三生制药
3SBIO INC.

Corporate Presentation

43rd Annual J.P. Morgan Healthcare Conference

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Chief Financial Officer

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San Francisco, California

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01. Overview

Over Three Decades of Excellence and Continuous Innovation

Interfen®
（interferon α-2ᵃ）

Inleusin®
(IL-2)

BCG-PSN®
(BCG Polysaccharide and Nucleic Acid injection)

EPIAO®
（rhEPO）

Mandi®
（Minoxidil）

SEPO®
（rhEPO）

SPARIN®
(low molecular-weight heparin calcium)

TPIAO®
（rhTPO）

Yisaipu®
(rhTNFR-Fc)

IV Sucrose®
(Iron sulcrose)

Qiming Keli®
（Diabetic retinopathy）

Xenopax®
(Recombinant humanized anti-CD25 mab)

Byetta®
(Exenatide Injection)

Cipterbin®
（Inetetamab anti-HER2 mAb）

YSP®
(Pre-filled injection)

Remitch®
(Narfuraphine hydrochloride orally disintegrating tablets)

Mandi®
(Minoxidil Foam)

TeAiSheng®
（Eltrombopag for Oral Suspension）

1993 · 1995 · 1996 · 1998 · 2001 · 2002 · 2005 · 2006 · 2007 · 2009 · 2011 · 2013 · 2014 · 2015 · 2016 · 2017 · 2020 · 2023 · 2024

1993 — Established main subsidiary Shenyang Sunshine co.,

1995 — The first IPO of Chinese biopharmaceutical company in NASDAQ

1996 — Privatized by a consortium led by management and CPE and delisted from Nasdaq

中信产业基金 CITICPE

1998 — Acquired Sciprogen co., and Sirton (Italy)

Sirton

2001 — Became the third largest shareholder of CITI-guojian and signed strategic cooperation agreement

三生国健

2002 — Listed on HKEX (1530.HK)

Acquired Zhejiang Wansheng

2005 — Included in Hang Seng Composite LargeCap & MidCap Index

恒生指数 HANG SENG INDEXES

2006 — Increased Guojian's share proportion to 97.8%

三生国健

Partnered with AZ for Ⅱ diabetes drugs

AstraZeneca

2007 — TPIAO, Yisaipu listed in 2017 NRDL

Partnered with Lilly for Exenatide

Lilly

Funded €300M through convertible bond

2009 — Sunshine-guojian listed on SSE Star Board (688366)

2011 — Redeemed €300M convertible bond

Obtained IFC granting $ 200mn equivalents long-term low-interest loan credit

IFC

Where We Are Today

24.5%
2013-2023 Revenue CAGR

¥ 7.8 Bn
Revenue in 2023

¥ 7.9 Bn
Financial Resources

28
Disclosed R&D Pipelines

~700
R&D Staffs

>10%
R&D as a % of Revenue

7
Facilities Globally

>4.5%
Dividend Yield at Current Valuation

>50
Approved Products

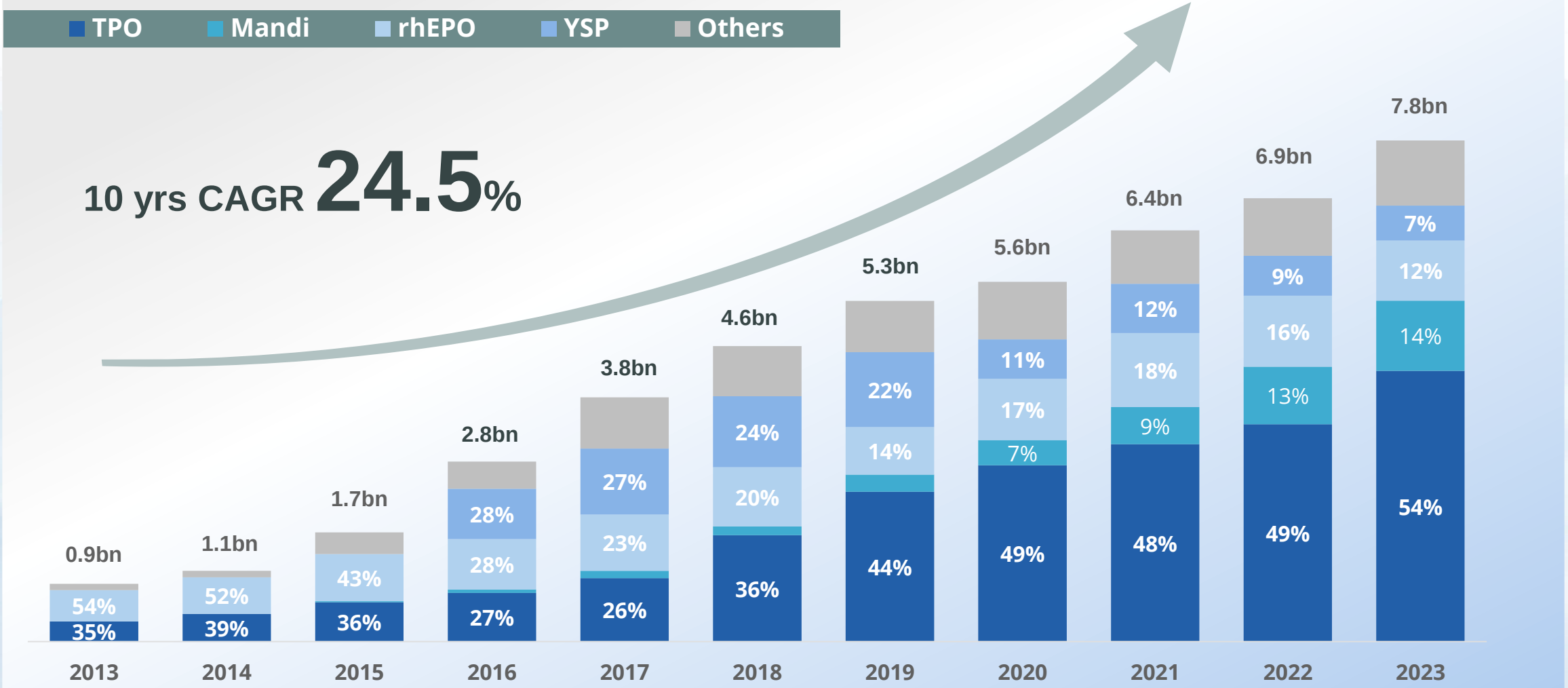
~3,000
Commercialization Professionals

20+
Countries Worldwide

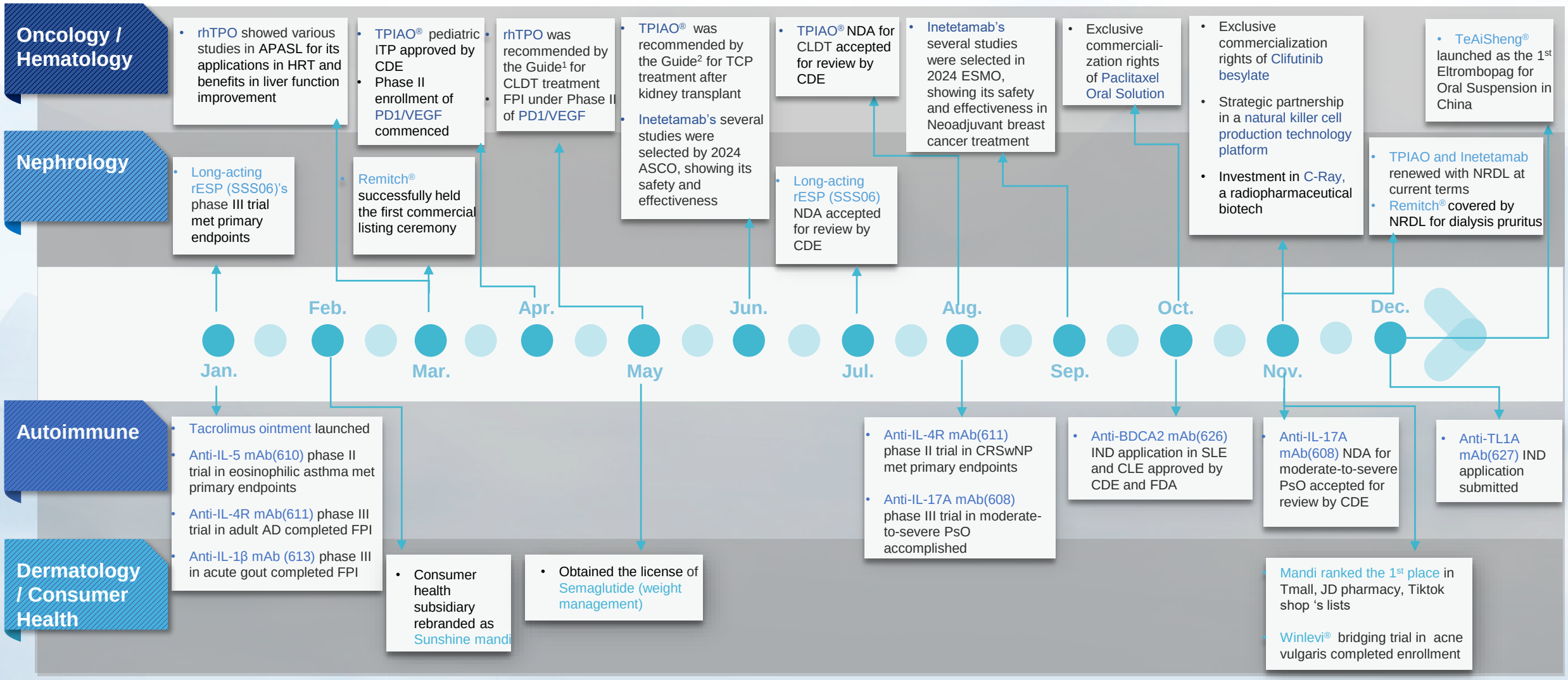
42nd
China's Top 100 Pharma by Overall Industry Capability

AA
MSCI ESG Rating for Three Consecutive Years

Consistent Track Record of Annual Growth for Over a Decade



Milestones in 2024



1. "Standard for diagnosis and treatment of primary liver cancer (2024 edition)"
2. "Clinical diagnosis and treatment guidelines for long-term systemic complications in kidney transplant recipients in China"

Strong Financial Performance

Revenue

16.0% YOY

Gross Profit

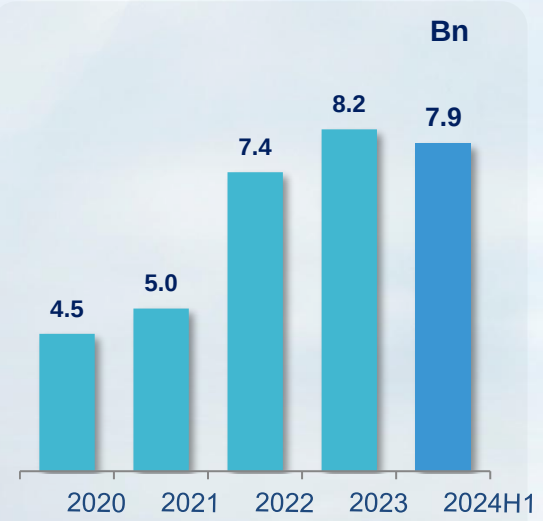
18.6% YOY

Attributable Profits

11.1% YOY

Financial Resources

7.9 Bn



Globally Recognized Commercialization Professionals

- Proven marketing team with over **30** years of recognition
- Covers **all** provinces, autonomous regions and special municipalities in China
- **c.3,000** sales and marketing employees
- Covers **c.2,900** Grade III hospitals
- Covers **6,800+** Grade II or lower ranking hospitals and medical institutions
- **Tens of millions** of online customers

- Various 3SBio's products have been approved overseas, including **TPIAO, Yisaipu, EPIAO, SEPO**, etc.
- The registration has covered nearly **40** countries and regions around the world, with the business and customer scope basically covering all the developing countries

EPIAO (rhEPO)

Marketed in **24** countries
including Philippines, Brazil, Thailand, Colombia, Egypt……

TPIAO (rhTPO)

Marketed in **9** countries including Uzbekistan, Thailand, Philippines……

YSP (Etanercept)

Marketed in **16** countries
including Indonesia, Mexico, Thailand……

Cipterbin (anti-HER2 mAb)

Marketed in **3** countries
including Egypt, Morocco, Philippines

Comprehensive Manufacturing Capabilities



7 plants worldwide with high manufacturing capacity supplying both development and commercialization



1500+ production professionals

Established manufacturing and R&D facilities in Shenyang, Shanghai, Hangzhou, Shenzhen, Dongguan and Italy


Shenyang - Biologics


Shanghai - Biologics

Shenzhen – Biologics/Chemicals


Dongguan – CGT / mRNA


Hangzhou - Chemicals


Como, Italy - CDMO

End-to-End R&D Centers and Platforms

Four Centers, Five Platforms - R&D, Registration, Clinical trials, Manufacture

Shenyang

Shanghai

Shenzhen

Hangzhou

BsAb & Multispecific Ab Platform

Multifunctional
New mechanism
Distinct druggability, easy to product (CLF2 BsAb Platform)

Multifunctional Fc Protein Platform

Discover new function based on new mechanism
Diversified forms

Ab Maturity and Optimization Platform

Humanized
Improve physicochemical properties
Mature affinity
Function expansion and optimization

Ab Selection Platform

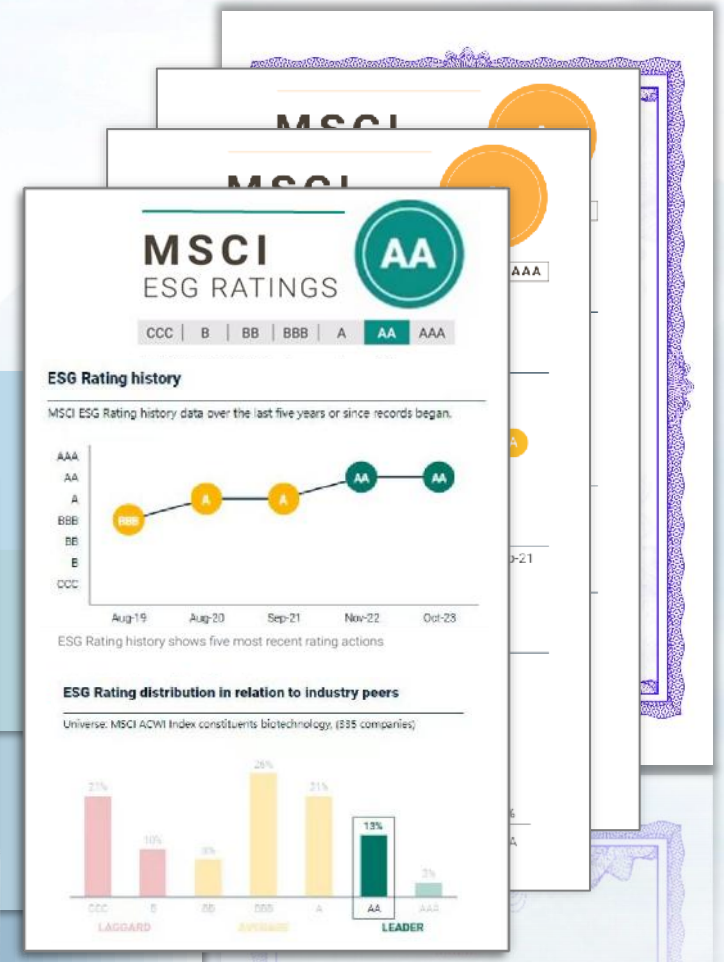
Facilitate new targets R&D
Convenient, fast, costs-efficient R&D

Pre-clinical Animal Drug Effect Platform

Convenient, fast, costs-efficient
On-demand design for explore new mechanism
Mouse, rat, rabbit etc. multi-species project design

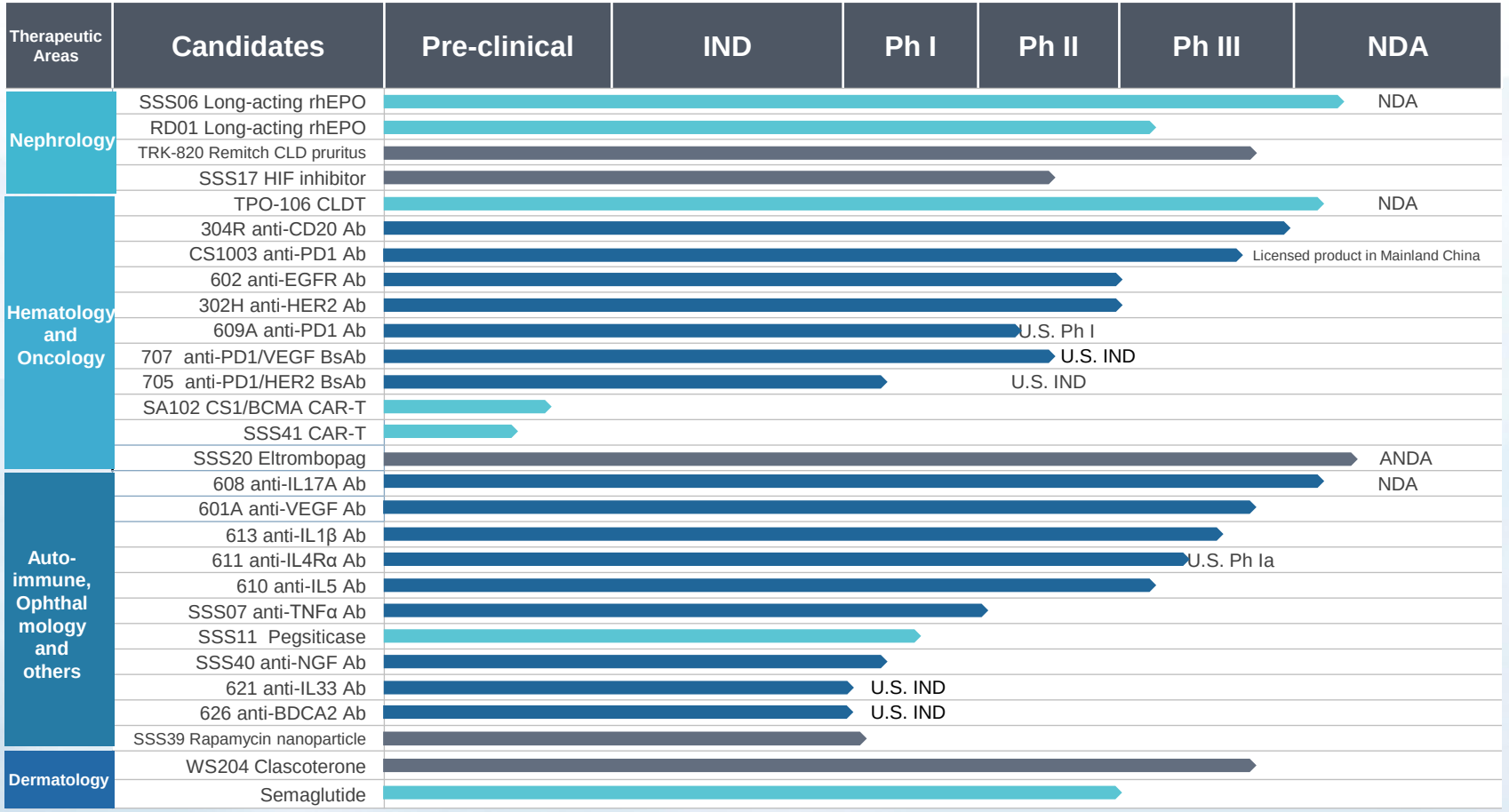
Various ESG Achievements

- Take social responsibilities, devote to public welfare actively
- Industry leading recognition, MSCI ESG rated **AA** for **3** consecutive years
- Listed in the "TOP20 ESG Competitiveness of Chinese Listed Pharmaceutical Companies" list for **3** consecutive years
- Wind ESG **A** rating
- Won the 2024 Yinghua Award of Hong Kong Stock ESG Value Award of China Listed Companies



02. Pipelines by Therapeutic Areas

Innovative Pipeline



2 Pre-clinical

6 IND& Phase I

6 Phase II

13 Phase III &NDA

1 BE/ANDA

3 Approved NDA or ANDA in 2024

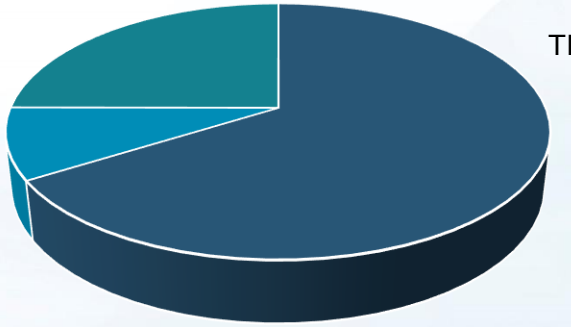
Hematology & Oncology:
TPIAO — the Only Commercialized rhTPO Globally

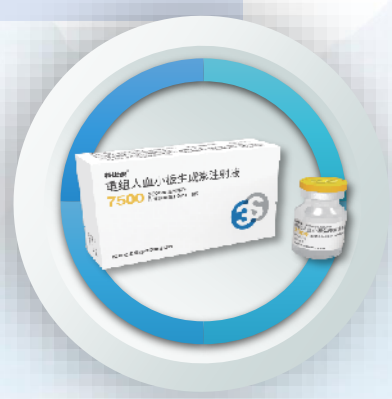
Revenue of TPIAO

1

Top 1 market share

66% [1] market share in terms of sales





Chemotherapy induced thrombocytopenia **(CIT)** → Primary immune thrombocytopenia **(ITP)** → Cancer therapy induced thrombocytopenia（**CTIT**）got Grade A recommendation in CSCO Guideline (2022) → **SIT and HRT** Expert Consensus preferred recommendation → **Pediatric ITP** → Chronic liver disease related thrombocytopenia（**CLDT**） → Myelogenous acute radiation etc.

2005 — 2011 — 2022 — 2023 — 2024.04 — 2025E

1Mn **Chemotherapy TCP pts** Persistent fundamental studies in CTIT treatment

+300k **Radiotherapy TCP pts** **+200k** **Surgery TCP pts**

The **NDA** for CLDT was accepted for review by CDE **in 2024**

+350k **CLDT pts**

Hematology & Oncology:
TPIAO — Improving Clinical Recognition

Liver Diseases

APASL[1]

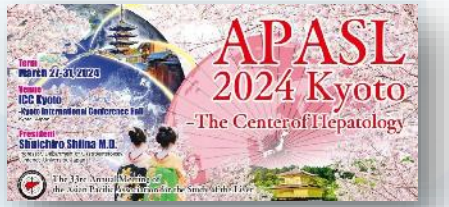
"Standard for diagnosis and treatment of primary liver cancer (2024 edition)"

CLDT

CLDT patients who are candidates for invasive surgery

Mar, 2024

- Several studies of rhTPO showed in APASL, shared academic achievements in acute liver failure, acute-on-chronic liver failure (ACLF), liver cancer ablation severe thrombocytopenia (sTCP) etc.



May, 2024

- "Standard for diagnosis and treatment of primary liver cancer (2024 edition)"released, Recommend rhTPO to treat Chronic liver disease related thrombocytopenia (CLDT)

Nov, 2024

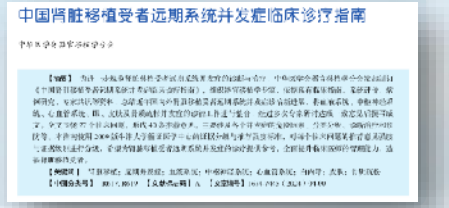
- "Concise guidelines for the clinical management of thrombocytopenia in cirrhosis" recommends rhTPO to treat thrombocytopenia in cirrhosis patients

Nephrology

Kidney Transplant Recipients TCP

Jun, 2024

- "Clinical diagnosis and treatment guidelines for long-term systemic complications in kidney transplant recipients in China" released, Recommend rhTPO to treat kidney transplant recipients TCP



Sepsis

Lower the sepsis mortality rate

Jul, 2024

- The study results of rhTPO for sepsis released that rhTPO could through Mpl combination stimulate the PI3K/Akt channel, reduce levels of IL-6 and TNF-α inflammatory factors, ameliorated endothelial injury, and lower sepsis mortality rate

Pediatrics

Pediatric ITP

Oct, 2024

- The results of phase III trial published in "British Journal of Hematology"

1. The Annual Meeting of the Asian Pacific Association for the Study of the Liver

Hematology & Oncology:
Cipterbin — More Choice for Patients

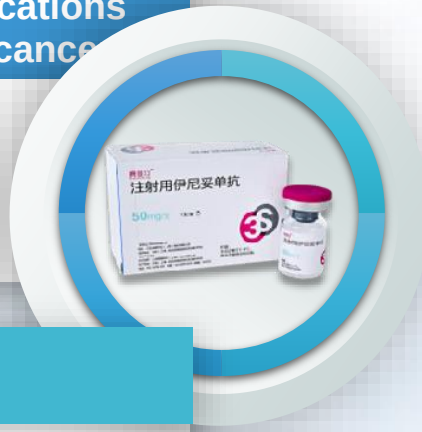
Revenue of Cipterbin

RMB Mn

Top recommendation among H medications for HER2-positive advanced breast cance

Top recommendations: (1) THP[1] (1A); (2) TXH[2] (2A)

Anti-HER2 mAb (H), including Trastuzumab, its biosimilars, and **inetetamab**

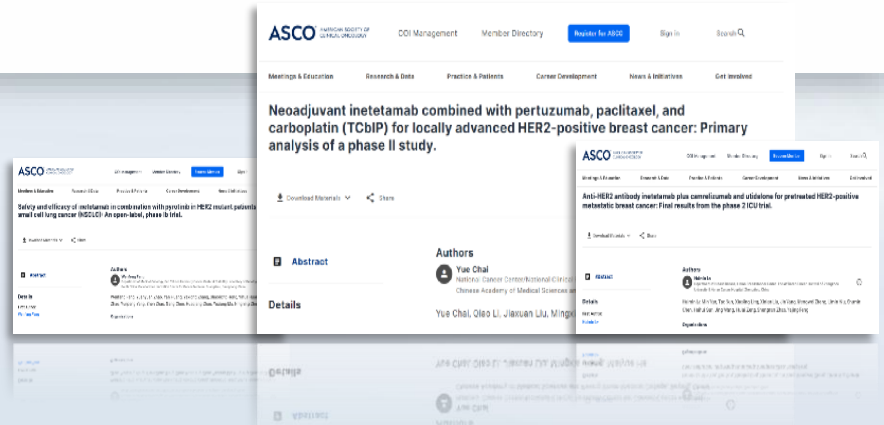


2024 ASCO

1) Neoadjuvant **pyrotinib and inetetamab** in combination with **nab-paclitaxel** for early-stage and locally advanced HER2-positive breast cancer

2) Neoadjuvant **pyrotinib and inetetamab** in combination with **chemotherapy** for early-stage and locally advanced HER2-positive breast cancer: data release

3) Various neoadjuvant and 1L/ 2L treatment combinations for metastatic / advanced HER2-positive breast cancer: date update



1. Taxotere, anti-HER2 mAb and Pertuzumab combined
2. Taxotere, Xeloda and anti-HER2 mAb combined

Hematology & Oncology:
Synergistic Candidates with TPIAO and Cipterbin

Hematology

Eltrombopag for Oral Suspension

ITP

ANDA Approved

- For ITP treatment, especially **benefit the elderly and children with dysphagia**

Clifutinib Besylate

FLT3-ITD+ R/R AML

Phase III

FLT3-ITD+ Initial treatment AML

Phase II

- **Obtained commercialization rights** in Mainland China
- Compared with the first-generation drug, Clifutinib exhibits **stronger FLT3 inhibitory activity**, potential of **lower off-target effect and better safety**
- **The first** highly selective FLT3 inhibitor developed domestically to enter **Phase III** clinical trial in China

Oncology

Paclitaxel Oral Solution

Advanced gastric cancer

Approved in Sep.2024

1L recurrent or metastatic Her2- breast cancer

Phase III finished

- **Obtained commercialization rights** in Mainland China & HK
- **The first launched oral formulation** of paclitaxel in China
- **Reduce the incidence** of adverse reactions such as alopecia, peripheral neuropathy, fatigue and allergic reactions

SSS40 anti-NGF Ab

Bone metastasis cancer pain

Phase Ib/IIa

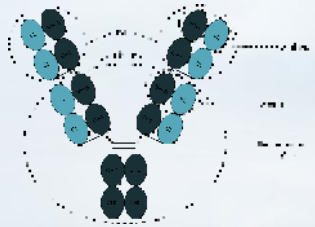
- **Top 3** in China by clinical stage

707 (VEGF/PD-1 BsAb）

NSCLC, mCRC, Advanced gynecologic tumors

Phase II

- Depend CLF^2 patent platform and developed anti-VEGF/PD-1 BsAb
- On-going phase II studies, mono and combined with chemotherapy, for 1L advanced NSCLC, mCRC etc.
- **U.S. IND approved**



CLF^2 (common light chain Linear-Fabs-IgG) BsAb platform

Hematology & Oncology: PD1/VEGF
Summary of Phase 1 and Phase 2 Data From Ongoing Trials

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Drug Name	707							
Phase (Trial)	Phase 1a/1b	Phase 2		Phase 2		Phase 2		
Indication	Advanced Solid Tumors	1L PD-L1+ NSCLC without EGFR/ALK alterations, ECOG 0-1, PD-L1 TPS ≥ 1%		1L NSCLC without EGFR/ALK alterations, ECOG 0-1		≥ 3L mCRC RASm or BRAFm, non-MSI-H or pMMR		1L mCRC RASm or BRAFm, non-MSI-H or pMMR
Dosing Group	707 Monotherapy			707 with Chemotherapy		707 Mono		707 Combo
Dosing Regimen	0.2 to 30 mg/kg QW 45 mg/kg Q3W	**NSQ:** 5 to 30 mg/kg Q3W	**SQ:** 5 to 30 mg/kg Q3W	**NSQ:** 5 to 20 mg/kg Q3W + pemetrexed + carboplatin PD-1/L1i + pemetrexed + carboplatin	**SQ:** 5 to 20 mg/kg + paclitaxel + carboplatin PD-1/L1i + paclitaxel + carboplatin	10 mg/kg Q2W		10 mg/kg Q3W or Q2W + chemo
N	85 (164 Estimated)	83 (120 Estimated)		108 (235 Estimated)		7 [3]		61 [3]
Overall Efficacy		10 mg/kg [2]		NSQ 10 mg/kg	SQ 10 mg/kg			
ORR	Total: 14% [1]	70.8% [5]		58.3%	81.3%	PR:	33.3%	PR: 36.3% [6]
DCR	Total: 59.6% [1]	100.0% [5]		100%	100%	SD:	66.7%[4]	SD: 63.6%
PFS	--	--		--	--	PD:	0%	PD: 0%
Overall Safety	Total [1]	10 mg/kg Q3W		10 mg/kg Q3W				
TRAE %	89.4%	88.2%		55.6%		--		
TRAE % (Gr3+)	33.3%	23.5%		8.9%		--		

Ph1

- No maximum tolerated dose as **no drug-related & dose-limiting toxicity** was observed despite dose escalation and QW dosing
- Modest ORR and DCR, but several patients still awaiting post-baseline tumor evaluation
- Showed promise in range of tumor indications with **anti-tumor activity observed in ≥ 3 mg/kg**
- **Data from ongoing trials still maturing** across many tumor indications (breast, gynecologic, colon and rectal, stomach, etc.)

Ph2

- Interim data from Phase 2 1L PD-L1+ NSCLC demonstrates that 707 is **well-tolerated with a favorable safety profile**
- **Promising anti-tumor activity at 10 mg/kg Q3W** in both monotherapy and combination therapy in NSCLC
- As a **monotherapy for ≥ 3L mCRC, promising efficacy** which has not been seen with any other clinical-stage PD-(L)1/VEGF bispecific antibody
- **Data from ongoing trials still maturing**, with planned completion of Phase 2 trials in NSCLC, mCRC, EC and PROC in 2025

Source: Company Materials

1. ≥ 2L advanced solid tumors (n=66); anti-tumor activity was observed in 3mg+/kg dose levels
2. Best overall response from 10 mg/kg arm (n=34), with 20 PR patients, 13 SD patients and 1 PD patient as of 12/27/2024
3. Estimated total mCRC enrollment of 130 patients
4. 1 SD patient with (29%) tumor size shrinkage
5. 10 mg/kg patients with ≥ 2 post-baseline tumor assessment scans (n=24)
6. Based on only one post-baseline tumor assessment

Nephrology:
Top Market Share rhEPO & Only Symptomatic Drug for Dialysis Pruritus in China

Revenue of rhEPO

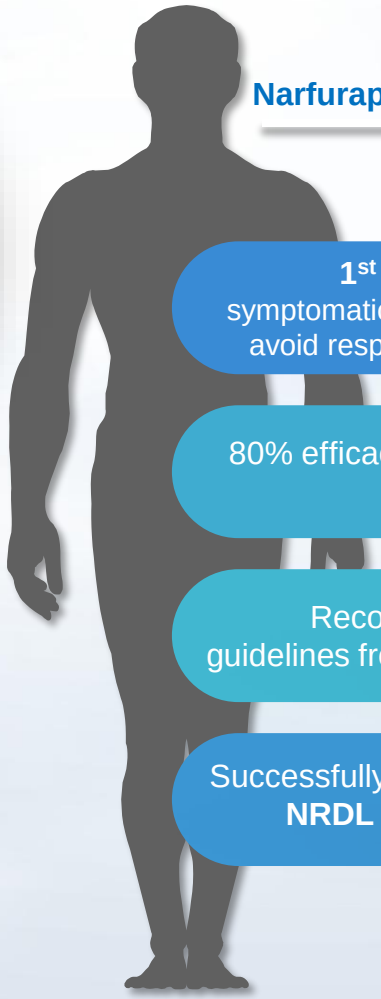
1 TOP 1 Market share

Two brands (EPIAO&SEPO) dominate **43%**[1] market share, Top 1 position in consecutive years

- EPIAO® quality standard is consistent with **EU Pharmacopeia**

Remitch®

Narfuraphine hydrochloride orally disintegrating tablets



1st and Exclusive commercialized domestic symptomatic drug of moderate-to-severe dialysis pruritus, avoid respiratory depression, constipation and addiction

80% efficacy rate within 1 year , VAS scores decreased sustainably[1]

Recommended by authoritative guidelines from Japan, Europe, China[2]

Successfully included in the **2025 NRDL for dialysis pruritus**

Effective and **Safe** treatment choice for the dialysis pruritus patients in China

1. Data source of market share: IQVIA
2. Kozono H, et al. Int J Nephrol Renovasc Dis. 2018 Jan 15;11:9-24； Kumagai H, et al. Am J Nephrol. 2012;36(2):175-83.
3. “European Chronic Pruritus Guideline”, “Chinese Chronic Pruritus in the Elderly Diagnosis and Treatment Consensus”, “Chinese Chronic Pruritus Management Guideline”, “Japanese Skin Pruritus Diagnosis and Treatment Guideline

Nephrology:
More Pipelines & Indications

SSS06 NuPIAO（rESA）

CKD anemia

NDA accepted for review

Cancer related anemia (CRA)

Phase II

SSS17 HIF inhibitor

CKD anemia, postoperative anemia (Exp. develop)

Phase II

Remitch (Narfuraphine hydrochloride orally disintegrating tablets)

CLD induced pruritus

Phase III

SSS06

Glycosylation sites modified EPO

- Extended half-life and longer dosing intervals, matching treatment cycles of chemotherapies
- NDA accepted for review
- Rank No.2 among domestic peers

10% CIA Penetration rate

2024 NDA

Remitch

Narfuraphine hydrochloride orally disintegrating tablets

Dialysis pruritus targeted patients

>300k

CLD pruritus targeted patients

>1 Mn

- The incidence of pruritus ranges from 5% to 70% in different types of liver diseases
- Current treatment are not effective to over **57%** liver disease pruritus

Alcoholic fatty liver disease, **62 mn**

Liver cirrhosis | Hepatitis C

chronic hepatitis B **90 mn**

Non-alcoholic fatty liver disease (NAFLD) **170-310 Mn**

2024

Autoimmune:
Yisaipu — The Preferred Biopharmaceutical for Chronic Diseases Treatment

Revenue of Yisaipu

RMB Mn

Improving market penetration

- Enhance hospitals coverage and related department coverage, prompt market penetration

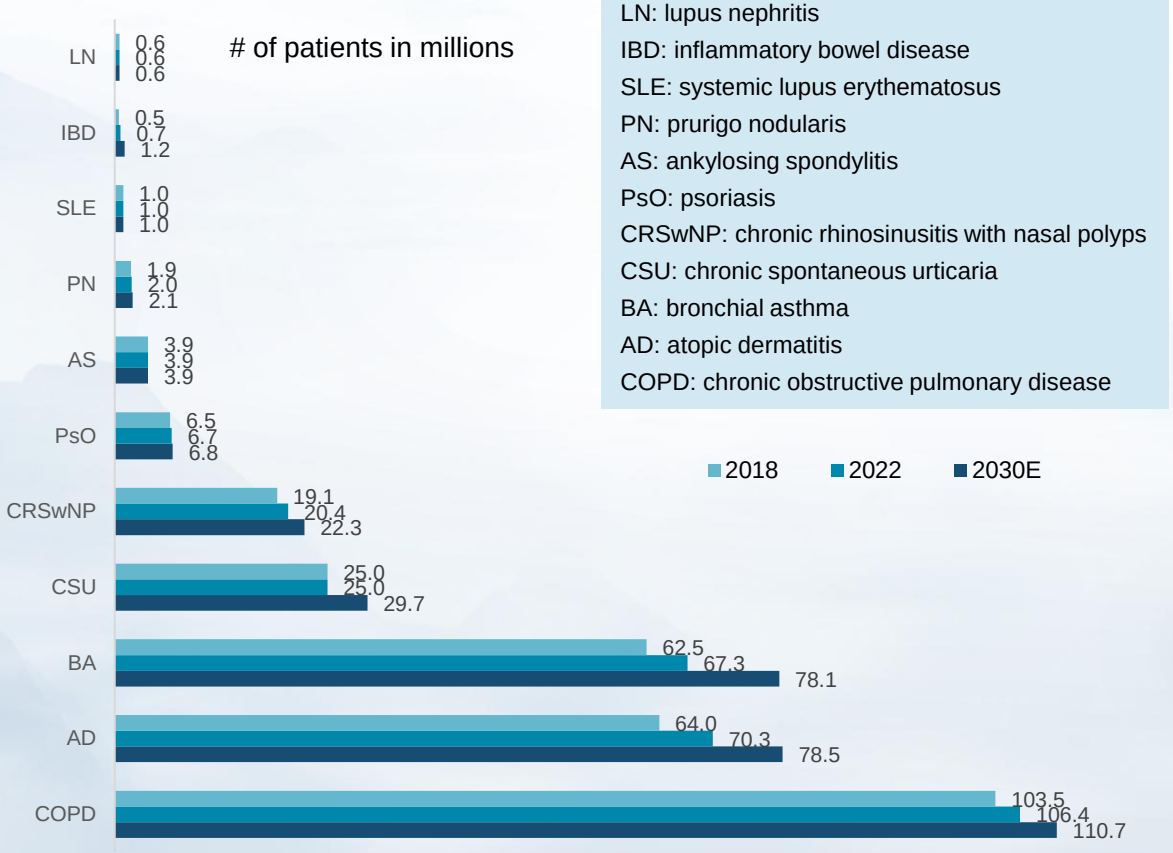
Expand new formulation

- Pre-filled syringe got approval and marketed in May 2023

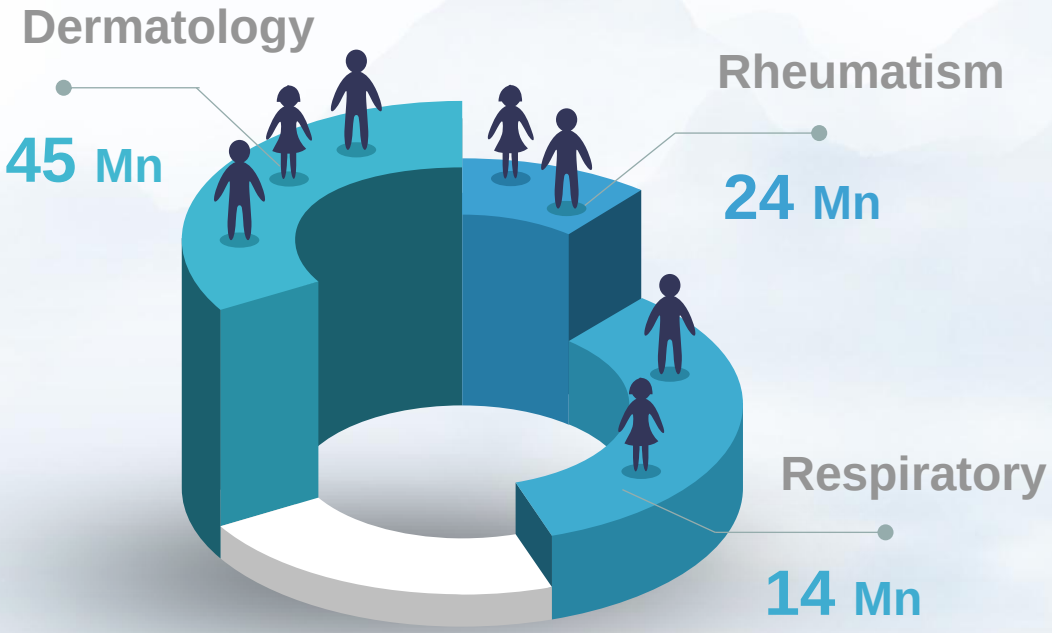
Persistent foundation work

- Promote NEDL entry and rural revitalization projects
- Improve treatment standard at basic level institutions

Autoimmune:
Focus on Broad Chinese Autoimmune Market



LN: lupus nephritis
IBD: inflammatory bowel disease
SLE: systemic lupus erythematosus
PN: prurigo nodularis
AS: ankylosing spondylitis
PsO: psoriasis
CRSwNP: chronic rhinosinusitis with nasal polyps
CSU: chronic spontaneous urticaria
BA: bronchial asthma
AD: atopic dermatitis
COPD: chronic obstructive pulmonary disease

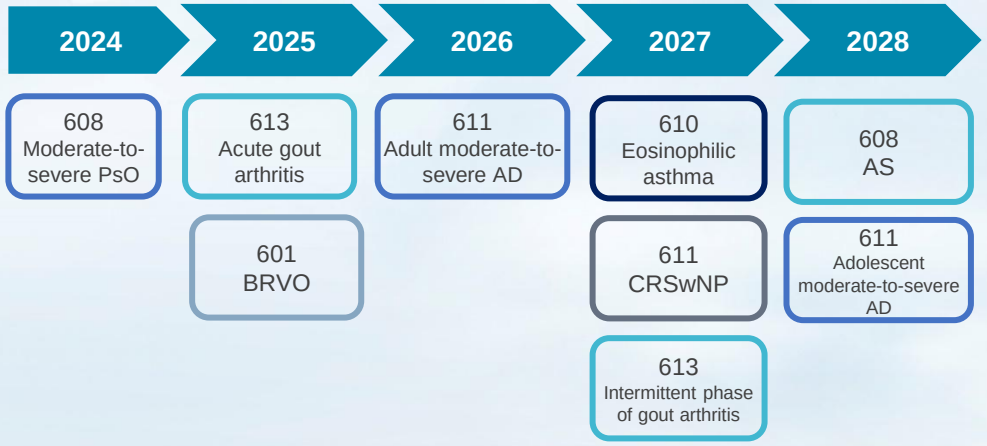


Autoimmune:
Build the most Competitive Autoimmune Pipeline in China

	Indication	IND	Ph I	Ph II	Ph III	NDA
608 anti-IL-17A Ab	Moderate-to-severe PsO					2024A
	AS					
	Nr-axSPA					
613 anti-IL-1β Ab	Acute Gout Arthritis					2025E
	Intermittent phase of gout arthritis					
611 anti-IL-4R Ab	Adult AD					2026E
	CRSwNP					
	Adolescent AD					
	COPD					
	AD (U.S.)					
610 anti-IL-5 Ab	Eosinophilic asthma					2027E
621 anti-IL-33 Ab	COPD					
626 anti-BDCA2 Ab	SLE/ CLE					

Autoimmune pipeline strategy

Indications coverage of marketed products	Product pipeline development, effort to build FIC/BIC products	The new indications include AD, CRSwNP, COPD, moderate to severe asthma, acute gouty arthritis, SLE, CLE etc
RA、AS、PsO		



rheumatology and immunology | otolaryngology | dermatology | pneumology | ophthalmology

Consumer Health:
Mandi — No.1 OTC Dermatology Brand in China

Highly recognized scientific and effective hair growth choice

- Minoxidil, as a scientific, effective, safe and convenient hair growth product, its market size is increasingly enlarging
- Mandi (5% minoxidil) got the highest endorsement level of recommendation in female androgenetic alopecia (FAGA)

Revenue of Mandi

Digital marketing covers the broadest population

- Deepen the cooperation with leading platforms
- Grasp new media platforms, expand new e-commerce channels
- In Double 11 2024, Mandi ranked **the 1st** in Tmall, JD pharmacy and ByteDance

Consumer Health:
Mandi — No.1 OTC Dermatology Brand in China

1st Generation
Mandi Tincture

- Mandi (60mL, 90mL)
- Mandi Pro (10mL)
- Mandi for Female (30mL)
- Mandi Mini bottle (10mL)

2nd Generation
Mandi Foam

Approved with OTC in Jan 2024;
Innovative technology, fill the gap for skin sensitive population

Everyday Products

- Mandi “Stand on” Shampoo, conditioner
- Selenium disulfide anti-dandruff shampoo
- Mandi Comb

Consumer Health:
New Acne Treatment Choice for Teenagers - Winlevi®

Winlevi® (clascoterone) cream 1%

WS204 Clascoterone cream

Acne vulgaris in 12 years and older

Phase III

Finished enrollment

Millions of adolescent patients

Safe, Effective, Convenient drug

Clinical trial shows:

Winlevi® could reduce the emergence of acne, blackheads, whiteheads

W4 treatment observes acne reduced;

W12 treatment shows obvious improvement

WINLEVI® is the only cream for acne treatment targeting sebum production

By inhibiting the activity of sebaceous androgens and reducing sebum production to reduce inflammation[1]

1st new mechanism of action in acne approved by the FDA in 40 years

- Approved by FDA in November 2021[1]

12 years older

- Global 1st external topical androgen receptor inhibitor for the acne vulgaris in patients aged 12 years or older

1.09 mn

- Winlevi® is already the most prescribed branded topical acne drug in the US. By June 2024, it generated over 1.09 mn prescriptions[2]

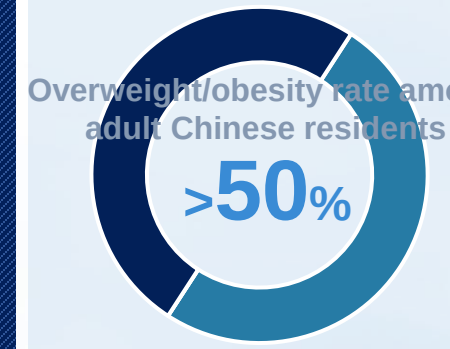
1: www.winlevi.com

2: Cosmopharma 2024 Interim Report

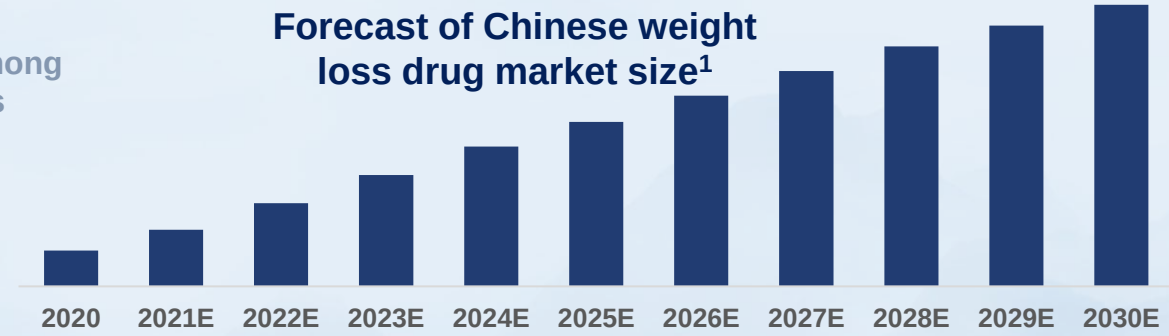
Consumer Health:
Vast Opportunities in Weight Management Market - Semaglutide

Number of people with obesity in China (Est. 2030):

329 mn[1]



Forecast of Chinese weight loss drug market size[1]



Semaglutide: Globally recognized safe and effective weight management products

➢ In May 2024

Achieve cooperation on Semaglutide injection weight management indication

- **The first batch of IND approval in China**
- **Reach a wide range of people online**
- **Multi-layered target clients**

➢ In Sep. 2024

Semaglutide (weight management)'s **phase III trial** plan approved by CDE, become **the first approval** among domestic Semaglutide-similars

Semaglutide progress

Weight management

Planned enrolled 408 pts

44 weeks evaluation time

1. Data source: Frost Sullivan, http://m.cnpharm.com/c/2021-09-22/803749.shtml

03. Business Development

Business Development Strategies

Strategic Investment

- In **start ups with FIC or BIC potential** to achieve long-term **strategic technology** cooperation

License-In

- Beef up product line in **existing therapeutic areas** to scale up revenues
- Strategically deploy resources into **new targets and new technologies**, build up long-term R&D pipelines

License-Out

- To promote self-developed innovative products abroad and enter **the global market**
- To complement the advantages of external partners and **maximize the commercial value** of innovative products

Strong Commercialization Platform

Near 3,000 sales and marketing employees
Covers **over 2,900** Grade III hospitals and altogether around **10,000** hospitals

Comprehensive Facilities

7 manufacturing plants with **100KL+** cost-effective manufacturing capabilities, covering **small molecule, large molecule, CGT, mRNA** etc.

Self-developed Pipelines

6 pipeline rank among the top in China, cover **rheumatology and immunology, dermatology, otolaryngology, pneumology etc.**

Sufficient Financial Resource

Nearly **RMB 8 bn** available
Over **RMB 2 bn** operating cash flow annually

Hematology /Oncology

- Paclitaxel Oral Solution
- Clifutinib
- Eltrombopag suspension
- PD-1 Ab
- CS1/BCMA CAR-T
- ……

Nephrology

- Remitch® (Narfuraphine hydrochloride orally disintegrating tablets)
- ……

Auto-immune

- Allorion Therapeutics Small molecule autoimmune medicines
- ……

Consumer Health

- Winlevi® (Clascoterone cream)
- Semaglutide injection
- ……

Professional R&D Support

Near 700 scientists, accounting for **over 10%** of total staff, R&D as a % of revenue of **>10%**

Experienced Digital Marketing Team

continues to build "hot selling products"

Flexible Cooperation Structure

Explore more opportunities with our partners through **license-in, CSO, CDMO, license-out, newco, co-development, etc.**

Recent License-in Deals:
Commercialization Rights of Late-stage Clinical Products

➢ **24 Oct 2024**

Obtained exclusive commercialization rights of **Paclitaxel Oral Solution** in Mainland China & HK

三生制药 3SBIO INC. 海和药物 Haihe Biopharma

- The **first launched** oral formulation of paclitaxel in China, offer **convenience** to chemotherapy patients, improve the **clinical efficacy**
- **Reduce the incidence of adverse effect** such as alopecia, peripheral neuropathy, fatigue and allergic reactions
- To extract synergies of commercialization capabilities of 3SBio in oncology space

➢ **25 Nov 2024**

Obtained exclusive commercialization rights of **Clifutinib besylate** in Mainland China

三生制药 3SBIO INC. HEC 东阳光药

- Compared with the first-generation, Clifutinib exhibits **stronger FLT3 inhibitory activity, potential of lower off-target effect and better safety**
- **The first** highly selective FLT3 inhibitor developed domestically to enter **Phase III** clinical trial in China
- To extract synergies of commercialization capabilities of 3SBio in hematology space

01

➢ **19 Sep 2024**

Obtained **marketing approval** by NMPA for **advanced gastric cancer**

02

➢ 1L recurrent or metastatic Her2- **breast cancer**

Ph III **Finished**

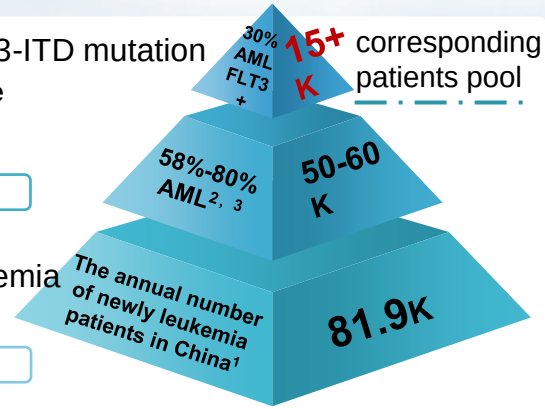
R/R acute myeloid leukemia with FLT3-ITD mutation

NDA submission according to **the first time interim analysis of** CR/CRh rate

Phase III

Initial treatment of acute myeloid leukemia with FLT3-ITD mutation

Phase II



1. "2024 China Cancer Report"
2. SIEGEL R S, MILLER K D, JEMAL A. Cancer statistics, 2020 [J]. CA Cancer J Clin, 2020, 70(1): 7-30.
3. DAVER N, SCHLENK R F, RUSSELL N H, et al. Targeting FLT3 mutations in AML: review of current knowledge and evidence [J]. Leukemia, 2019, 33(2): 299-312.

Recent Investments:
Innovative Early-Stage R&D Platform

Strategically investing in FIC/BIC start-ups and empower R&D from long term perspective

15 Nov 2024

Lead the A+++ financing round of NK CellTech

三生制药 3SBIO INC. 恩凯赛药 NK CELLTECH

NK CellTech —— Focusing on the discovery and development of innovative technology of natural killer cell therapy

- Unique ABCDE-NK® industrial production platform with **allogeneic peripheral blood NK cell expansion & cryopreservation and clinical "spot" level** (a single blood supply can produce **trillion-level** NK cells)
- In 2024, **two NK cell products** have obtained **the US FDA and China CDE IND** approval, respectively. Multiple ongoing IIT programs in the **non-oncology field**

2024.11.16

Participate in the A+ financing round of C-RAY

三生制药 3SBIO INC. C-RAY 通瑞生物

C-Ray Therapeutics —— Innovative radiopharmacology drugs' R&D, manufacturing, clinical application and commercialization

- Built nearly **30000㎡** of radiopharmacology research and production plant; Obtained **the first grade A** "Radiation Safety License" for innovative radiopharmaceutical enterprise; **13 cGMP high standard** workshops in line with the requirements of **US FDA, Chinese NMPA and EU EMA**
- The team has accumulated rich experience in **68Ga, 64Cu, 18F, 89Zr, 177Lu, 225Ac** and other isotope labeling of small molecules, peptides, antibody drugs, and the ability covered **all stages from pilot test to commercial production**

What to Expect in 2025?

Continuous Growth in Revenue and Profits

NDAs

IND Applications

License In and Out Transactions

Technical Supplements

SSS06 (rESP) in Anemia of CRF(Chronic Renal Failure)

The phase III trial demonstrated that rESP was safe and effective for anemia of CRF[1] patients on stable hemodialysis as rhEPO

2nd- generation EPO

- Genetically modified rhEPO in **which 3N-glycosylation sites** are added by site mutagenesis
- **Longer acting** ESPs (erythropoiesis stimulating Protein Injection)

Clinical superiority

- **Longer mean half-life** than rEPO
- Sufficient circulating exposure time
- Dosing at **longer intervals**
- rESP QOW was **safe and effective** for anemia of CRF patients on stable hemodialysis

Progress rank No.2 in China

- Follow up of all subjects in Phase III trial has been **completed**

2024
NDA

rESP vs. rhEPO clinical efficacy data:

Efficacy Endpoint*	rhEPO (dosage and schedule identical to the screening period)	rESP QOW (starting dose 50μg)
Mean baseline Hb (g/L)	110.43	**110.47**
Mean Hb during evaluation (g/L)	108.47	**108.64**
Primary Efficacy Endpoint		
Mean Change from baseline in mean Hb during the evaluation period (g/L)	-1.85	**-1.87**
Adjusted mean (standard error)	-1.58 (0.956)	**-1.46 (1.000)**
Adjusted mean difference (95% CI)	—	**0.12 (-1.82, 2.06)**

1. CRF: chronic renal failure

608 (anti-IL-17A mAb) in PsO

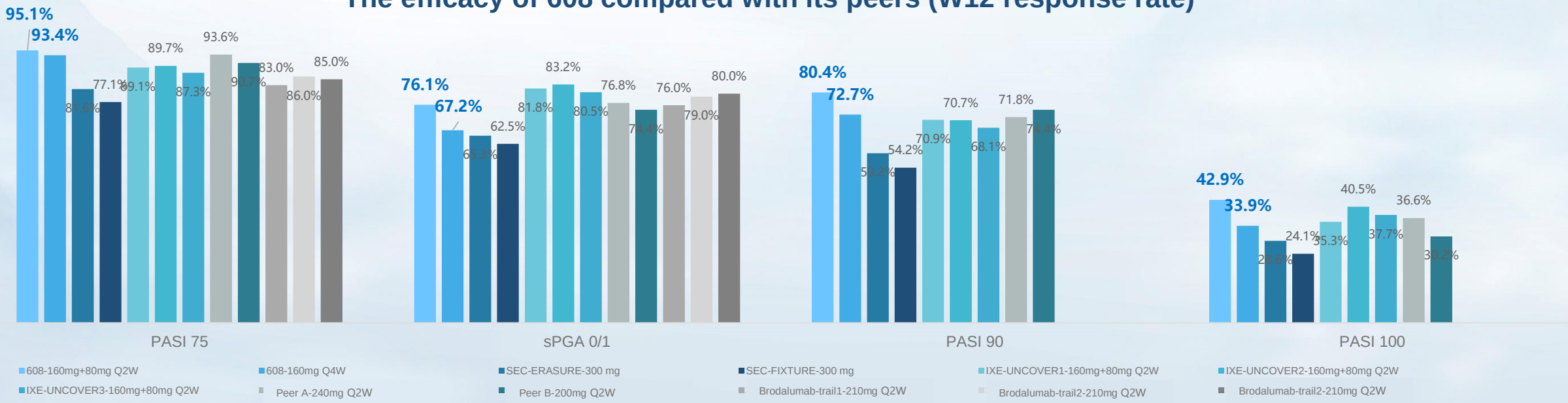
Phase III study data in PsO unblinds: met primary endpoints and all secondary endpoints

	Primary endpoints		Key secondary endpoints			Secondary endpoints		
	PASI 75 (W12)	sPGA 0/1 (W12)	PASI 90 （W12）	PASI 100 （W12）	PGA 0 （W12）	maintenance -PASI100 （W52）	DLQI[1]	Pruritus NRS[2]
608 160+80 mg Q2W	95.1%	76.1%	√	√	√	63.6%	√	√
608 160mg Q4W	93.4%	67.2%	√	√	√	56.8%	√	√

- The primary efficacy data at 12 weeks were excellent, with rapid response rate and obvious efficacy advantages
- In the maintenance treatment period, the 608 dosing interval was extended to Q4W or Q8W, and the efficacy remained high, which was expected to achieve a longer dosing interval in PsO

2024 NDA reviewing

The efficacy of 608 compared with its peers (W12 response rate)



Note: SEC- Secukinumab, IXE- Ixekizumab

1. DLQI: Dermatology Life Quality Index, 2. Pruritus NRS: Pruritus Numerical Rating Scale

611 (Anti-IL-4R mAb) in Atopic Dermatitis

Phase II trial of 611 in AD shows better performance than control group

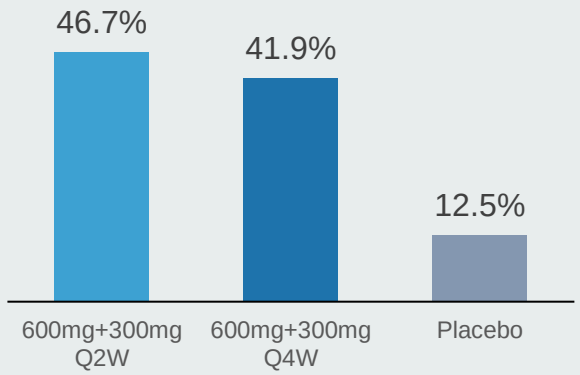
- Data from Week shows 611 has better performance than Dupilumab on EASI-75 and NRS

	EASI 75[2]	IGA 0 /1	EASI 50	NRS ≥4[3]
Group A[1] N=30	**60%**	**33.3%**	**73.3%**	**46.7%**
Group B N=31	48.4%	35.5%	77.4%	45.2%
Placebo N=32	15.6%	9.4%	18.8%	15.6%
Dupilumab（Q2W）	48~51%	27~36%	65~69%	36~41%

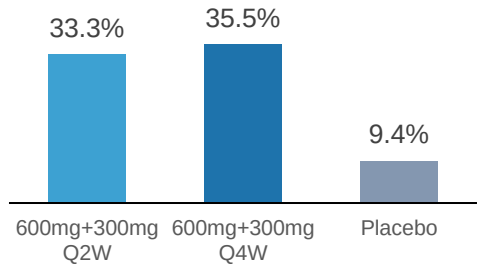
- Progress ranks **No.3** in China

2026
Est. NDA

IGA declined ≥2 from baseline



IGA 0/1[4] and declined ≥2 from baseline



Company	Indication	Code
A	AD approved CRSwNP NDA reviewing Asthma NDA reviewing	
B	AD Phase III Asthma Phase II completed	
3SBio	AD Phase III CRSwNP Phase III COPD Phase II	SSGJ-611

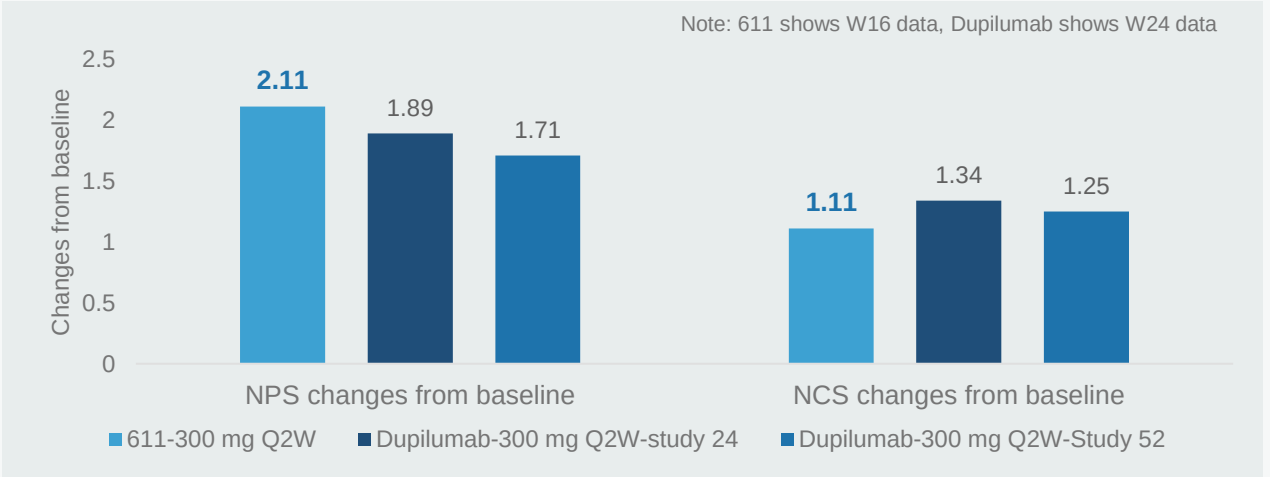
1. 611 GroupA：600mg LD(loading dose)+300mg Q2W，Group B：600 mgLD+300mg Q4W；
2. EASI75,,EASI50 :EASI change from baseline≥75%和≥50%
3. NRS≥4 : weekly average value of itching declined ≥4 from baseline
4. IGA 0/1: Investigator Global Assessment equals (affected body surface area completely cleared) or 1(affected body surface area almost cleared)

611 (anti-IL-4R mAb) in CRSwNP

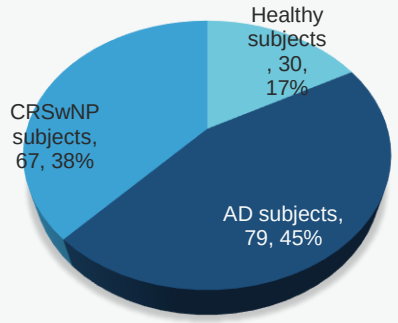
Phase II study in CRSwNP shows significant efficacy

- **The W16 data showed that the efficacy of all 611 doses (Q2W and Q4W) was clear and significantly better than that of placebo**
- **At the same dose, the response of 611 NPS tended to be higher than that of marketed drugs with the same target**

Dosage group	NPS[2]	NCS[2]
W16 changes from baseline		
611 GroupA[1] N=33	**-2.11**	**-1.11**
611 GroupB[1] N=34	**-1.61**	**-1.16**
W24 changes from baseline		
Dupilumab (Q2W)	-1.71~-1.89	-1.25~-1.34



- The safety data of 176 cases showed that the incidence of TEAE in 611 studies was lower than that of similar products at the same dose
- The incidence of common adverse events was lower than that of similar products



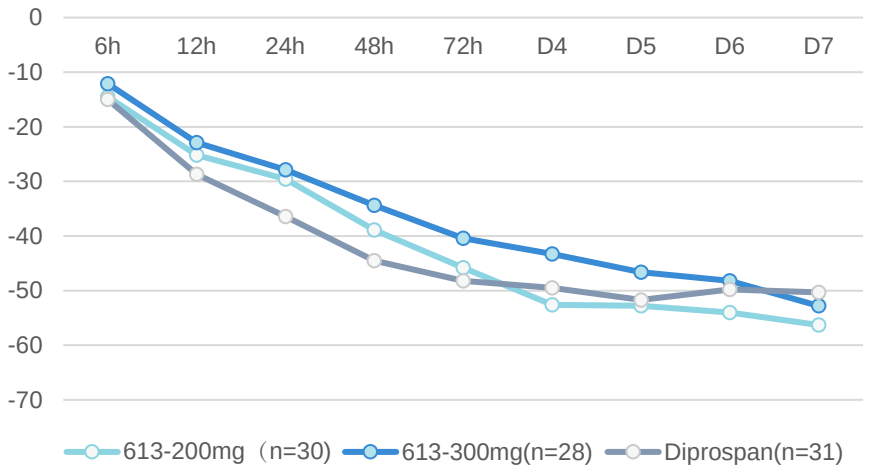
1. 611 Group A representative: 300mg Q2W, Group B representative: 450mg Q4W;
2. NPS: Nasal polyps score under bilateral nasal endoscopy; NCS: Mean weekly nasal congestion score

613 (Anti-IL-1β mAb) in Acute Gouty

Phase II study of 613 in acute gouty arthritis met primary endpoints

- Effect begins **6 Hrs** after administration
- 613 performed better in reducing pain with time

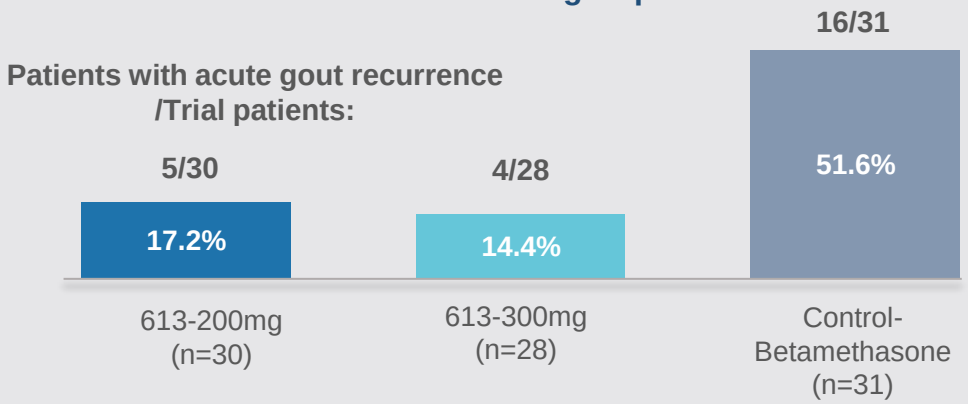
Mean changes of target joint VAS score from baseline



- Progress ranks **No.2** in China

2025
Est. NDA

Recurrence rate of acute gout in 12 weeks was significantly lower than control group



Company	Indication	Code
A	Acute gouty arthritis-Phase III CTD-ILD-Phase II Intermittent phase of gout arthritis Phase II	
3SBio	Acute gouty arthritis-Phase III Intermittent phase of gout arthritis Phase II	SSGJ-613
C	Prevention of chemotherapeutic diarrhea in colorectal cancer patients-Phase II; Gouty arthritis-Phase II; Prevention of chemotherapeutic toxic effects and relapse colorectal cancer-Phase II	

610 (Anti-IL-5 mAb) in Eosinophilic Asthma

Phase II data indicates 610 could significantly improve the pulmonary function of asthma patients, and shows a better trend than its similar products

- Progress ranks **NO.1** in China

Company	Code	Indication
3SBio	SSGJ-610	Phase II in eosinophilic asthma completed recruitment
B		Phase II in eosinophilic asthma completed recruitment; Phase II/III in EGPA recruiting; phase I in asthma in recruitment; phase I in bronchial asthma completed recruitment
C		Phase I in chronic rhinosinusitis with polyposis completed recruitment

- Phase II trial in severe eosinophilic asthma patients **met primary endpoints**

2027
Est. NDA

610 VS its similar products: improvement in lung function (FEV_1) in subjects with severe asthma

The change of FEV_1 from baseline

- Mep-study88 (n=194, W32)
- Ben-SIROCCO (n=398, W48)
- Res-study3082 (n=245, W16)
- Res-study3083 (n=232, W16)
- 610 100 mg (n=42, W16)
- 610 300 mg (n=43, W16)
- Placebo

Notes: Mep=Mepolizumab, Ben=Benralizumab, Res=Reslizumab

FEV_1= Forced expiratory volume in one second

626 2nd Generation BDCA2 mAb with BIC Potential

	SSGJ-626
Mechanism	Through inhibiting plasmacytoid dendritic cell (pDC), the secretion of IFNα was inhibited. Thus regulating the activity of a range of immune cells
BDCA2 affinity	**Strong** (KD: 2.48E-11)
Degree of humanization	**Very high** (There were no revertant mutations in either light or heavy chain)
Inhibit the secretion of IFNa and IgM	**Very strong** (IC_{50} 20 folds+ stronger thanLitifilimab)
In vivo efficacy in animals	**Strong**
Fc function optimize	Extend PK, strengthen Fc effect
R&D Situation	**Phase I initiated in China** **U.S. IND application got approved**

Anti-BDCA2 Ab: SLE Ph II shows significant efficacy

- Two hallmarks of SLE are IFNa and anti-nucleic acid autoantibody, so it has been proven that targeting IFNa and B cells (producing antibodies) can effectively control the disease
- Disclosed clinical data show that Litifilimab has shown promising efficacy in clinical phase II trials in SLE

Huge Unmet Medical Needs

- The global market for SLE drugs is expected to reach **US $16.9 billion in 2030**, of which biologics will reach **US $14.2 billi**on, while the Chinese market is expected to reach **US $4.3 billion**, of which biologics will reach **US $3.2 billion**
- **Benlysta**, anti-B Lymphocyte stimulator (BLyS) mAb, its annual global sales in 2023 reached **$1.63 billion**, with a growth rate of **18%** compared to 2022
- **Anifrolumab**, the anti-IFNaR mAb developed by AZ, which will be launched in July 2021, will achieve annual sales of **$280 million** in 2023 and is expected to become a blockbuster drug with annual sales of **more than $1 billion** in 2029
- **Litifilimab**, Biogen's anti-BDCA2 mAb met all primary and secondary endpoints in two CLE and SLE Phase II trials, and multiple Phase III trials are currently underway

627 A Potential BIC Long-Lasting anti-TL1A Humanized mAb

Program Highlights

- **Best-in-class, preclinical stage, anti-TL1A mAb;**
- Biological activities superior to PRA023 (Merck) or RVT3101 (Roche)
- High expression: **yield > 10g/L**; (indicating superior physicochemical properties and thermo)
- **Extended** PK for long - acting effects

Favorable Preclinical Results

- Much stronger cell based bioactivities compared to PRA023
- Excellent efficacy in DSS-induced **UC** model
- Superior efficacy in TNBS-induced **CD** model

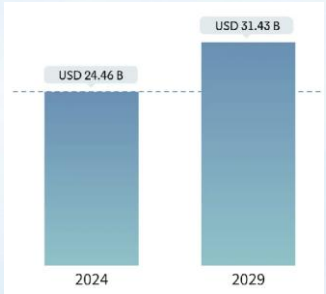
Current Status

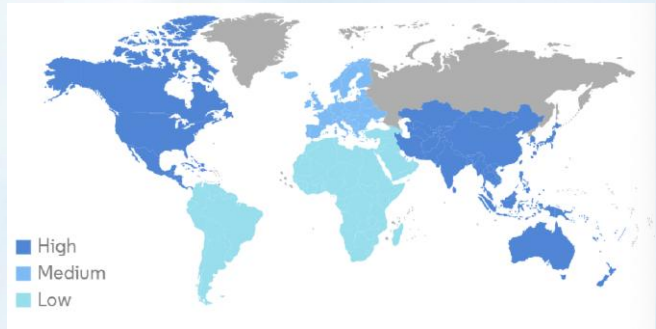
- **IND submitted and approved**

TL1A: A Novel Target for IBD Treatment

- **TNF-like ligand 1A,** a member of the tumor necrosis factor family
- **Potential Indication: Ulcerative Colitis, Crohn's disease**
- Abnormal expressed in autoimmune disease incl. Rheumatoid Arthritis, Psoriasis, and participate in inflammatory bowel disease.

Market Size





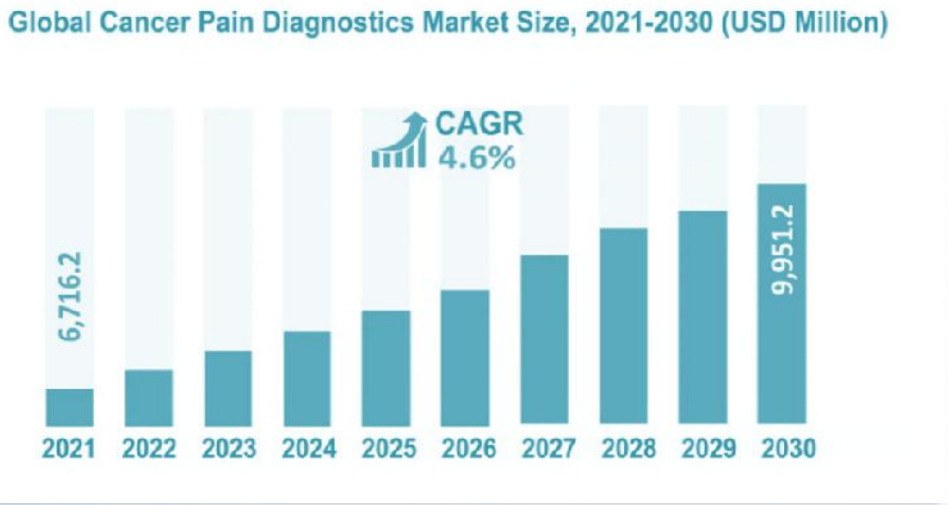
- Global IBD market size: **$24.46 billion** and is expected to grow to $31.43 billion in 2029
- Growth mainly driven by North America, which stands for 60% of global market

Unmet Medical Needs

- 1/3 of IBD patients don’t response to TNF inhibitors
- 40% patients that responded initially become refractory to TNF inhibitors over time

SSS40 (Anti-NGF mAb) in Cancer Pain

$10 billion cancer pain market globally millions of cancer pain patients in China



- There were 18.19 million cancer patients worldwide in 2018 and is expected to surpass 20 million by 2030. Cancer pain is present in **69%** of patients with cancer[1]. According to the astuteanalytica report, the global cancer pain market size is expected to grow from about **USD 6.7 billion to about USD 10 billion** during 2021-2030, at a CAGR of about **4.6%.**[2]

- According to the WHO International Agency for Research on Cancer (IARC) report, **4.57 million** new cancer patients were diagnosed in China in 2020. The incidence of pain in newly diagnosed cancer patients is about **25%,** while the incidence of pain in patients with advanced cancer can reach **60%-80%,** of which **1/3** of patients have severe pain.[3]

The progress of SSS40 cancer pain indications ranked among the top three in China

- SSS40 anti-NGF mab is currently undergoing **phase Ib/II** enrollment, and is expected to finish the enrollment within 2024

- No anti-NGF mAb has been approved for cancer pain-related indications worldwide[4], and SSS40 ranks among the **top 3** anti-NGF mAb developed for cancer pain indications in China

Company	Trial Drug	Phase	Situation
Pfizer Inc.;	Tanezumab	Phase III	Finished (refused by FDA for safety reason)
A	DS002	Phase Ib/IIa	Enrolling
3SBio	**SSS40**	**Phase I/II**	**Enrolling**
B	EP-9001A	Phase I/II	Enrolling
C	TNM009	Phase I	Ongoing

1. "Research progress on the pathogenesis and treatment of cancer pain"
2. https://www.astuteanalytica.com/zh-cn/industry-report/cancer-pain-diagnostics-market#:
3. 新药 | NGF：疼痛新药潜力靶点，或改善癌痛治疗现状，国内又一抗NGF单抗获批临床-世展网 (shifair.com)
4. Data source：Yiyaomofang database