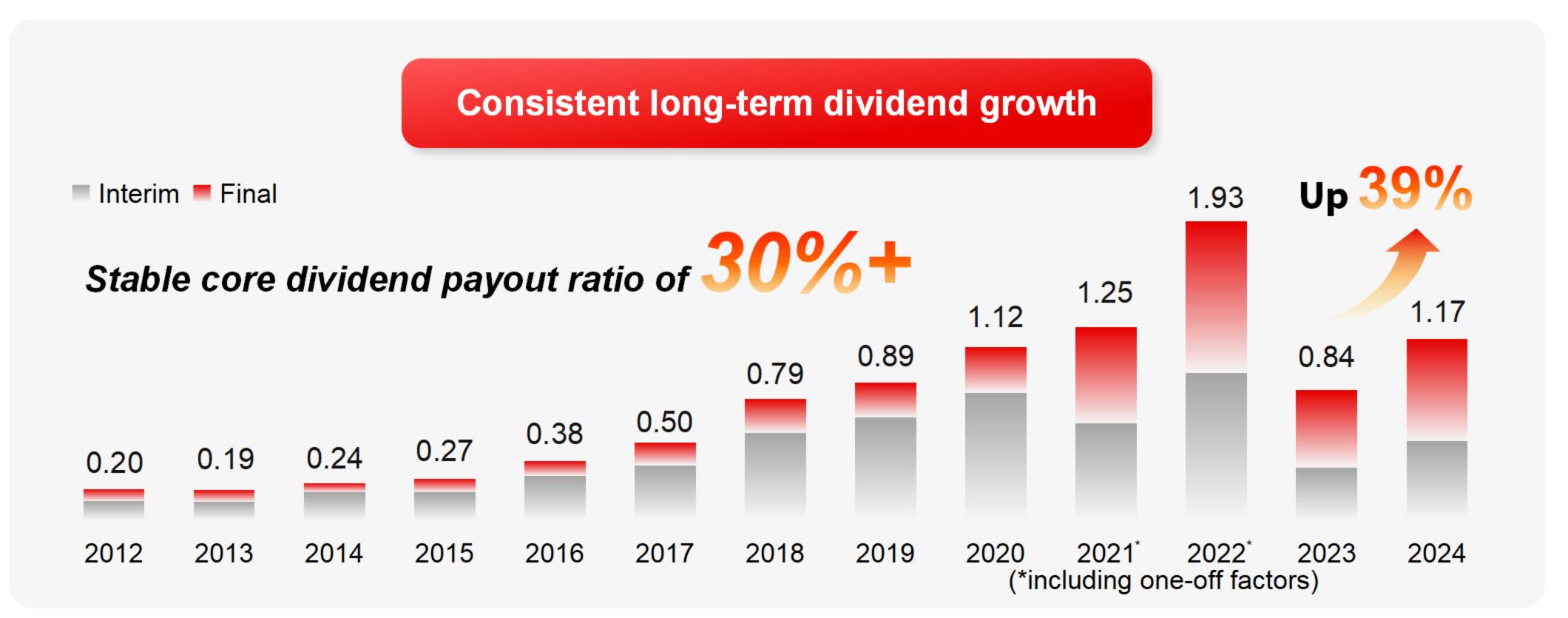
# **Fund Management**

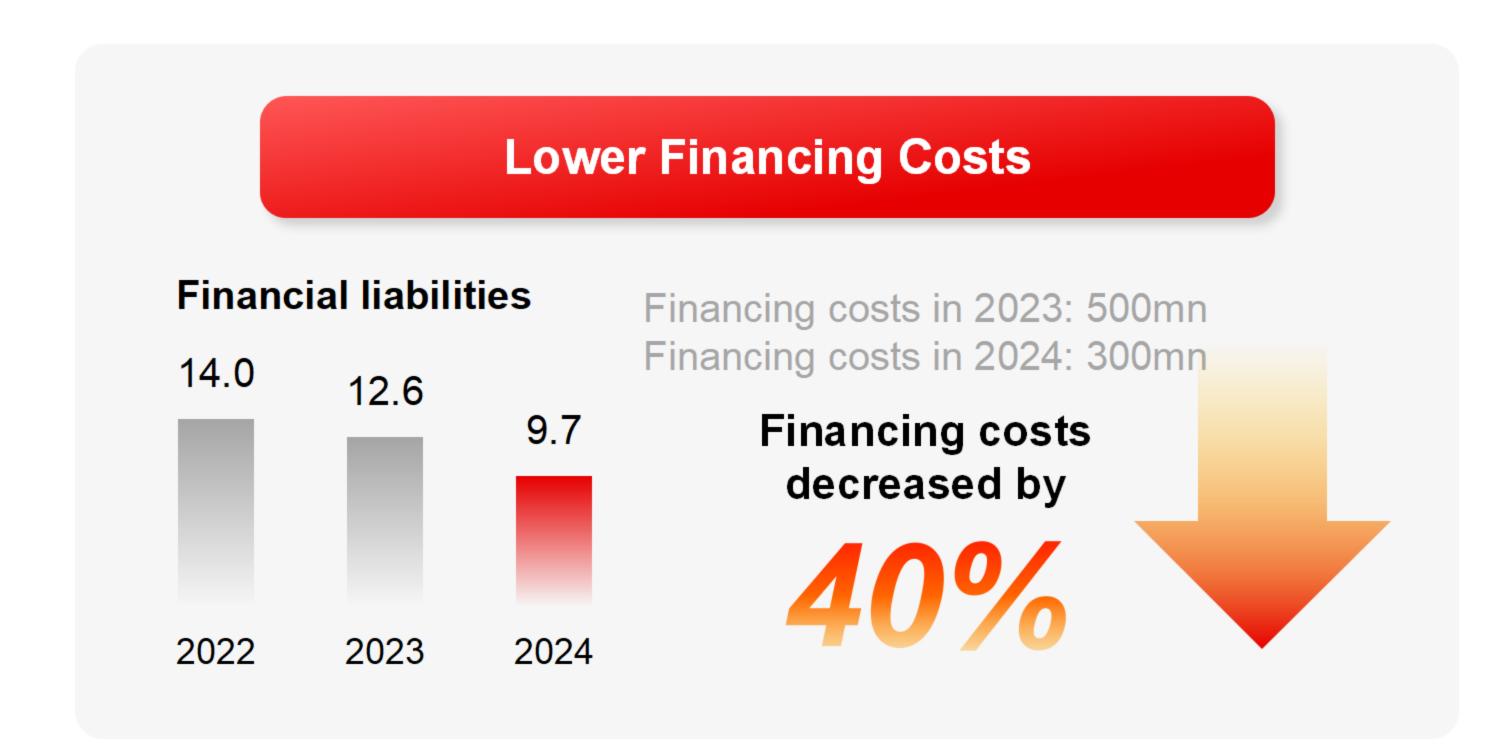
# Sound financial position and consistent long-term growth in shareholder returns



(RMB bn)









Notes: 1) Fund reserve includes cash and bank balances, bank deposit, and the wealth management products as at 31 Dec 2024; Net cash is the fund reserve minus financial liabilities such as bank loans and financial bonds

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Pipeline Highlights

# Four Key TAs

# Rapid launch of innovative products, further strengthening competitive advantages



#### Andewei (安得卫®) Benmelstobart Injection

Category 1 innovative drug, 2 indications approved in 2024: 1L SCLC and ≥2L endometrial cancer

#### Anfangning (安方宁®) Garsorasib Tablet

Category 1 innovative drug, the 2<sup>nd</sup> KRAS G12C inhibitor approved in China, for the treatment of 2L KRAS G12C mutated NSCLC

#### Anboni (安柏尼®) Unecritinib Fumarate Capsules

Category 1 innovative drug, the first domestic targeted drug approved for the treatment of ROS1+ NSCLC

#### Anluoqing (安洛晴®) Envonalkib Citrate Capsules

Category 1 innovative drug, for the treatment of ALK+ NSCLC patients who have not been treated with ALK inhibitors

#### Paletan (帕乐坦®) Pertuzumab injection

First pertuzumab biosimilar approved in China, for the treatment of HER2+ early/metastatic breast cancer and metastatic gastric cancer

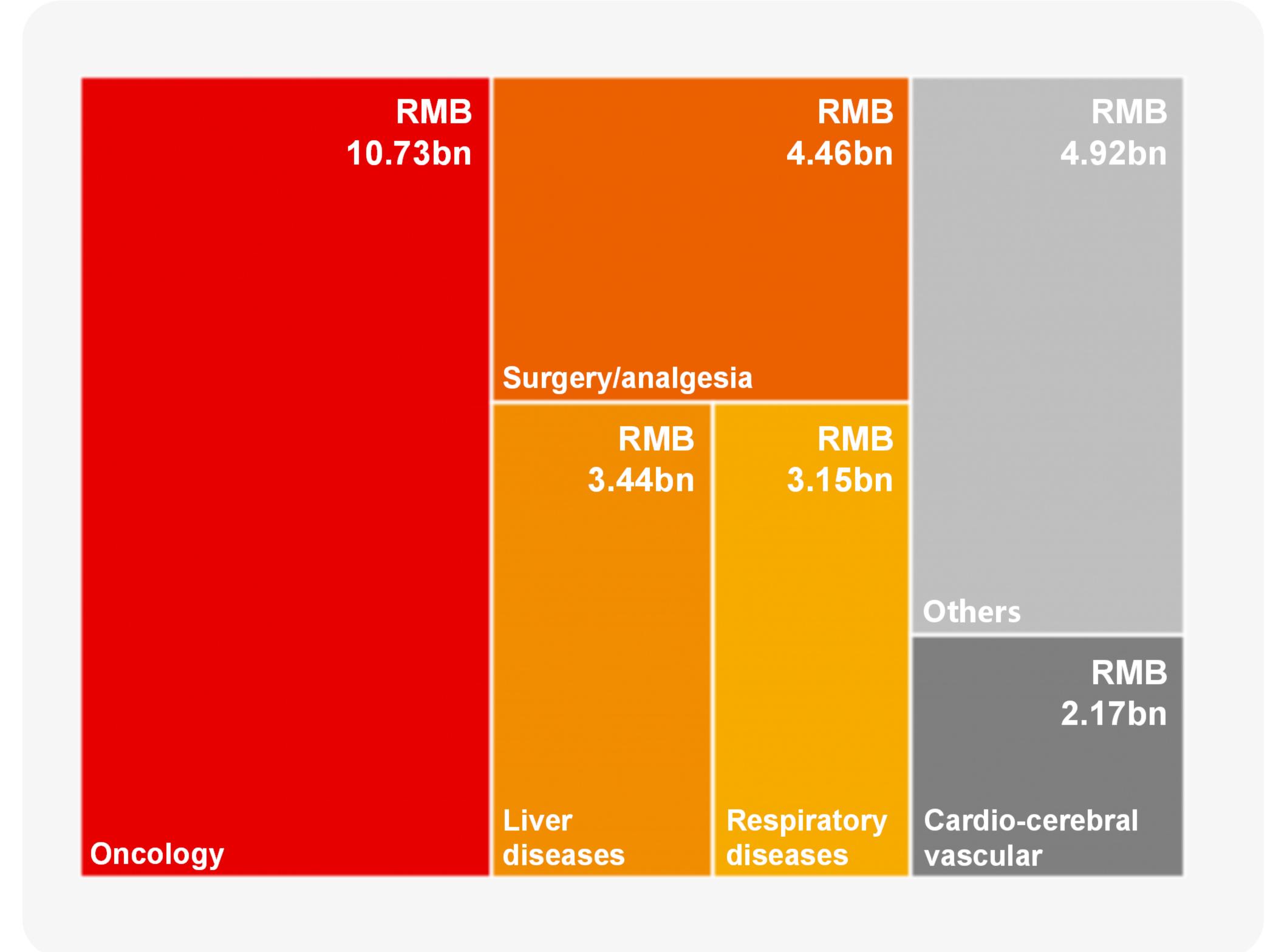
#### Beilelin (贝乐林®) Liraglutide Injection

One of the first 3 liraglutide biosimilars approved in China, for the treatment of type 2 diabetes

6 innovative products and 28 generic drugs approved in 2024.

The company with the most amount of

Class 1 innovative drugs approved in 2024.



Notes: 1) Innovative products include innovative drugs and biosimilars

# **Innovative Products**

Achieved 21.9% growth, driven by optimal hospital access and market penetration



(RMB bn)

# Innovative products launched in 2023 contributed the majority of this year's growth



Yilishu (亿立舒®) Efbemalenograstim alfa Injection

FIC 3rd-gen G-CSF
Better efficacy and safety



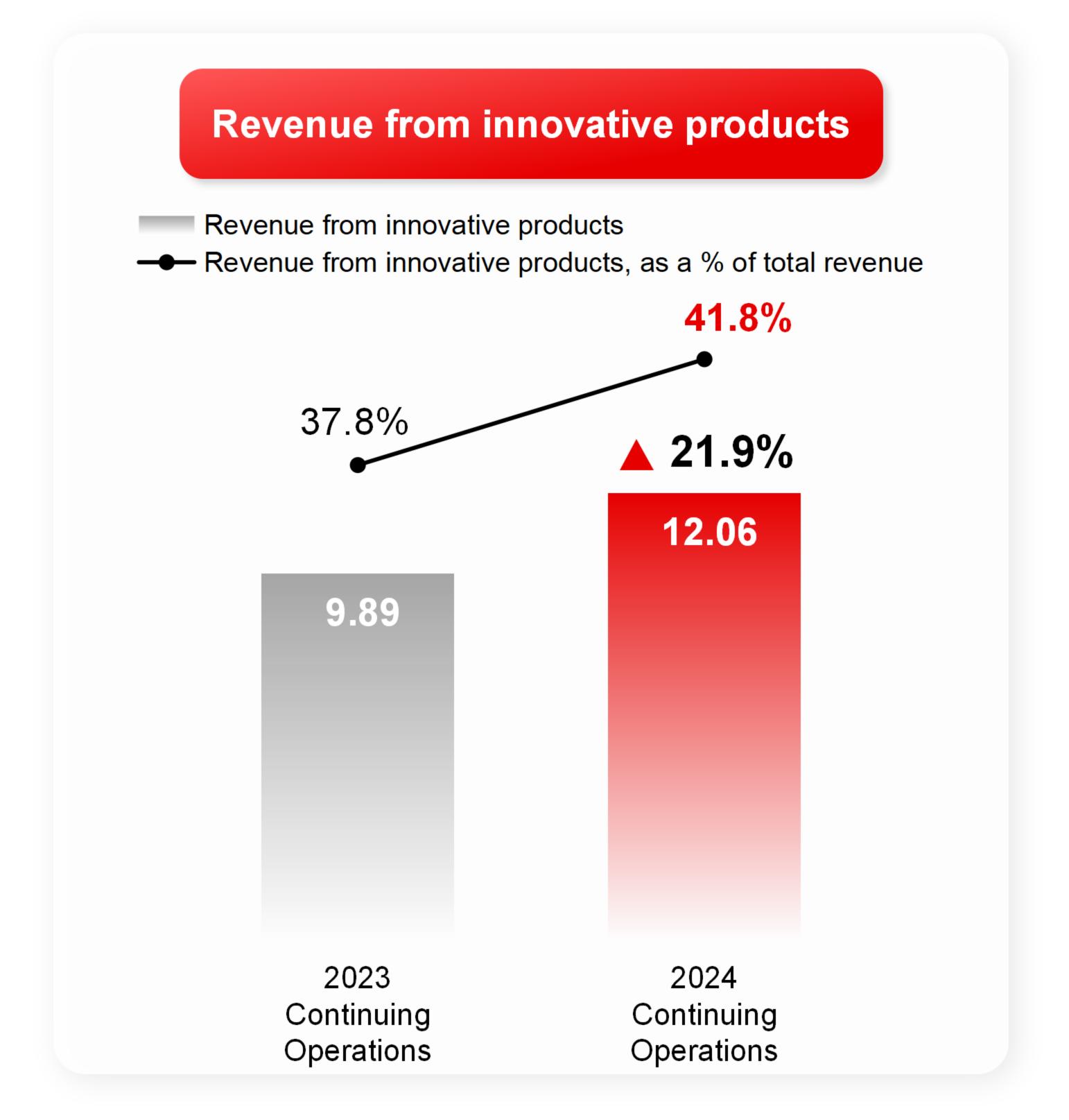
Anbeisi (安倍斯®) Bevacizumab Injection







Anhengji (安恒吉®) Recombinant Human Coagulation Factor VIII for Injection



Notes: 1) Innovative products include innovative drugs and biosimilars

# **Innovative Products**

Achieved 21.9% growth, multiple new products launched in 2024 to accelerate growth in 2025



(RMB bn)

# 6 innovative products launched in 2024 % of revenue from innovative products kept increasing



Category 1 innovative

**BIC** treatment for 1L SCLC

Andewei (安得卫®) Benmelstobart Injection



Category 1 innovative drug

First

China

pertuzumab

biosimilar

approved in

2<sup>nd</sup> KRAS G12C inhibitor approved in China

Anfangning (安方宁®) Garsorasib Tablet



Anboni (安柏尼®) Unecritinib Fumarate Capsules

#### Category 1 innovative drug

1st domestic targeted drug approved for the treatment of ROS1+ NSCLC

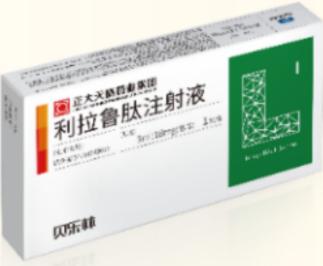


Anluoqing (安洛晴®) **Envonalkib Citrate** Capsules



Significantly extended PFS in patients

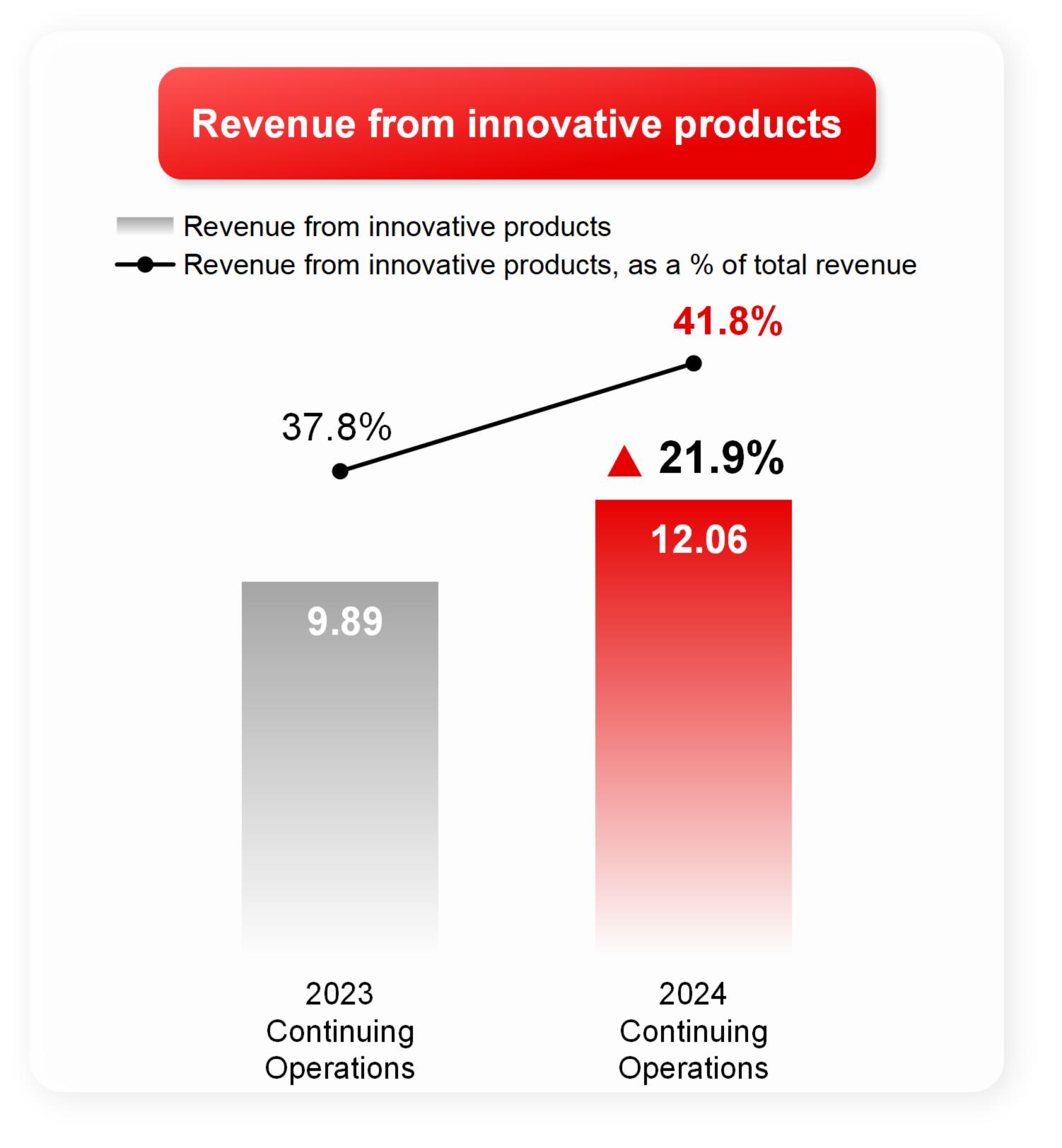
> Paletan (帕乐坦®) Pertuzumab injection



Beilelin (贝乐林®) Liraglutide Injection



liraglutide biosimilars approved in



Notes: 1) Innovative products include innovative drugs and biosimilars

# **Generic Drugs**

Realized 3.1% growth with a high-quality product portfolio



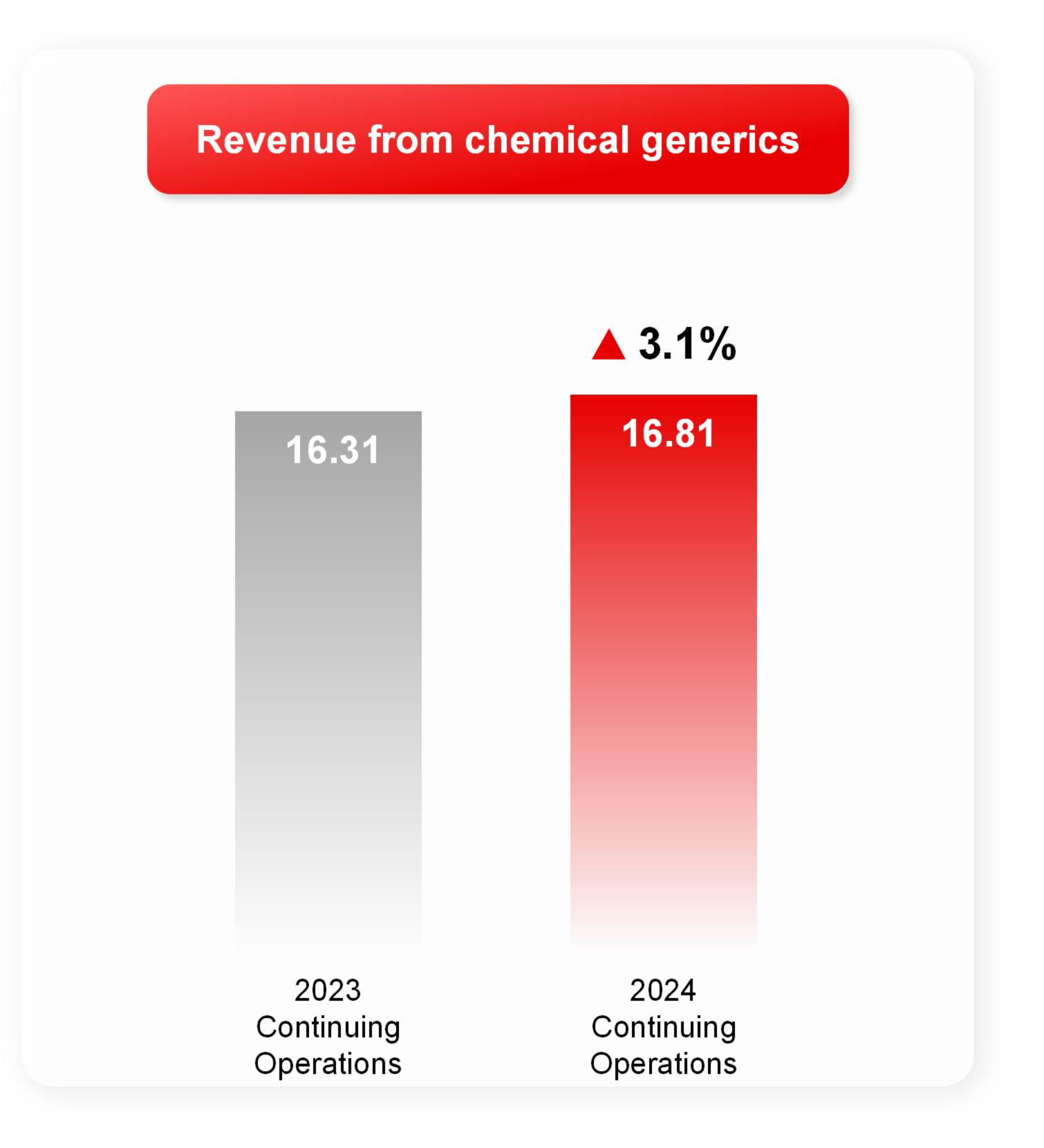
(RMB bn)

Generic drugs expected to maintain positive growth going forward

Back to growth

10+ generic drugs launched each year, nearly 80% of generic drugs approved in the past 10 years were first / top 3 to market<sup>1)</sup>

Target first



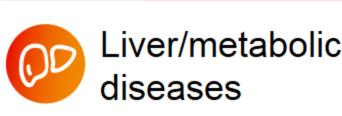
Notes: 1) Statistics of CTTQ

# **Innovation Driven**

60% Rapid growth in innovative products revenue as pipeline enters high-yield phase













% of revenue from

22

**50%** 

innovative products

TQ05105 (JAK/ROCK inhibitor)

QP001 (Meloxicam Injection)

Flurbiprofen Patches

rhFVIIa for Injection

Anlotinib 1L RCC



innovative products

M701 (CD3/EpCAM BsAb)

innovative

products

**55%** 



60

BI: Zongertinib (HER2 inhibitor)



PL-5 (Antimicrobial peptide)



Naldemedine (µ-opioid receptor antagonist)



Insulin Degludec Injection



Anlotinib 1L HCC, 1L sq-NSCLC, etc.



TQB3616 (CDK2/4/6 inhibitor)

1L HR+/HER2- breast cancer

4

Lidocaine Cataplasms DPNP

2025

2026

30+ innovative products



TQB2102 (HER2 BsAb ADC)



TQB3909 (BCL-2 inhibitor)



CPX102 (Type III IFN)



TQH2722 (IL-4 mAb)



TRD303 (Ropivacaine extended-release solution)



Lanifibranor (pan-PPAR agonist)



Semaglutide Injection



Anlotinib

1L nsq-NSCLC, 1L CRC, etc.



TQB3616 (CDK2/4/6 inhibitor)

HR+/HER2- breast cancer (adjuvant)

2027

# Global FIC Pipeline-Internal R&D

# TQ05105 (JAK/ROCK inhibitor) Global FIC, conducting clinical trials in China and US



# TQ05105

# Rovadicitinib

JAK/ROCK inhibitor

# Global first-in-class potential

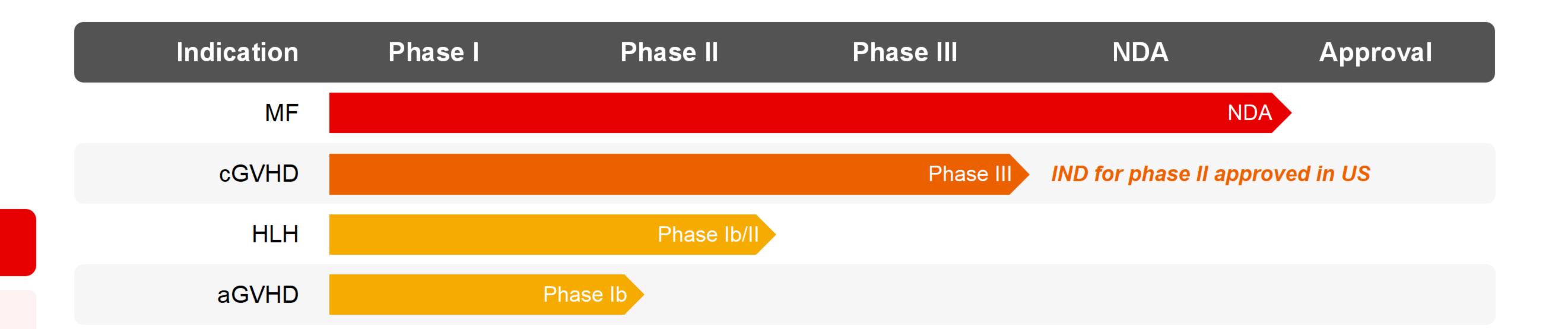
- Dual inhibition of JAK (anti-inflammatory) and **ROCK** (anti-fibrotic)
- NDA submitted, global first-in-class potential

# Durable responses in cGVHD

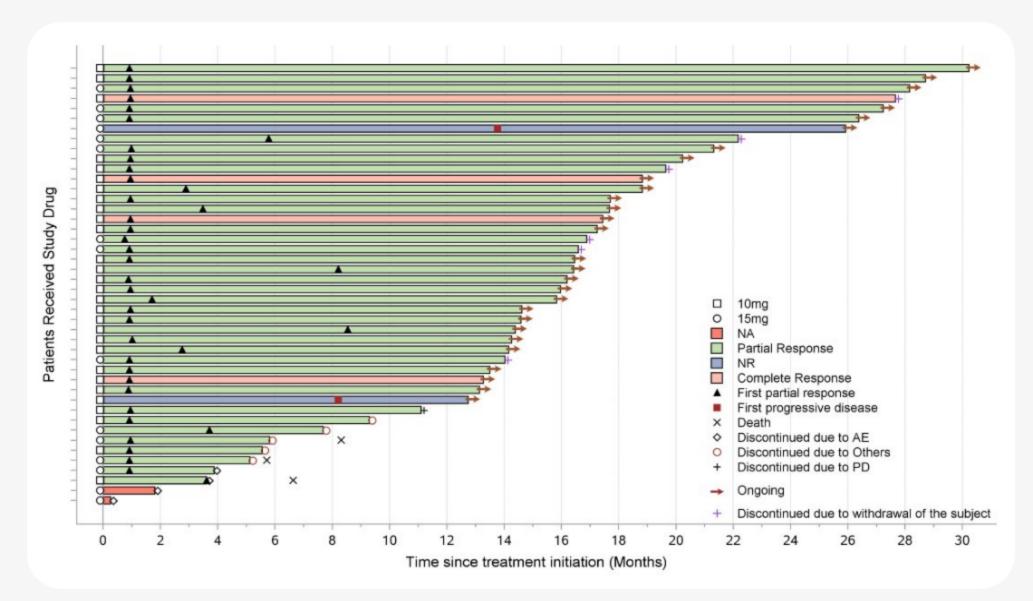
Better failure-free survival (FFS) at 12 months and better responses in fibrosis-dominated organs as compared with competitors

# 3 oral presentations at ASH 2024

 Chronic graft-versus-host disease (cGVHD) phase Ib/lla data, myelofibrosis (MF) phase Ib data, hemophagocytic lymphohistiocytosis (HLH) phase I data



#### TQ05105 phase lb/ll clinical trial in patients with glucocorticoid-refractory or -dependent cGVHD1)



- ORR (24 weeks): 66% (29/44)
- FFS (12 months): 87.7% (95%CI 73.0, 94.7)
- Median treatment duration: 13.8 months
- Rapid responses: ~70% responders achieving response at 4 weeks

#### Organ specific response rates:

	TQ05105	Ruxolitinib <sup>2)</sup>	Belumosudil <sup>3)</sup>
Skin	65% (17/26)	41%	37%
Eyes	54% (20/37)	26%	42%
Mouth	44% (15/34)	50%	55%
Esophagus	79% (15/19)	50%	45%
Upper GI	40% (2/5)	40%	52%
Lower GI	91% (10/11)	53%	69%
Liver	100% (5/5)	24%	39%
Lung	23% (6/26)	9%	26%
Joints/fascia	68% (13/19)	38%	71%

 Compared with similar drugs, TQ05105 has higher response rates in multiple organs, especially in the main organs with fibrosis (such as liver)

# Global FIC Pipeline-Internal R&D

# TQC3721 (PDE3/4 inhibitor) available in both DPI and nebulizer, global BIC potential



# TQC3721

PDE3/4 inhibitor

## Global best-in-class potential

- Synergistic MOA with bronchodilation (PDE3) and anti-inflammation effect (PDE4)
- Significantly stronger inhibitory effect on PDE3 and PDE4 families than that of ensifentrine

# R&D progress ranks 2<sup>nd</sup> globally

- Only one PDE3/4 inhibitor approved for marketing globally, and it has not been approved in China yet
- TQC3721 ranks 2<sup>nd</sup> globally in R&D progress

# A wider range of patients

- Available in both DPI and nebulizer to maximize commercialization potential
- COPD cases: ~500mn globally, ~100mn in China<sup>1)2)</sup>

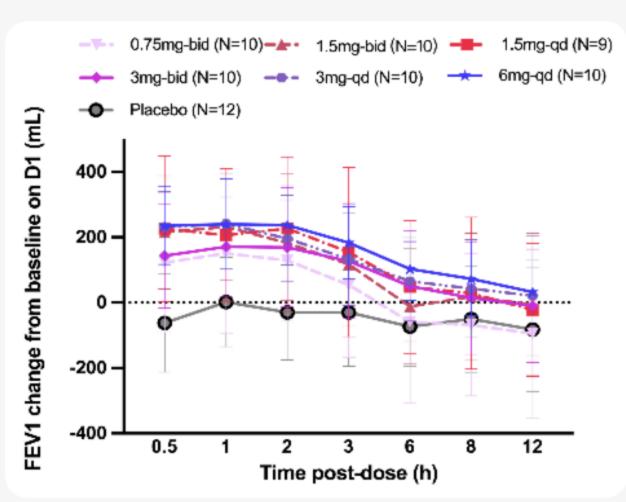
Dosage form	Indication	Phase I	Phase II	Phase III	NDA	Approval
Nebulized suspension	COPD		Phase II	Phase III expected	in 2025	
DPI	COPD	Phase I				

#### Comparison of selectivity of TQC3721 and ensifentrine for PDE3 and PDE4 families

PDE	Ensifentrine	TQC3721	Ratio	
isozymes	IC <sub>50</sub> (nM)	IC <sub>50</sub> (nM)	Ratio	
PDE3A	0.534	0.0383	14	
PDE3B	1.07	0.0974	11	
PDE4A	60.50	0.308	196	
PDE4B	76.10	0.872	87	
PDE4C	395	11.0	36	
PDE4D	33.6	0.152	221	

Preclinical studies have shown that TQC3721 has a higher selectivity and **inhibitory** ability towards the PDE3 and PDE4 families, especially towards PDE4A and PDE4D.

#### TQC3721 phase lla clinical trial in patients with COPD<sup>3)4)</sup>



- Except for 0.75mg cohort, other cohorts of TQC3721 produced a significant and dosedependent increase in peak FEV<sub>1</sub> from baseline to week 4.
- Adverse events were similar in frequency between the TQC3721 and placebo.

#### TQC3721 covers a wider range of COPD patients than ensifentrine

#### Global Initiative for Chronic Obstructive Lung Disease (GOLD)

0-1 moderate exacerbations	mMRC 0-1, CAT < 10	<b>Group A</b> A bronchodilator
(not leading to hospital admission)	mMRC ≥ 2, CAT ≥ 10	<b>Group B</b> LABA+LAMA
		Group E

≥2 moderate exacerbations or ≥1 leading to hospitalization

LABA+LAMA LABA + LAMA + ICS if EOS ≥ 300 cells/µL

#### TQC3721 phase IIb clinical design (TQC3721 II-03, N=240)

#### Therapy used Group TQC3721 3 mg BID LAMA or LABA (20%)

TQC3721 6 mg BID LAMA + LABA (70%) Placebo BID

LAMA + LABA + ICS (10%)



#### Ensifentrine phase III clinical design (ENHANCE-1 and 2, N=800)

Group	Therapy used	Only including
Ensifentrine 3 mg BID	<ul> <li>Not used (30%-45%)</li> </ul>	Group A
	<ul> <li>LAMA or LABA (40%-50%)</li> </ul>	•
Placebo BID	<ul> <li>LAMA+ICS or LABA+ICS (15%-20%)</li> </ul>	patients

# Global FIC Pipeline-BD

# QP001 (Meloxicam Injection) national Class 2 drug, 1st long-acting analgesic NSAID injection



## Delova Biotech

# QP001

Meloxicam Injection (COX-2 selective inhibitor)

# 1st long-acting analgesic NSAID injection

 A single injection achieves 24-hour potent analgesia, marking the first once-daily long-acting analgesic NSAID injection in China

#### **Exclusive national Class 2 new drug**

- The only Meloxicam Injection registered as a National Class 2 New Drug, NDA submitted in China and US
- The solution formulation which avoids the risks of particle aggregation and sedimentation caused by improper storage of nanosuspensions, thereby preventing capillary embolism

#### Huge unmet clinical needs

- In 2022, the number of inpatient surgical procedures in China exceeded 82 million<sup>1)</sup>
- 91.8% inpatients suffer from post-surgical pain<sup>2)</sup>
- The adoption rate of postoperative analgesia in China remains suboptimal, with even top-tier (Class 3A) hospitals reporting an analgesia utilization rate of only ~30%

Indication	Phase I	Phase II	Phase III	NDA	Approval
Postoperative Pain in adults					NDA

#### QP001 phase III clinical trial for the treatment of patients with moderate to severe postoperative pain

# Patients with moderate to severe postoperative pain after orthopedic surgery

	QP001 30mg (N=128)	Placebo (N=66)	Morphine sparing/pain reduction	p-value
0-24h total morphine consumption (mg)*	12.5	26.1	52.1%	<0.0001
24-48h total morphine consumption (mg)	3.7	10.3	64.1%	<0.0001
0-24h area under the curve of pain (AUC <sub>0-24</sub> )	50.4	77.3	34.8%	<0.0001
24-48h area under the curve of pain (AUC <sub>24-48</sub> )	43.3	61.0	29.2%	<0.0001
18-24h area under the curve of pain (AUC <sub>18-24</sub> )	10.3	18.8	45.4%	<0.0001
42-48h area under the curve of pain (AUC <sub>42-48</sub> )	9.5	12.7	25.2%	0.0014

# Patients with moderate to severe postoperative pain after abdominal surgery

	QP001 30mg (N=170)	Placebo (N=85)	Morphine sparing/pain reduction	p-value
0-24h total morphine consumption (mg)	4.19	7.35	42.9%	<0.0001
24-48h total morphine consumption (mg)	0.2	0.7	85.7%	0.0027
0-24h area under the curve of pain (AUC <sub>0-24</sub> )*	50.5	85.19	40.7%	<0.0001
24-48h area under the curve of pain (AUC <sub>24-48</sub> )	36.3	57	36.6%	<0.0001
18-24h area under the curve of pain (AUC <sub>18-24</sub> )	8.7	18.1	52.5%	<0.0001
42-48h area under the curve of pain (AUC <sub>42-48</sub> )	6.0	10.4	42.3%	<0.0001

\*Primary endpoint, others are secondary endpoints

- Both the primary and secondary efficacy endpoints demonstrated statistically significant differences.
- The first dose was administered 10 minutes preoperatively, followed by a second dose 24 hours after the initial administration. Potent
  analgesia was maintained at the end of the drug effect period (18–24h, 42–48h).
- The incidence of adverse reactions was comparable to that of the placebo group, with no serious adverse reactions observed.
- Compared to other NSAIDs, QP001 demonstrated a higher 0-48h morphine-sparing effect (reduction rate: 26.0% for ketorolac tromethamine, 28-37% for parecoxib sodium, and 30-45% for dexketoprofen)<sup>4)</sup>, positioning it as the **NSAID injection with the strongest potential analgesic efficacy**.

# Global FIC Pipeline-BD

# CPX102 (Type III IFN) global FIC nebulized treatment for RSV infection



# **Sciwind Biosciences**

# **CPX102**

Type III interferon (IL-29/IFN-λ1)

#### First nebulized treatment for RSV globally

- Local administration through nebulization has a lower systemic exposure at ~1/100 of that of an injection, thereby significantly reducing systemic adverse reactions
- Directly targets respiratory epithelial cells with rapid onset of action
- Avoids the discomfort of injection administration, higher acceptance among children

## The only Class 1 innovative drug in China

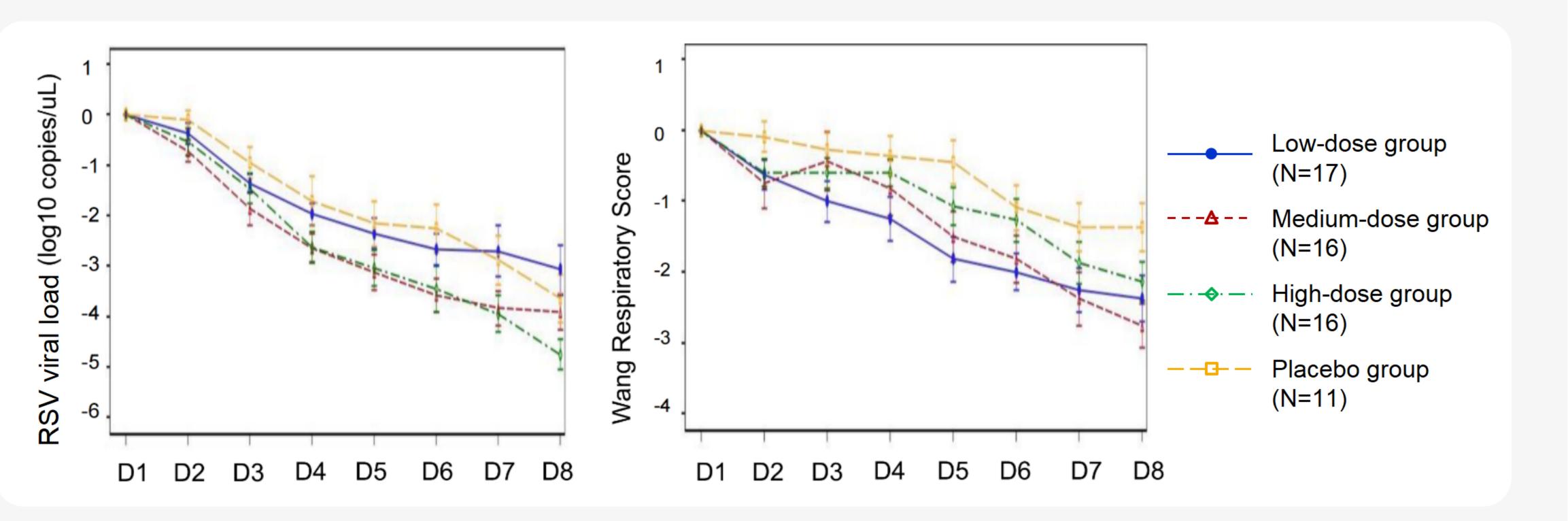
- The only National Class 1 innovative drug in clinical development for nebulized treatment of RSV in China
- In 2015, there're ~330mn cases of RSV-associated respiratory infections globally, with China ranking among the countries with the highest incidence rates<sup>1),2)</sup>

#### **Broad-spectrum antiviral drug**

- Clearance of virus by activation of host immunity, unaffected by viral mutation
- Potential for treating influenza, SARS-CoV-2 and multiple types of respiratory viral infections



# CPX102 phase Ila clinical trial for the treatment of infants with RSV infection



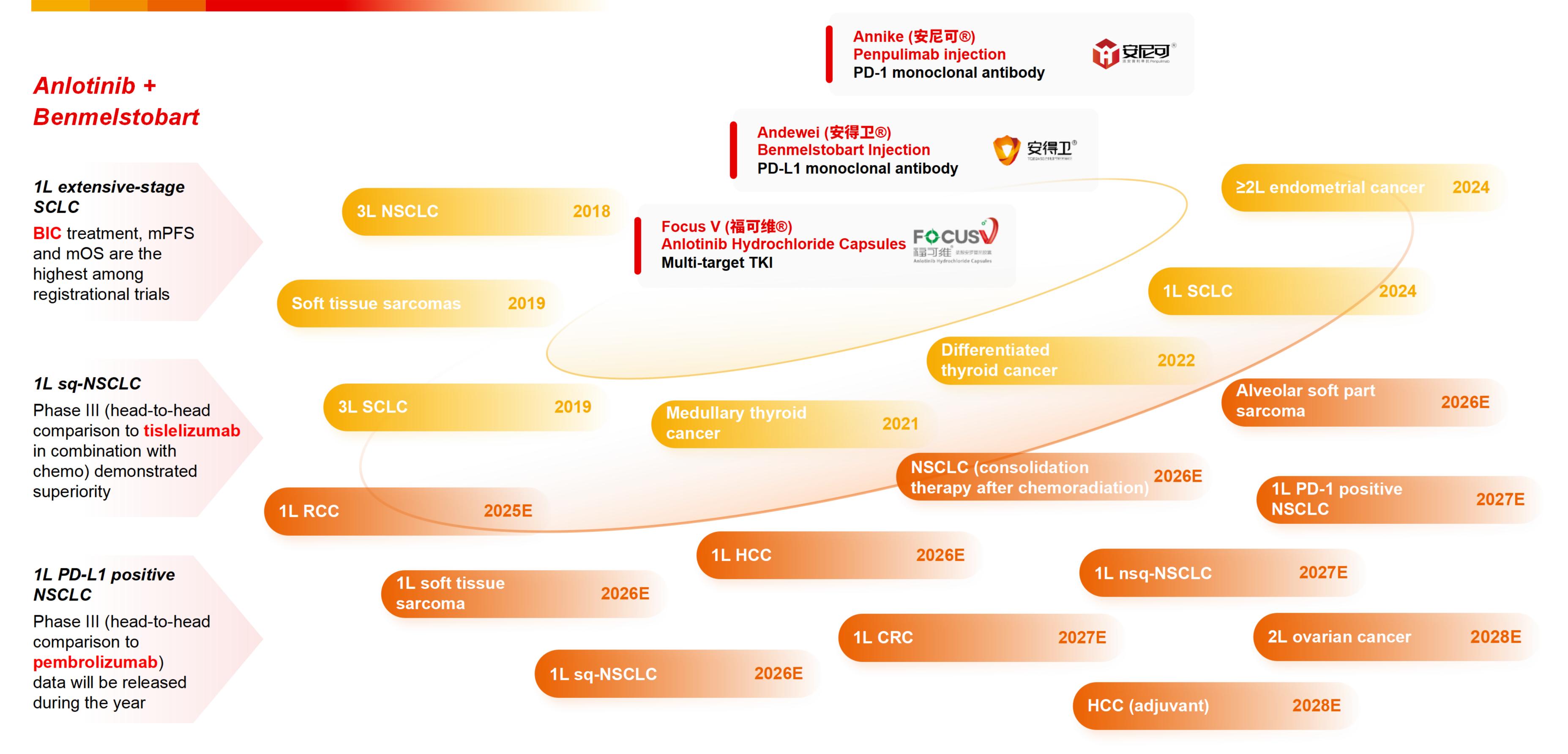
- Significant reductions in RSV viral load and symptom scores were observed across the low-, medium-, and high-dose groups.
- By Day 3, the medium- and high-dose groups demonstrated a viral load difference of approximately 1 log<sub>10</sub> compared to the placebo group.
- The incidence of TEAEs was 57.1% in the treatment group vs. 54.5% in the placebo group.
- No TEAEs leading to dose discontinuation/interruption, premature withdrawal, or fatal outcomes were observed across all dose groups.

Notes: 1) Shi T, McAllister DA, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. Lancet, 2017, 18 390(10098):946–958.; 2) National Center for Respiratory Medicine. Consensus among experts on immunoprophylaxis against common respiratory pathogens in children. Chinese Journal of Applied Clinical Pediatrics, 2021, 36(22): 1681-1709.

# Blockbusters launched in 2024







# Blockbusters launched in 2024

# Garsorasib (KRAS G12C inhibitor) approved for ≥2L NSCLC, filling the market gap



# Anfangning (安方宁®) Garsorasib

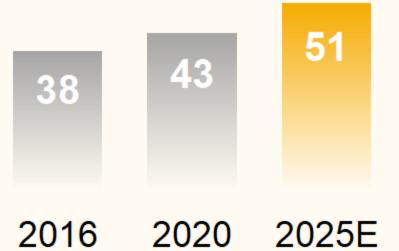


KRAS G12C inhibitor

#### Unmet clinical needs

- >50,000 new cancer cases with KRAS G12C mutation in China every year
- No standard-of-care treatment before KRAS G12C inhibitors

Incidence of major KRAS G12C mutated cancers in China (ppl 000)



# 1L potential for multiple cancers

- One of the most common oncogenic gene drivers in human cancers
- Potential for 1L treatment, synergized with EGFR mAb, SHP2 inhibitors, FAK inhibitors or others

# Frequency of KRAS mutations

10-13% NSCLC

3-4%
Colorectal cancer

1-2%
Pancreatic cancer

Indication	Phase I	Phase II	Phase III	NDA	Approval
≥2L NSCLC					Approved
≥2L pancreatic cancer		Phase II (p	pivotal)		
≥3L CRC		Phase II (CA application)			
1L CRC		Phase II			

#### Comparison of efficacy and safety of garsorasib with peer studies<sup>1)</sup>

	Garsorasib	Fulzerasib	Glecirasib	Sotorasib	Adagrasib				
Trial	D1553-102	NCT05005234	NTC05009329	CodeBreak100	KRYSTAL-1				
Phase		Single-arm phase II trial							
Patients		Locally advanced or me	etastatic NSCLC harbor	ring KRAS G12C mutatio	n				
Dosage	600mg BID	600mg BID	800mg QD	960mg QD	600mg BID				
Sample size	123	116	119	124	112				
ORR	52.0%	49.1%	47.9%	41%	42.9%				
DCR	88.6%	90.5%	86.3%	84%	79.5%				
mDOR (month)	12.5	NE	NE	12.3	8.5				
mPFS (month)	9.1	9.7	8.2	6.8	6.5				
mOS (month)	14.1	NE	13.6	12.5	12.6				
Grade≥3 TRAE	51.2%	41.4%	38.7%	21%	44.8%				
TRAE leading to permanent discontinuation of treatment	0	7.8%	5%	6%	6.9%				

Better efficacy and safety results than other KRAS G12C inhibitors approved by FDA

# Blockbusters launched in 2024

# First pertuzumab biosimilar, together with trastuzumab for HER2+ BC



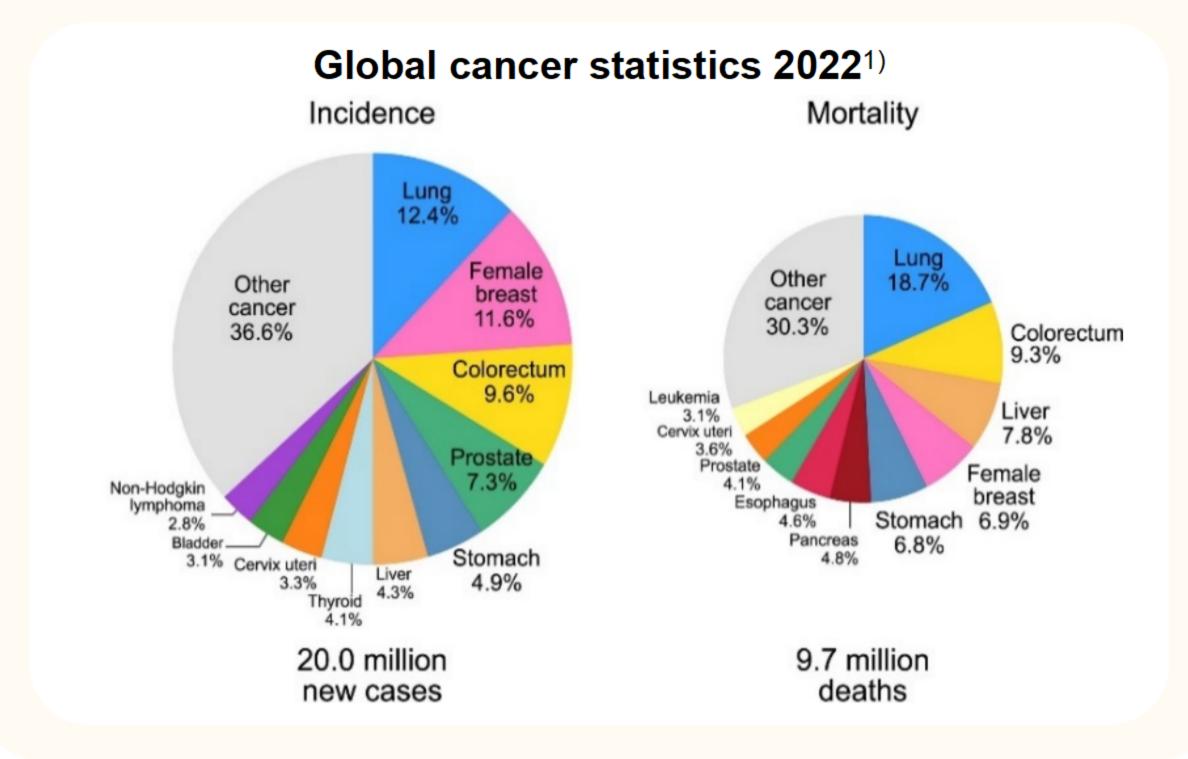
# Paletan (帕乐坦®) Pertuzumab



Biosimilar

Breast Cancer is the 2<sup>nd</sup> most common cancer worldwide

- Breast cancer has the 2<sup>nd</sup> highest incidence rate and 4<sup>th</sup> highest mortality rate among all cancers worldwide
- In 2022, the number of new breast cancer cases was ~2.3mn worldwide<sup>1)</sup>
- In 2022, the number of new breast cancer cases was ~0.36mn in China<sup>2)</sup>



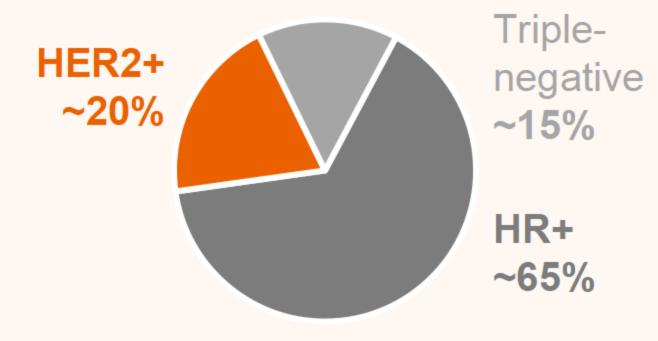
# "Pertuzumab + Trastuzumab" portfolio with great commercial potential

#### Pertuzumab (indications)

HER2+ early breast cancer
with trastuzumab and chemo
Neoadjuvant therapy,
Adjuvant therapy

HER2+ metastatic breast cancer
with trastuzumab and docetaxel
First-line treatment

# Types of breast cancer





First pertuzumab biosimilar approved in China

45000L

Overall biologics manufacturing capacity

~70%

Manufacturing costs lower than the industry level

9

GMP-compliant production lines for biologics

# TQB3616 (CDK2/4/6 inhibitor) potential BIC treatment for HR+/HER2- breast cancer



## **TQB3616**

# Culmerciclib

CDK2/4/6 inhibitor

## Addressing drug resistance

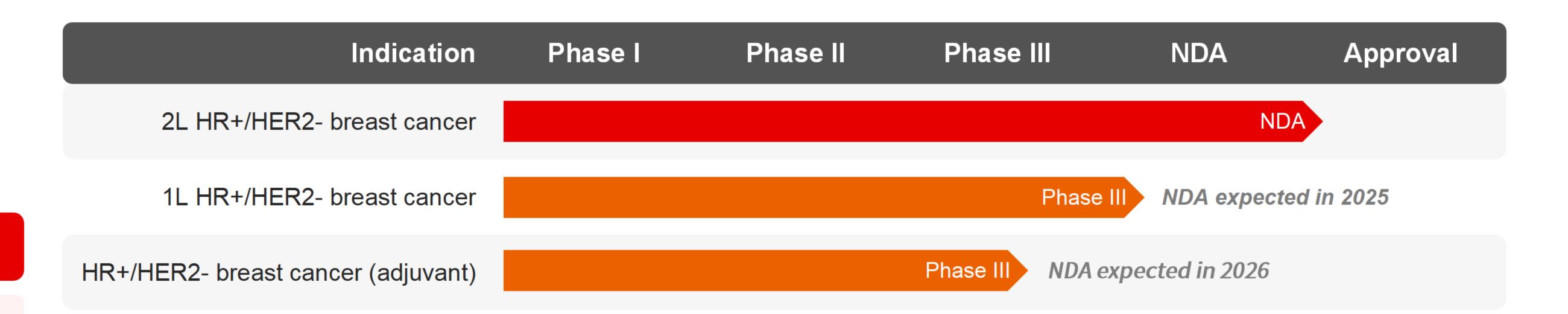
 Superior inhibitory activity against CDK2 and CDK4 compared to abemaciclib and palbociclib, potentially reversing early-stage resistance to CDK4/6 inhibitors<sup>1)</sup>

# Better efficacy

- Clinical data demonstrated that TQB3616 achieved superior PFS and ORR (OS not yet mature) compared to historical data from similar studies
- 2L phase III data was presented at the 2024 CSCO
- 1L phase III data is planned to be presented at 2025 ESMO

#### Improved safety

 Preclinical data demonstrated that TQB3616 has a wider therapeutic window, exceeding that of abemaciclib and palbociclib by more than 3x



## Comparison of efficacy of TQB3616-III-01 with peer studies<sup>2)</sup>

Drug	TQB3	3616	Abemaciclib			Riboo	iclib	Palbo	ciclib	
Trial	TQB361	6-III-01	MONA	RCH 2	MONARCH plus cohort B		MONALI	EESA-3	PALOMA-3	
Patients	2L locally advanced or metastatic BC		nts		1L/2L locally or metas		≥2L locally a metasta			
Group	Treatment	Placebo	Treatment	Placebo	Treatment	Placebo	Treatment	Placebo	Treatment	Placebo
Sample size	194	99	446	223	104	53	237	109	347	174
mPFS (m)	16.62	7.46	16.4	9.3	11.5	5.6	14.6	9.1	11.2	4.6
mPFS HR	0.36 (0.2	26-0.51)	0.55(0.4	5-0.68)	0.38 (0.24-0.59)		0.57 (0.44-0.74)		0.50 (0.40-0.62)	
mOS (m)	Not yet	mature	46.7	37.3	Undisc	closed	40.2	32.5	34.9	28.0
mOS HR	Not yet	mature	0.76 (0.6	0.76 (0.61-0.95) Undisclosed		0.73 (0.53–1.00)		0.81 (0.64-1.03)		
ORR	40.2%	12.1%	35.2%	16.1%	38.5%	7.5%	32.4%	21.5%	19.0%	8.6%
Measurable ORR	46.4%	14.1%	48.1%	21.3%	50.0%	10.5%	40.9%	28.7%	24.6%	10.9%
CBR	76.3%	50.5%	72.2%	56.1%	77.9%	45.3%	70.2 %	62.8%	66.6%	39.7%

Safety events associated with TQB3616 in combination with fulvestrant were predominantly Grade 1-2 and could be managed effectively
through dose adjustments and/or symptomatic treatment. No treatment-related adverse events leading to discontinuation or death were
observed, indicating an overall manageable and tolerable safety profile.

# M701 (CD3/EpCAM BsAb) potential first-in-China SOC for MA and MPE



YZY Biopharma

# **M701**

CD3/EpCAM BsAb

Treatment	Indication	Phase I	Phase II	Phase III	NDA	Approval
Monotherapy	Malignant ascites (MA)			Phase		
+ Systemic treatment	Malignant pleural effusion (MPE)		Phase II			

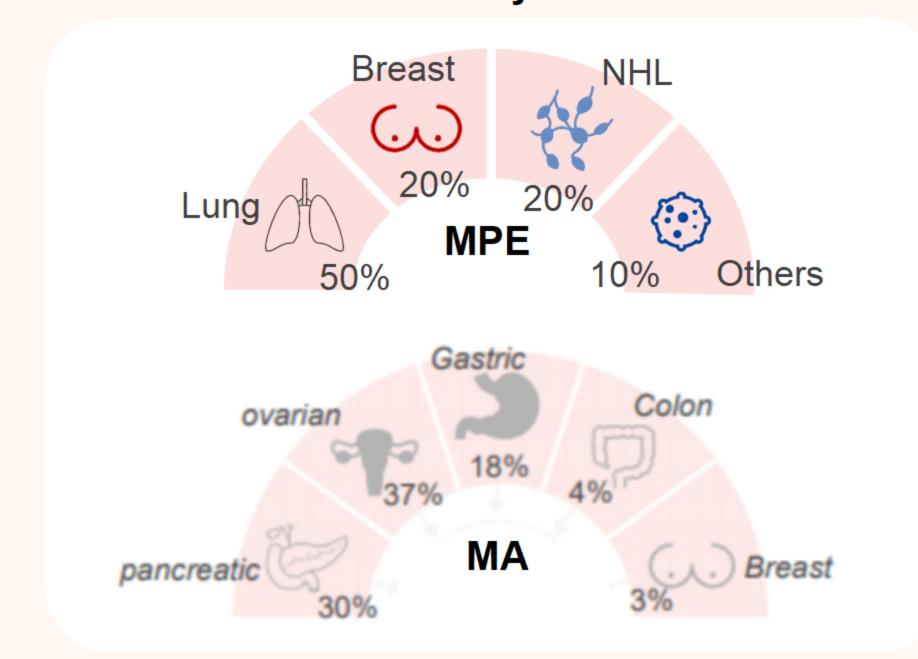
#### Potential first-in-China SOC for MA and MPE

# Structure and mechanism of M701 Anti-EpCAM Anti-EpCAM Fc of human IgG1 Fc of human IgG1

- M701 targets both EpCAM (as the target on tumor cells) and CD3
  (as the target on T cells), thereby directing and activating T cells
  to kill the tumor cells
- Currently, there is a lack of effective SOC in clinical practice, and fluid drainage combined with local drug perfusion remains the primary treatment
- M701 is better in terms of safety and efficacy, as compared with the current primary treatment

Huge market with 600k+ new cases per year

#### MPE and MA caused by difference cancers



- MPE or MA is a common complication for cancer patients at the middle or advanced stages, 10%+ of cancer patients will encounter MPE or MA
- More than 600,000 new MPE or MA cases per year in China

#### Potential peak sales of RMB 2bn

#### M701 Phase II clinical trial for the treatment of MA<sup>1)</sup>

	Intraperitoneal infusions M701 (N=43)	Paracentesis (N=41)		
	75 Days	23 Days		
mPuFS <sup>2)</sup>	HR= 0.40, 95% CI: p=0.008	,		
	111 Days	86 Days		
mOS	HR=0.65, 95% CI 0.39-1.09, p=0.102			

- All three types of cancer patients (gastric, colorectal and ovarian) benefited from M701 infusion, with prolonged mPuFS and mOS
- M701 demonstrated an acceptable safety profile, with ≥ Grade 3 TEAEs occurring in 52% of the M701 group vs. 55% in the control group
- Notably, the incidence of CRS was low (6%)

Notes: 1) 2024 ESMO Asia; 2) PuFS (puncture-free survival)

# BI: Zongertinib (HER2 TKI) remarkable safety profile with BIC potential



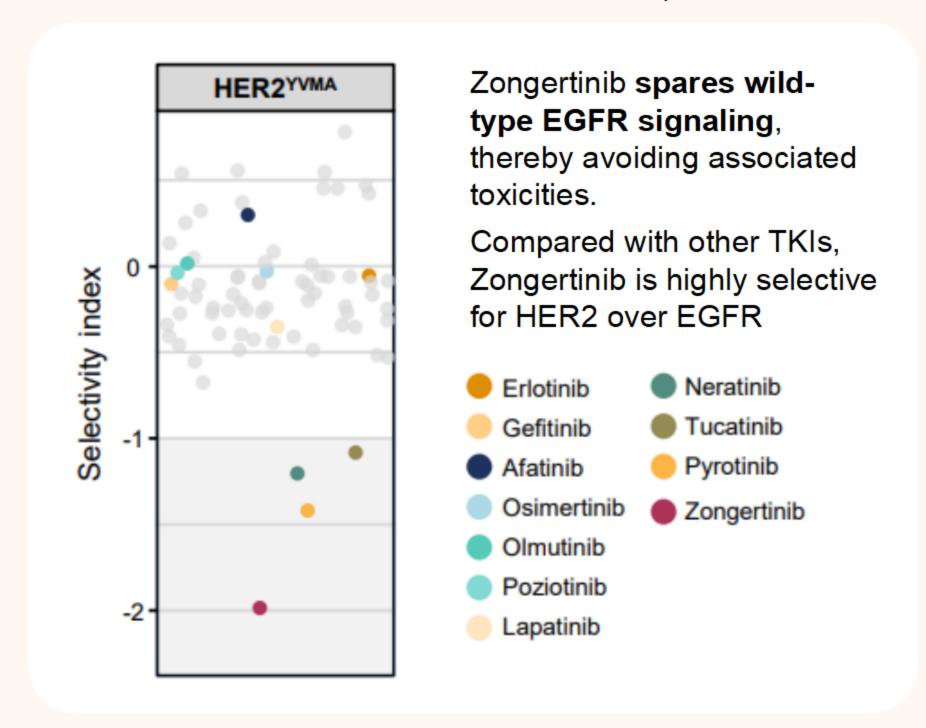
# Boehringer Ingelheim

# Zongertinib

HER2 selective TKI

#### Potent, irreversible, highly selective HER2 TKI

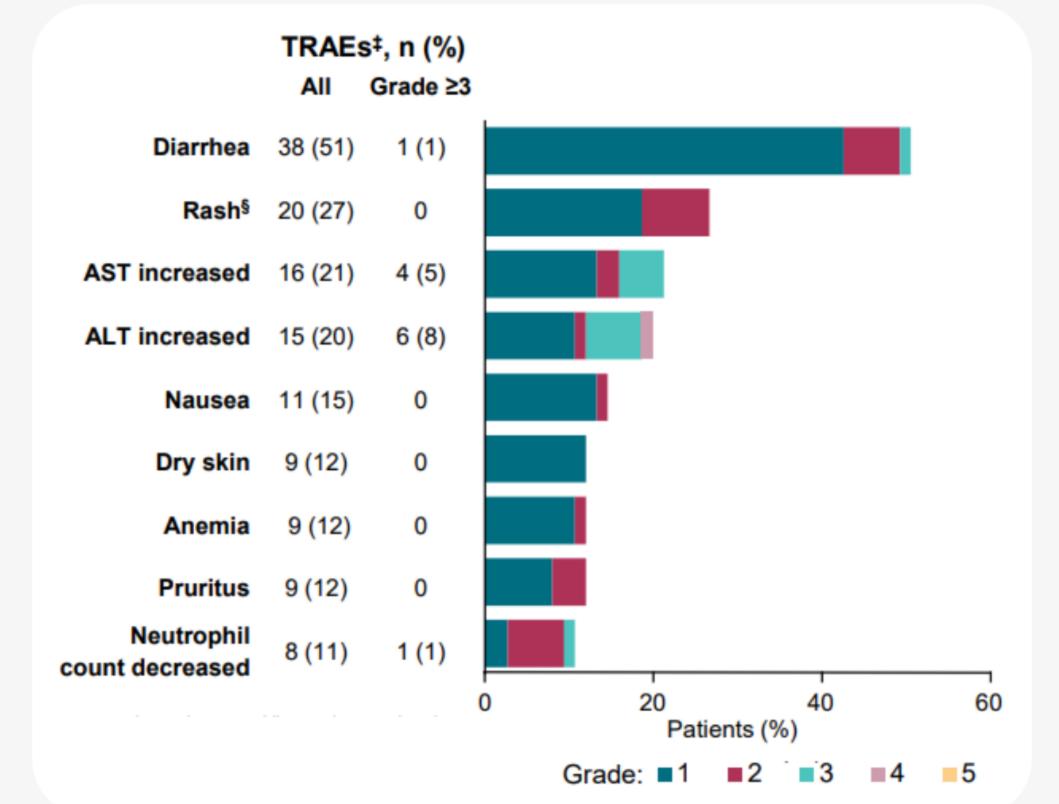
 Covalently binds to the TKD of wild-type and mutated HER2 receptors (including exon 20 mutations, which account for ~48% of HER2 mutations)

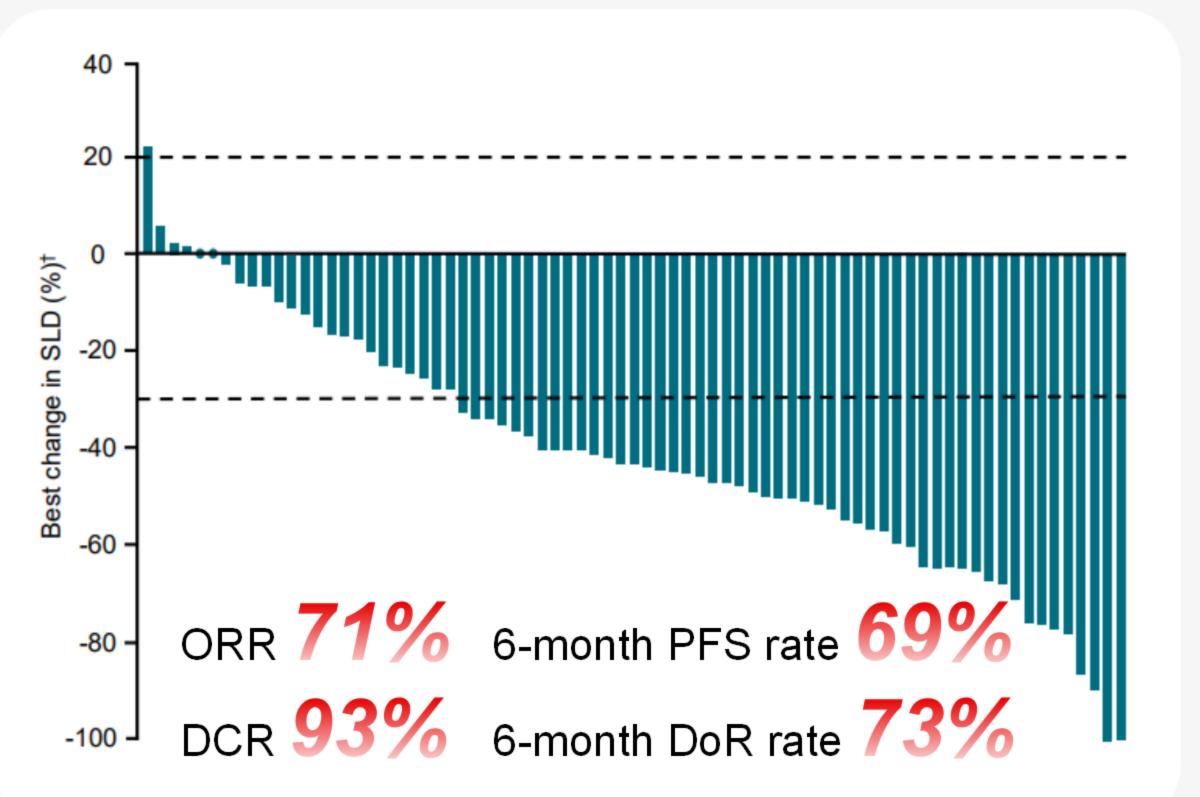


 Multi-indication potential: HER2 mutations exist in lung cancer (2-4%), bladder cancer (12-13%), colorectal cancer (5-6%), cervical cancer (3-6%), and breast cancer (3-4%), etc.









- There were no fatal TRAEs, no reported cases of ILD. Most TRAEs were mild and manageable, only one patient had grade 3 diarrhea
- Only 2 (3%) patients had AEs leading to treatment discontinuation
- Superior safety profile compared to HER2 ADCs and nonselective TKIs
- ORR 71% (95% CI, 60–80), p<0.0001
- At data cut-off, 55% of patients remained on treatment
- Efficacy comparable to HER2 ADCs, with deep and durable responses observed, showing potential for 1L treatment

# PL-5 (Antimicrobial Peptide) first non-antibiotic antimicrobial drug, addressing AMR



# Peceleganan ProteLight Pharma PL-5

# Antimicrobial Peptide

#### First non-antibiotic antimicrobial drug in China

- PL-5 employs innovative membrane differentiation mechanism, exerting antimicrobial effects through targeted disruption of bacterial cell membranes
- First antimicrobial peptide and non-antibiotic antimicrobial drug in China

# Low resistance risk, broad-spectrum, excellent safety profile, and ease of use

- Traditional antibiotics typically target a specific enzyme or protein within a bacterial metabolic pathway. Bacteria can develop resistance through genetic mutations that alter these targets. PL-5 directly kills bacteria by disrupting their cell membranes, minimizing resistance risk
- Broad-spectrum, effective against G+/G- bacteria, including drug-resistant strains
- Topical application with no systemic absorption for enhanced safety
- Spray formulation ensures uniform coverage of wound surfaces, enhancing convenience

#### Significant market demand

 ~30mn patients suffer from burn wounds, diabetic foot ulcers, traumatic wounds, and other infections

Indication	Phase I	Phase II	Phase III	NDA	Approval
Secondary wound infections				NDA	

#### PL-5 Phase III clinical trial for the treatment of secondary wound infections<sup>1)</sup>

Clinical efficacy rate	2‰ Peceleganan (n=381)	1% SSD (n=189)	p value
Day 8	339 (90.4%)	144 (78.7%)	<0.001
Day 5	222 (59.2%)	90 (49.2%)	0.03
	2‰ Peceleganan	1% SSD	p value
	Burns		
Subgroup case number	221	117	
Clinical efficacy rate (D8)	205 (92.8%)	99 (86.4%)	0.0179
	Diabetic foot ulcer	S	
Subgroup case number	17	2	
Clinical efficacy rate (D8)	16 (94.1)	0 (0.0)	0.0175
	Physical injuries		
Subgroup case number	51	29	
Clinical efficacy rate (D8)	41 (80.4)	18 (62.1)	0.0734

	2‰ Peceleganan (n=381)	1% SSD (n=189)
AEs	93 (24.5%)	44 (23.7%)
AEs related to the study drug	28 (7.4%)	13 (7.0%)
Serious AEs	3 (0.8%)	3 (1.6%)
Serious AEs related to the study drug	0 (0.0%)	0 (0.0%)
AEs leading to discontinuation	2 (0.5%)	2 (1.1%)
AEs related to the study drug that led to discontinuation	1 (0.3%)	2 (1.1%)

#### Superior Efficacy

- The primary efficacy outcome was the clinical efficacy rate on the first day following the end of treatment (day 8), which was achieved by 90.4% of the patients in the PL-5 group and 78.7% in the control group (P<0.001)</li>
- A subgroup analysis showed that, on day 8, the clinical efficacy of the PL-5 group was better than that of the control group for infected burn wounds, physical injuries and diabetic foot ulcers

#### **Comparable Safety**

- The safety profile is comparable to that of the control group
- No serious adverse events related to the investigational drug observed

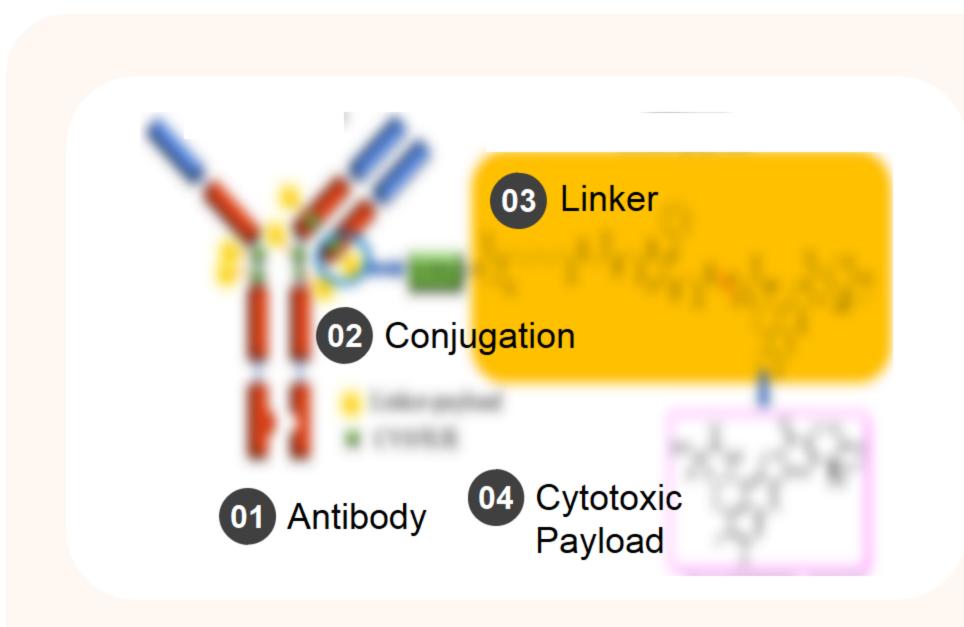
# TQB2102 (HER2 BsAb ADC) potential safety superiority over DS-8201



# **TQB2102**

HER2 BsAb ADC

#### Dual HER2 blockade (trastuzumab + pertuzumab)



- Bispecific antibody, targeting ECD2 and ECD4 (trastuzumab + pertuzumab) epitopes of HER2, promoting endocytosis
- Cys site-specific conjugation technology with a moderate drug-to-antibody ratio (DAR = 6), achieving a balanced efficacy and safety profile
- Cleavable Linkers with bystander effect
- DDDXd (TOP1 inhibitor), deuterated Dxd enables enhanced safety and activity

Cancer	Indication	Phase I	Phase II	Phase III	NDA	Approval
	HER2 low			Phase III		
Drocot Concer	HER2+ (≥2L)	Phase Ib	(Phase III soon)			
Breast Cancer	HER2+ (neoadjuvant)		Phase II			
	HER2-		Phase II			
BTC	HER2+ (≥2L)		Phase Ib/II			
NSCLC	HER2 mutated/overexpression		Phase II			
Gastrointestinal cancers	HER2+ (CRC, GC)		Phase Ib			

#### Comparison of efficacy and safety of TQB2102 with DS-8201 (HER2 low breast cancer)<sup>1)</sup>

	TQB2102 7.5mg/kg Phase I/Ib (N=39)	DS-8201 5.4mg/kg Phase III (N=373)
ORR	51.3%	52.3%
DCR	87.2%	87.1%
ILD	0.0%	12.1%
Dose reduction due to AE	10.3%	22.6%

#### **Comparable efficacy**

ORR and DCR were similar to those of DS-8201

#### Superior safety

- The incidence of ILD was significantly lower than that of DS-8201
- The incidence of bilirubin increase and alkaline phosphatase increase were significantly lower than those of DS-8201, and less hepatotoxicity

Notes: 1) DS-8201: DESTINY-Breast04, 2022 ASCO

Lanifibranor (pan-PPAR agonist) potential FIC in China, addressing the unmet need in MASH



#### Inventiva

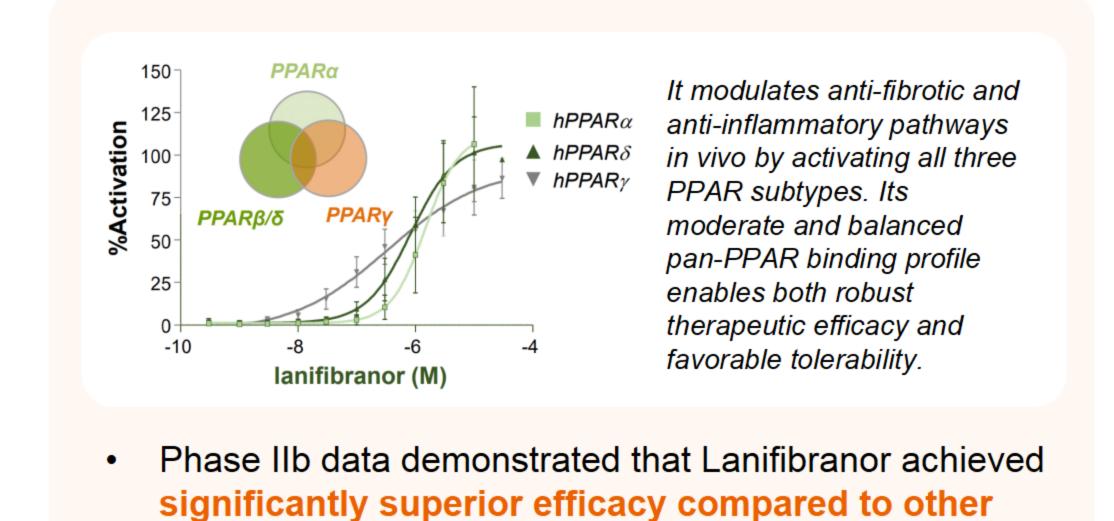
# Lanifibranor

pan-PPAR agonist

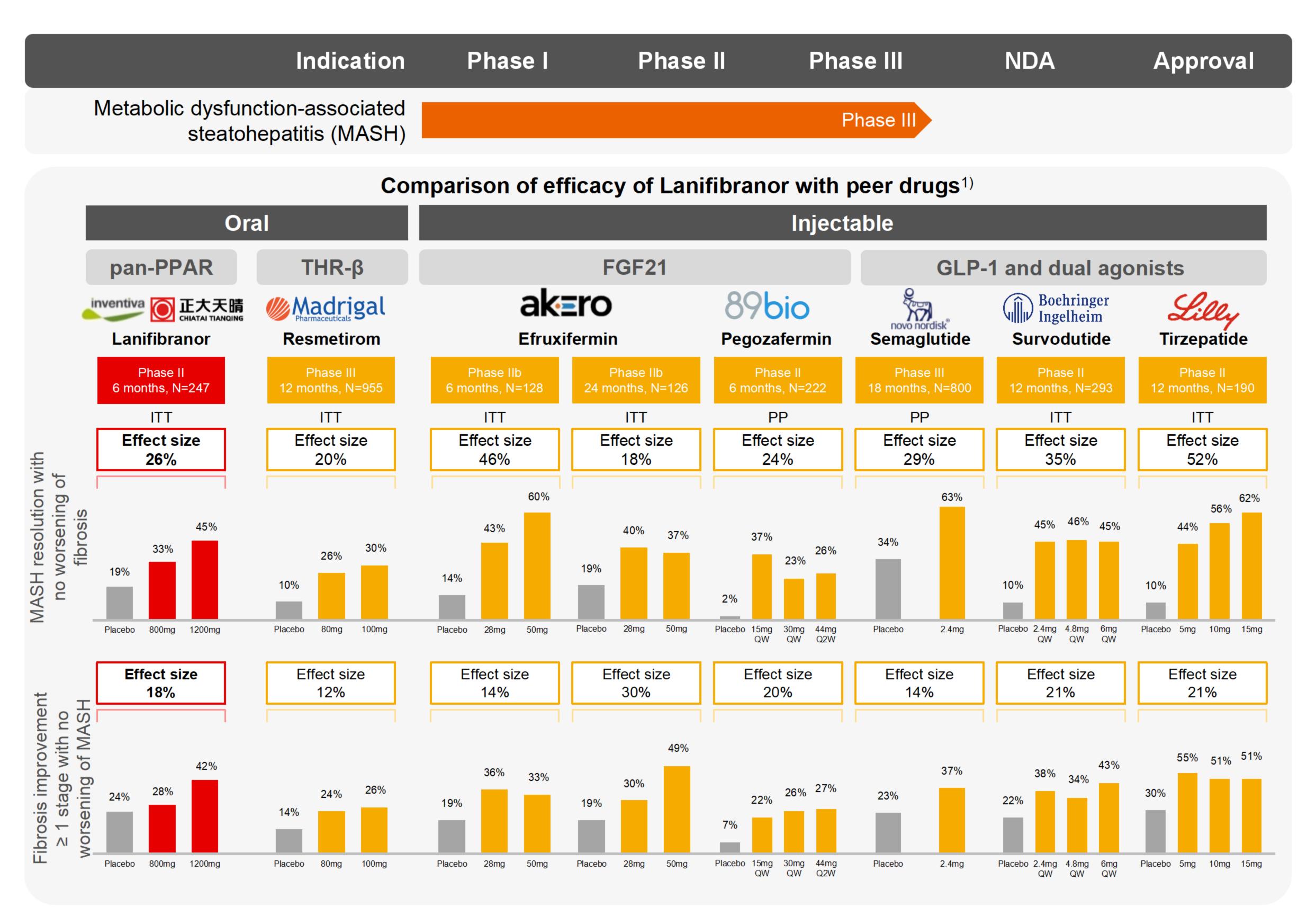
# **China FIC drug for MASH**

- Phase III clinical trials in China and US
- The first MASH drug entering Phase III in China
- Granted Breakthrough Therapy designation by CDE, with a plan to submit NDA in China by 2026
- Granted Fast Track designation and Breakthrough Therapy designation by FDA

# Global BIC potential



oral drugs, with comparable efficacy to injections



Notes: 1) Inventiva official website

# Major Data Readouts 2025



# Oncology

#### **Anlotinib**

#### **Anlotinib + Benmelstobart**

- 1L PD-L1+ NSCLC, vs. pembrolizumab Phase III [ASCO]
- 1L sq-NSCLC, vs. tislelizumab Phase III [ASCO]
- NSCLC (consolidation therapy after chemoradiation)
   Phase III [ASCO]
- 1L RCC Phase III [ASCO]
- TNBC Phase III [ASCO]
- 1L lung adenocarcinoma Phase III [ESMO]
- Endometrial cancer Phase II [ASCO]

#### Anlotinib + Chemo

- 1L CRC Phase III [ASCO]
- 1L soft tissue sarcoma **Phase III** [ASCO]

## **Anlotinib + Penpulimab**

Cervical cancer Phase II [SGO]

#### **Anlotinib**

Glioma Phase II [ASCO]

# Oncology

# ADC, mAb

#### TQB2102 (HER2 BsAb ADC)

- HER2 low BC Phase lb [ASCO]
- HER2+ BC Phase Ib [ESMO/SABCS]
- HER2-aberrant lung cancer Phase Ib/II [ESMO]
- HER2-aberrant BTC Phase II [ESMO]
- HER2+ BC (neoadjuvant) Phase II [ASCO]

# **TQB2103 (Claudin18.2 ADC)**

Gastrointestinal cancers Phase I [ASCO]

#### LM-108 (CCR8 mAb)

Pancreatic cancer Phase II [ASCO]

#### TQB2928 (CD47 mAb)

Multiple sarcomas Phase Ib [ESMO]

# Oncology

#### **BsAb**

## M701 (CD3/EpCAM mAb)

Malignant pleural effusion Phase II [TBD]

#### TQB2930 (HER2 BsAb)

HER2+ BC Phase lb/II [ASCO]

## TQB2825 (CD20/CD3 BsAb)

• Multiple B-cell lymphomas Phase I [EHA/ASH]

#### TQB2868 (PD-1/TGF-β BsAb)

Pancreatic cancer Phase II [ASCO]

# Major Data Readouts 2025



# Oncology

inhibitor

## TQB3616 (CDK2/4/6 inhibitor)

- 1L HR+/HER2- BC Phase III [ESMO]
- CDK4/6i-resistant BC Phase II [ESMO/SABCS]

#### AL2846 (AXL/MET TKI)

Differentiated thyroid cancer Phase Ib [ESMO]

#### TQB3909 (BCL-2 inhibitor)

Acute myeloid leukemia Phase Ib/II [EHA]

#### TQB3454 (IDH1 inhibitor)

Acute myeloid leukemia Phase Ib [EHA]

#### TQB3617 (BET inhibitor)

Myelofibrosis Phase Ib/II [ASH]

# Respiratory

## TQC2731 (TSLP mAb)

- Asthma Phase II [ERS]
- CRSwNP Phase II [ISIAN]
- COPD Phase II [CTS]

#### TDI01 (ROCK2 inhibitor)

- IPF Phase II [TBD]
- cGVHD Phase II [TBD]

## TCR1672 (P2X3R antagonist)

• Refractory chronic cough Phase II [TBD]

## TQC3721 (PDE3/4 inhibitor)

COPD Phase II [ERS]

## TQH2722 (IL-4Rα mAb)

CRSwNP, CRSsNP Phase II [ISIAN]

# Liver diseases

#### TQB3038 (siRNA)

Hepatitis B Phase Ib/IIa [AASLD]

# TQB3810 (TLR-8 agonist)

Hepatitis B Phase IIa [AASLD]

# Surgery/analgesia

#### TRD303 (Ropivacaine)

Postoperative pain Phase II [TBD]

# Holistic Al Strategy

# Empowering growth through strategic partnerships, investments, and localized application



# Al Strategy



#### 2019

# **Partnership**

Entered into an Al technology development service agreement with CTFH to co-develop innovative oncology drugs





#### 2020

# **Partnership**

Entered into an Alpowered oncology drug development agreement with **Beijing Tide** to codevelop novel small molecule oncology drugs





#### 2021

# Partnership & investment

Entered into a collaboration agreement with CTTQ to co-develop novel small molecule drugs in oncology and liver diseases, coupled with a USD12mn investment in the Series D financing round





#### 2022

# Investment

Sino Biopharm invested USD5mn in the Series D financing round



中國生物製藥有限公司



#### 2024

# **Partnership**

Entered into a collaboration agreement with invoX to leverage Al for expanding potential novel indications in oncology pipelines



中國生物製藥有限公司











#### 2025

# Localized application

Sino Biopharm has implemented localized deployment of Al models including DeepSeek, ChatGPT, KIMI, Tongyi Qianwen, and Ernie Bot, etc.



中國生物製藥有限公司 SINO BIOPHARMACEUTICAL LIMITED

# Sustainability

Recognized by multiple authoritative bodies with steadily rising ratings



# MSCI ESG RATINGS

Maintained A rating for two consecutive years, with the overall score demonstrating further improvement from the previous year



# S&P Global CSA

Ranked in the global top 4% with three consecutive years of sustained improvement



# Carbon Disclosure Project

Upgraded two levels to **B**, attaining domestic industry leadership



Accelerated growth in financial performance

5 BD projects
license in and out

5 innovative products

expected to launch

Multiple data readouts



# CONTENTS



# Pipeline-Oncology innovative drugs

No.	Program	Target/MOA	Туре	Indication	 II	Ш	NDA/BLA
1	TQB3616	CDK2/4/6 inhibitor	Small molecule	HR+/HER2- breast cancer			
2	TQ05105	JAK/ROCK inhibitor	Small molecule	Myelofibrosis, GVHD, hemophagocytic lymphohistiocytosis			
3	AL2846	AXL/MET TKI	Small molecule	NSCLC, differentiated thyroid cancer			
4	TQB3454	IDH1 inhibitor	Small molecule	Advanced biliary tract cancer (IDH1 mutation)			
5	TQB2102	HER2 bispecific antibody ADC	Biologics	Breast cancer, NSCLC, biliary tract cancer, gastrointestinal cancer, etc.			
6	M701	CD3/EpCAM bispecific antibody	Biologics	Malignant ascites, malignant pleural effusion			
7	TQB3473	SYK inhibitor	Small molecule	Primary immune thrombocytopenia			
8	FHND9041	EGFR inhibitor (3rd gen)	Small molecule	NSCLC			
9	TQB3909	BCL-2 inhibitor	Small molecule	CLL/SLL, AML, ALL, etc.	Pivotal		
10	LM-108	CCR8 monoclonal antibody	Biologics	Advanced cancers	Pivotal		
11	TQB2868	anti-PD-1/TGF-β bifunctional fusion protein	Biologics	Pancreatic cancer			
12	TQB2930	HER2 bispecific antibody	Biologics	Breast cancer, gastric cancer			
13	TQB2916	CD40 agonistic antibody	Biologics	Advanced cancers			
14	TQB2928	CD47 monoclonal antibody	Biologics	Osteosarcoma			
15	TQB3702	BTK inhibitor	Small molecule	Relapsed/refractory advanced blood cancers			
16	TQB3617	BET inhibitor	Small molecule	Myelofibrosis			
17	TQB3915	SERCA	Small molecule	HR+/HER2- breast cancer			
18	TQB2825	CD20/CD3 bispecific antibody	Biologics	Follicular lymphoma, DLBCL, mantle cell lymphoma			
19	FHND6091	Proteasome inhibitor	Small molecule	Multiple myeloma, biliary tract cancer, lupus erythematosus			
20	FHND5071	RET inhibitor	Small molecule	Solid tumors			
21	NTQ1062	AKT inhibitor	Small molecule	Solid tumors			
22	TQB3720	AR antagonist	Small molecule	Prostate cancer			
23	TQB2103	Claudin18.2 ADC	Biologics	Advanced cancers			
24	TQB2934	BCMA/CD3 bispecific antibody	Biologics	Multiple myeloma			
25	TQB2922	EGFR/cMET bispecific antibody	Biologics	Advanced cancers			
26	TQB3006	SOS1 inhibitor	Small molecule	Advanced cancers			
27	TQB3107	XPO1 inhibitor	Small molecule	Lymphoma, leukemia and various solid tumors			
28	TQB3117	ATM inhibitor	Small molecule	Advanced cancers			
29	TQB3911	BCR-ABL1 TKI	Small molecule	Blood cancers			
30	TQB3002	EGFR inhibitor (4th gen)	Small molecule	Advanced cancers			
31	TQB2029	GPRC5D/CD3 bispecific antibody	Biologics	Multiple myeloma			
32	TQB2252	PD-1/LAG-3 combo	Biologics	Advanced cancers			
33	TCC1727	ATR selective inhibitor	Small molecule	Advanced cancers			
34	NTQ3617	MAT2A inhibitor	Small molecule	Advanced cancers			2

# Pipeline-Oncology biosimilars and generics

No.	Program	Indication	BE trial	ı	Pivotal trial	ANDA/BLA
1	Degarelix Acetate for Injection	Advanced prostate cancer				
2	Enzalutamide Soft Capsules	Prostate cancer				
3	Ruxolitinib Tablets	Myelofibrosis				
4	Ibrutinib Capsules	MCL, CLL, etc.				
5	Pamidronate Disodium Injection	Bone metastasis				
6	Apalutamide Tablets	Prostate cancer				
7	Nelarabine injection	Lymphocytic leukemia, Lymphoma				
8	Abiraterone Acetate Tablets (II)	Prostate cancer				
9	Daratumumab Injection	Multiple myeloma				
10	Netupitant and Palonosetron Hydrochloride Capsules	Chemotherapy-induced nausea and vomiting				
11	Ixazomib Citrate Capsules	Multiple myeloma				
12	Relugolix Tablets	Prostate cancer				
13	Chidamide Tablets	Breast cancer, DLBCL, etc.				

# Pipeline-Respiratory diseases

# Innovative drugs

No.	Program	Target/MOA	Туре	Indication	II	III	NDA/BLA
1	TQH2722	IL-4Rα monoclonal antibody	Biologics	CRSwNP, CRSsNP, atopic dermatitis, seasonal allergic rhinitis			
2	TQC2731	TSLP monoclonal antibody	Biologics	Severe asthma, CRSwNP, COPD			
3	TQC3721	PDE3/4 inhibitor	Small molecule	COPD			
4	TQC2938	ST2 monoclonal antibody	Biologics	Asthma, COPD			
5	TDI01	ROCK2 inhibitor	Small molecule	IPF, GVHD			
6	CPX102	Type III interferon (IL-29)	Biologics	RSV infection			
7	TCR1672	P2X3 antagonist	Small molecule	Refractory chronic cough			
8	TQC3927	MABA	Small molecule	COPD			
9	TQD3524	Polymyxin E2	Small molecule	CRO infection			
10	TQD3606	Meropenem/avibactam	Small molecule	CRO infection			
11	TQC3301	Budesonide soft mist inhaler	Small molecule	Asthma			

# Biosimilars and generics

No.	Program	Indication	BE trial	Pivotal trial	ANDA/BLA
1	Tedizolid Phosphate for Injection	Bacterial infections			
2	Umeclidinium Bromide and Vilanterol Trifenatate Powder for Inhalation	COPD			
3	Tiotropium Bromide Powder for Inhalation	COPD			
4	Amphotericin B Liposome for Injection	Deep fungal infections			
5	Posaconazole Injection	Fungal Infections			
6	Procaterol Hydrochloride Granules	Bronchodilator			
7	Arformoterol Tartrate Inhalation Solution	COPD			
8	Bromhexine Hydrochloride Solution for Inhalation	Chronic bronchitis, asthma, etc. that cause excessive or thickened mucus			
9	Mepolizumab Injection	Asthma, CRSwNP			
10	Delamanid Tablets	Multidrug-resistant tuberculosis			
11	Fluticasone Furoate and Vilanterol Trifenatate Powder for Inhalation	Asthma, COPD			
12	Salmeterol Xinafoate and Fluticasone Propionate Powder for Inhalation	Asthma			
13	Beraprost Sodium Sustained-release Tablets	PPH, scleroderma-associated pulmonary hypertension			

# Pipeline-Surgery/analgesia

# Innovative drugs

No.	Program	Target/MOA	Туре	Indication	1	II	III	NDA/BLA
1	PL-5	Antimicrobial peptide	Class 1	Secondary wound infection				
2	QP001	Meloxicam injection (COX-2 inhibitor)	Class 2	Postoperative pain (Adults)				
3	Naldemedine	Peripherally acting µ-opioid receptor antagonist	Class 1	Opioid-induced constipation				
4	TRD205	AT2R antagonist	Class 1	Neuropathic pain				
5	TRD303	Ropivacaine extended-release solution (local anesthetic)	Class 2	Postoperative pain				
6	YMP	Dexmedetomidine transdermal patches (α2 adrenoceptor agonist)	Class 2	Perioperative insomnia				

# Biosimilars and generics

No.	Program	Indication	BE trial	ı	Pivotal trial	ANDA/BLA
1	Recombinant Human Coagulation Factor VIIa for Injection	Hemorrhagic episodes				
2	Eldecalcitol Soft Capsules	Osteoporosis				
3	Flurbiprofen Patches (2nd gen)	Analgesia and anti-inflammation for various diseases				
4	Mirogabalin tablets	Neuropathic pain				
5	Methocarbamol Injection	Discomfort caused by acute painful muscle or bone conditions				
6	Risedronate Sodium Tablets	Osteoporosis in women after menopause				
7	Pregabalin Extended-release Tablets	Diabetic peripheral neuropathic pain				
8	Elagolix Sodium Tablets	Pain caused by endometriosis				

# Pipeline-Liver/metabolic diseases

# Innovative drugs

No.	Program	Target/MOA	Туре	Ind	ication	ı	II	III	NDA/BLA
1	Lanifibranor	Pan-PPAR agonist	Small molecule	MASH					
2	TQA2225	FGF21 fusion protein	Biologics	MASH					
3	TQ-A3334	TLR-7 agonist	Small molecule	Hepatitis B					
4	TQA3810	TLR-8 agonist	Small molecule	Hepatitis B					
5	TQA3605	HBV capsid assembly modulator	Small molecule	Hepatitis B					
6	TQA3038	siRNA	Small molecule	Hepatitis B					
7	CPX101	GIPR antagonist/GLP-1R agonist	Biologics	Weight loss					

# Biosimilars and generics

No.	Program	Indication	BE trial	Pivotal trial	ANDA/BLA
1	Obeticholic Acid Tablets	Primary biliary cholangitis			
2	Saxagliptin and Metformin Hydrochloride Sustained-release Tables	Type 2 diabetes			
3	Metformin Hydrochloride and Empagliflozin Extended-release Tablets	Type 2 diabetes			
4	Insulin Degludec Injection	Type 2 diabetes			
5	Semaglutide Injection	Type 2 diabetes, weight loss			
6	Insulin Degludec and Liraglutide Injection	Type 2 diabetes			
7	Empagliflozin, Linagliptin, and Metformin Hydrochloride Extended-release tablets	Type 2 diabetes			