三生制药
3SBIO INC.

2019 Annual Results Announcement

March 31, 2020

珍爱生命 / 关注生存 / 创造生活
CHERISH LIFE CARE FOR LIFE CREATE LIFE

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2019 Highlights

R&D

302H (Cipterbin)	Technical reviews, clinical trial site inspection and manufacturing site inspection have all been completed
301S (Pre-filled injection of Yisaipu)	NDA was accepted
Xenopax (Anti-CD20 antibody)	Obtained the GMP Certificate and launched to market
609A (Anti-PD1 antibody)	IND approval in NMPA and FDA
608 (Anti-IL17 antibody)	IND approval
Remitch (TRK-820)	IND approval
SSS17 (HIF-PHI)	IND approval

Collaboration

SAMSUNG BIOEPIS · tlc · verseau · numab Drug Innovators · GenSight BIOLOGICS · Sensorion · MPM Powering Breakthroughs in Life Sciences · Dana-Farber Cancer Institute

Sales

- **2019 NRDL Update**: **Fluticasone Propionate Cream (Shinuo)**; Severe plaque psoriasis in adult patients, one of the indications of **rhTNFR-Fc (Yisaipu)** was newly covered; chemotherapy-induced anemia in patients with non-hematological malignancies, one of the indications of **rhEPO (EPIAO and SEPO)** was newly covered; **Protamine Zinc Recombinant Human Insulin (Humulin NPH)** was reclassified from Class B to Class A
- **Byetta** succeeded in the negotiation with the National Healthcare Security Administration
- **TPIAO** sales exceeded RMB2 billion. Rank climbed from 49th in 2018 to 15th in 2019
- **Mandi** sales performed strongly, increasing 96.6% to RMB250 million

Finance

- Revenue increased by **16.0%** to RMB**5,318.1 million**
- Gross profit increased by **18.5%** to RMB**4,392.7 million**
- Research and development expenses increased by **45.2%** to RMB**526.6 million**
- Normalized net profit attributable to owners of the parent increased by **19.4%** to **RMB1,392.3 million**
- Net cash flows from operating activities increased by **64.1%** to RMB**1,887.4 million**
- Gearing ratio excluding bonds decreased to **4.8%** at 31 December 2019 from 11.2% at 31 December 2018.

**1 Source IQVIA*

Industry Policy Reform Deepens, and Innovation Continues to be Encouraged

- R&D and sale of innovative drugs will be encouraged continually
- Higher generic drug quality and more regulated competition

Continuing to speed up new drug application[1]

- In 2019, the total applications to CDE increased by 13% to 7,506. Biologic applications increased by 23% to 1,078.
- NDA applications increased by 25% to 177
- The average time for NDA approval decreased 50% to 427 days
- 100% of NDAs for domestic new drugs were included as priority applications

2019 NRDL update

- The new version of NRDL was published in August 2019 and 148 new products were included. Most of the newly-listed drugs were cancer, chronic disease and pediatric drugs
- Medical insurance negotiation finished in November 2019 and 97 drugs were included in the catalog. According to PharmCube, among 53 drugs launched in 2018, 20 were included in the catalog

Pharmaceutical Administration Law was put into force

- New version of Pharmaceutical Administration Law was passed on 26 August, 2019 and was put into force on 1 December 2019
- Accelerating applications, encouraging innovation and drug quality safety were emphasized in the form of law
- The exposure draft of *Provisions for Drug Registration* has published

Drug centralized bidding and purchasing deepened

- 25 drugs won the drug centralized bidding and purchasing in 2018. The average price decreased 52% and the highest drop was 96%
- A new round of centralized bidding was implemented and more drugs and more provinces were included in the bidding

*1 Source: PharmCube

Major Progress in R&D in 2019

Product	Target	Situation
302H (Inetetamab)	HER2	• Technical reviews, clinical trial site inspection as well as manufacturing site inspection have all been completed
301S (Pre-filled aqueous injection of Yisaipu)	TNFα	• NDA was accepted
Xenopax	CD25	• Obtained the GMP Certificate and launched to market
304R (Jiantuoxi)	CD20	• Completed a Phase I comparing head-to-head with Rituxan®; Phase III trial site inspection
TPIAO	MplR	• Phase III in pediatric ITP is ongoing • Phase I in surgery patients with hepatic dysfunction at the risk of thrombocytopenia has been completed
SSS06	Long Acting EPO	• Completed multiple Phase I trials and initiated patient enrollment in Phase II
RD001	PEG-EPO	• Completed Phase I and is planning for Phase II
SSS07	TNFα	• Completed Phase I and is planning for Phase II
602	EGFR	• Completed 2 Phase I trials and is planning advanced trials in patients with colorectal cancer
601A	VEGF	• Patient enrollment in AMD Ib and DME I/Ib
SSS11	Uric acid	• Patient enrollment in Phase I
608	IL-17A	• Patient enrollment in Phase I
609A	PD1	• IND approval by NMPA, planning patient enrollment in Phase I • IND approval by FDA, patient enrollment is progressing smoothly
TRK-820 (Remitch)	κ-opioid	• IND approval and planning patient enrollment
SSS17	HIF-PHI	• IND approval and planning patient enrollment in Phase I
VTX-0811	PSGL-1	• Obtained the license

Key Collaboration in R&D

verseau
NUMAB Drug Innovators
tlc
SAMSUNG BIOEPIS
GenSight BIOLOGICS
Sensorion
MPM Powering Breakthroughs in Life Sciences
Dana-Farber Cancer Institute

Robust and Innovative Product Pipeline

32 product candidates, including 22 National New Drugs

Therapeutic Area	Product Candidate	Pre-Clinical	Clinical Trial Application	Phase I	Phase II	Phase III	New Drug Registration	Production Permit
Nephrology	SSS06 Long-acting EPO							
	RD001 Long-acting EPO							
	SSS17 HIF inhibitor							
	SSS12				BE 2020			
	SSS13				BE 2020			
	TRK-820/Remitch							
Oncology	302H Anti-HER2 antibody							
	304R Anti-CD20 antibody							
	602 Anti-EGFR antibody							
	609A anti-PD1 antibody							
	SB8 Anti-VEGF antibody							
	612 Anti-HER2 antibody							
	705 BsAb1							
	704 BsAb2							
	706 BsAb3							
	707 BsAb4							
	61x Anti-PSGL-1 antibody							
Auto-Immune Diseases and Other Areas	301S TNFR-Fc fusion protein							
	SSS07 Anti-TNFα antibody							
	SSS11 Pegsiticase							
	601A Anti-VEGF antibody							
	TPIAO – New indications							
	AP506							
	SSS20				BE 2020			
	SSS32				BE 2020			
	608 Anti-IL17 antibody							
	610 Anti-IL5 antibody							
	611 Anti-IL4R antibody							
	613 Anti-IL1β antibody							
Metabolic Diseases	Bydureon DCP & AI							
	SSS26				BE 2020			
Dermatological Diseases	MN709							

Antibody Other Biologics Small Molecule Drug

Biologics Pipeline in Nephrology, Auto-immune and Other Diseases

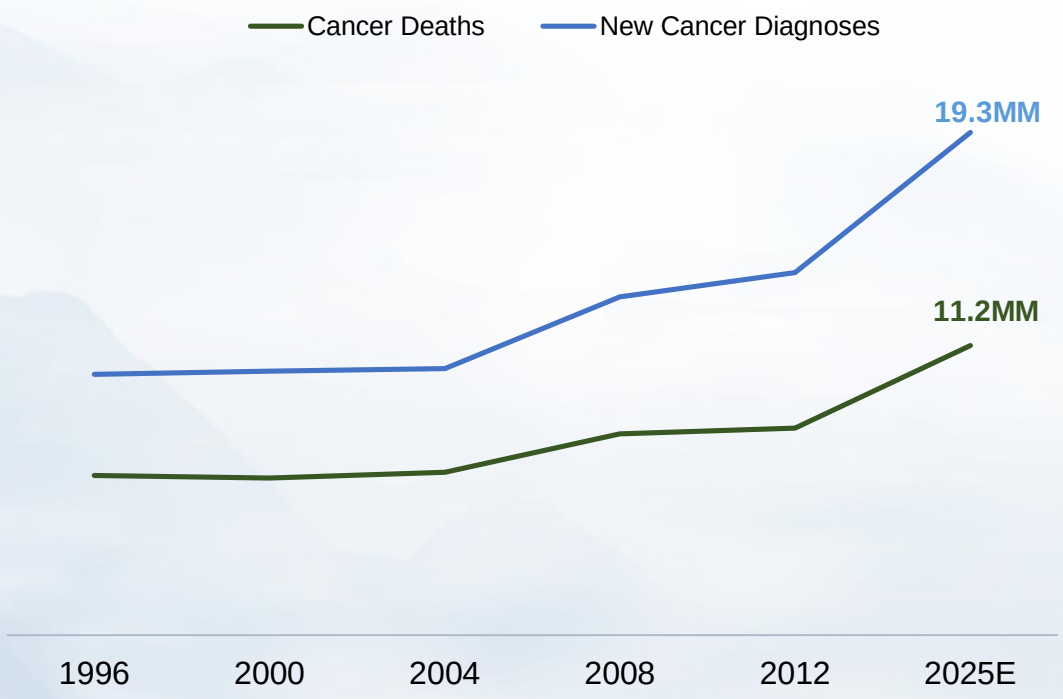
Product	Target	Indication	Pre-Clinical	CTA	Phase I	Phase II	Phase III	BLA/NDA	Production Permit
301S	TNFα	Rheumatoid arthritis, plaque psoriasis and ankylosing spondylitis							
SSS07	TNFα	Rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis							
608	IL17A	Psoriasis, psoriatic arthritis, ankylosing spondylitis							
610	IL5	Asthma, COPD							
611	IL4R	Atopic dermatitis, Asthma							
613	IL1β	Multiple auto-immune diseases							
SBxx	XX	Bone diseases							
601A	VEGF	Ophthalmologic diseases (AMD/DME, etc.)							
SSS11	Uric Acid	Hyperuricemia, refractory gout							
SSS06	EopR	Anemia associated with CKD							
RD01	EopR	Anemia associated with CKD							

Biologics Pipeline in Oncology

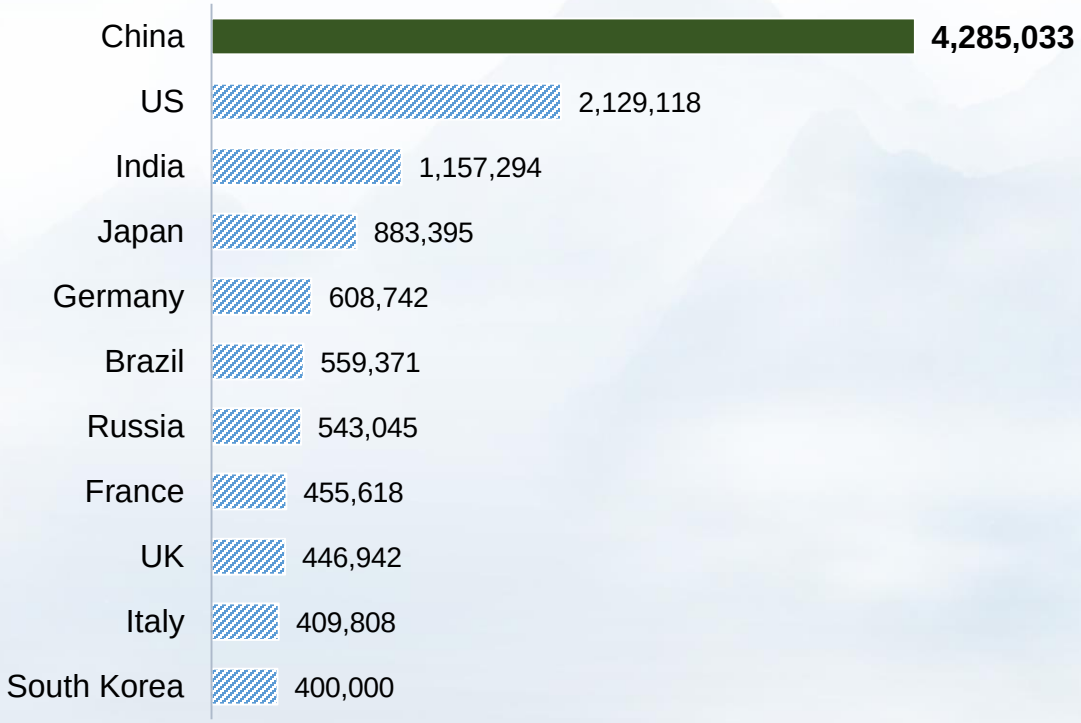
Product	Target	Indication	Pre-Clinical	CTA	Phase I	Phase II	Phase III	BLA/NDA	Production Permit
302H	HER2	Breast Cancer							
304R	CD20	NHL							
602	EGFR	Colorectal cancer (CRC)							
609A	PD1	NSCLC, Gastric and Liver cancer							
SB8 (615)	VEGF	Multiple Cancer							
612	HER2	Breast and Gastric Cancer							
705	BsAb1	Multiple Cancer							
704	BsAb2	Multiple Cancer							
706	BsAb3	Multiple Cancer							
707	BsAb4	Multiple Cancer							
61x	PSGL-1	Multiple Cancer							

Growing Cancer Patient Population Globally and in China

Rising Mortality and Diagnosis Rates



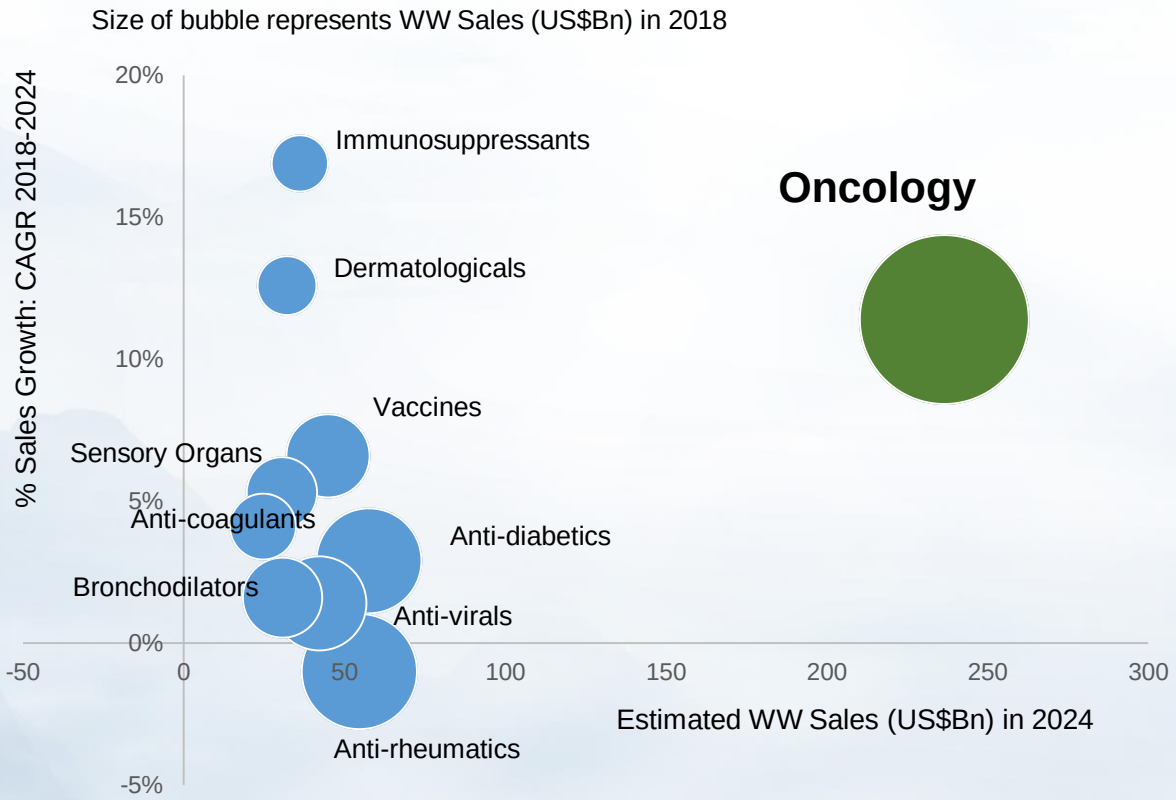
Estimated Number of New Cases in 2018



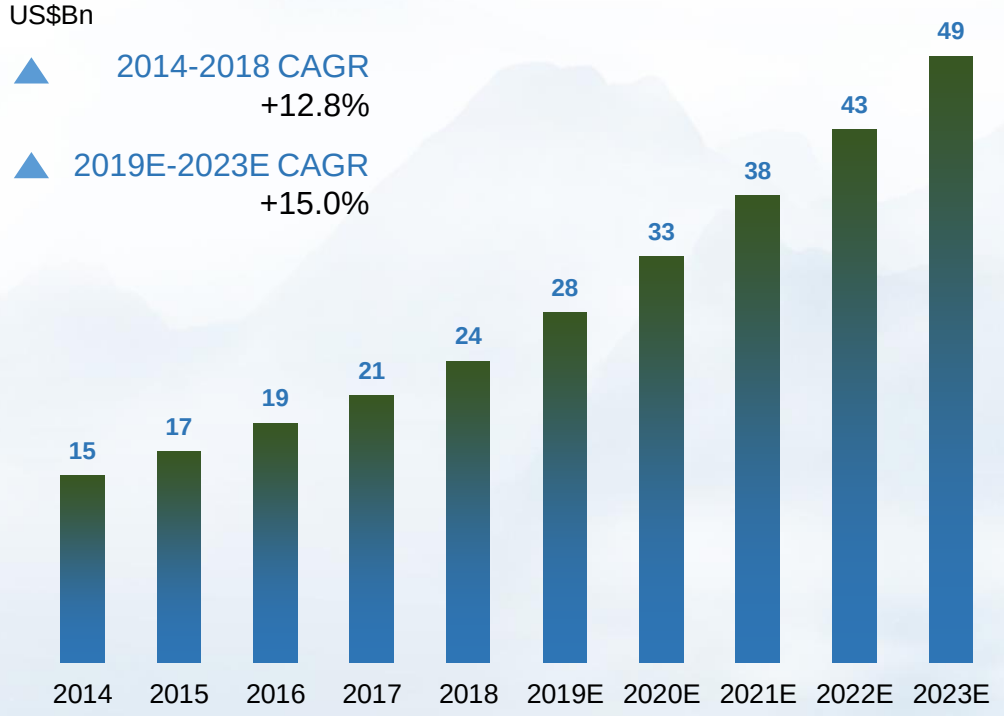
*Source：WHO, GLOBOCAN

Well Positioned to Meet the Needs of Patients in Oncology

Key Challenge for Healthcare Systems Globally



China Oncology Market Forecast (2014-2023E)



**Source: EvaluatePharma, Frost & Sullivan*

Top 10 Oncology Drugs by Generic Name Globally and in China

Top 10 Oncology Drugs Globally in 2019

Generic Name	Market Size (US$Bn)
Pembrolizumab	11.3
Lenalidomide	9.4
Nivolumab	8.6
Ibrutinib	8.1
Bevacizumab	7.2
Rituximab	6.6
Trastuzumab	6.2
Denosumab	5.0
Palbociclib	5.0
Enzalutamide	4.3

Top 10 Oncology Drugs in China in 2019

Generic Name	Sales from Sample Hospitals (RMB¥Bn)
Paclitaxel	3.1
Trastuzumab	1.9
Pemetrexed	1.6
Bevacizumab	1.6
Rituximab	1.4
Docetaxel	1.3
Tegafur,Gimeracil and Oteracil	1.3
Oxaliplatin	1.2
Capecitabine	1.0
Osimertinib	1.0

**Source: GlobalData, PDB*

Extensive Coverage of Key Targets and Next-Generation Biologic Therapies

4 R&D Centers and over 380 Experienced Scientists


Shenyang-Biologics/Chemicals


Shanghai - Biologics


Shenzhen - Biologics


Hangzhou - Chemicals

Covered Key Oncology Targets

- HER2
- CD20
- EGFR
- PD1
- VEGF
- PSGL-1

Next Generation Biologic Therapies

- MCM [1]
- Programmed CAR-T
- Multi-specific Antibody
- Bi-specific Antibody

*1: Macrophage Checkpoint Modulators, MCM

Integrated International Strategic Collaborations (con'd)

Mature Products and Platforms

AstraZeneca	Exclusive license for the commercialization of GLP-1 products in China
Lilly	Exclusive license for the distribution and promotion of insulin products
tlc	Exclusive partnership to commercialize liposomal products utilizing NanoX™ in Mainland China
TORAY	Exclusive right to develop and commercialize Remitch in China
SAMSUNG BIOEPIS	Collaboration for clinical development and commercialization of multiple biosimilars in China

Innovative Products and Platforms

REFUGE biotech	Exclusive license to develop and commercialize programmed therapeutic cells in Greater China
verseau	Collaboration for clinical development and commercialization of MCM[1] in China
GenSight BIOLOGICS	Priority for potential licensing or development of two ophthalmic-related disease products
NUMAB Drug Innovators	Partnership focused on the development and commercialization of novel bi- and multi-specific antibodies in the field of immuno-oncology
Sensorion	Potential licensing priorities for four inner ear disease related research products
MPM Powering Breakthroughs in Life Sciences / Dana-Farber Cancer Institute	Investment to research and develop early stage cancer drugs

**1: Macrophage Checkpoint Modulators, MCM*

2020-2022 R&D Outlook

Production Permit (2020-2021)

- 302H (H1 2020)
- 301S (H1 2021)

Initiation of Registration Clinical Trials (2020-2021)

- SB8
- TPIAO [1]
- 304R [2]
- TRK-820
- MN709
- 601A [3]

Phase II - III (2020-2022)

- SSS06
- RD01
- 602
- 608
- 609A
- 601A [4]

Phase I-II (2020-2022)

- 610
- 611
- 612
- 613
- 705
- SBxx

New IND / Phase I (2020-2022)

- IND of 10-15 new mAbs and bispecific antibodies (China and US)

Generics BE Studies (2020-2021)

Autoimmune and Inflammation		Nephology	
• SSS20	• SSS32	• SSS12	• SSS34
• AP506	• TK805	• SSS13	• SSS38

BLA/NDA (2021-2022)

- TPIAO [1] (2021)
- TRK-820 (2021)
- MN709 (2021)
- SSS12 (2021)
- SSS13 (2021)
- SSS20 (2021)
- SSS32 (2021)
- TK805 (2021)
- SB8 (2022)
- SSS34 (2022)
- SSS38 (2022)
- AP506 (2022)
- 601A (2023)
- 304R (2023)

**Note*
1: Pediatric ITP Indication
2: Cancer (NHL) and autoimmune indications
3: Age-related macular degeneration(AMD)
4: Diabetic macular edema (DME)

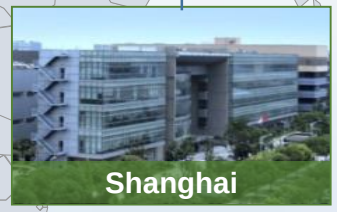
Comprehensive Manufacturing Capabilities Adhere to Int'l Quality Standards

- All 10 production lines for different dosage forms are certified by GMP in 2010
- QA personnel represent 20%+ of all manufacturing employees at the site
- General manager has 10+ years' experience of pharmaceutical R&D, manufacturing and quality control

- Plant certified by 11 countries, including Ukraine, Brazil and Mexico
- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 20+ years' experience of pharmaceutical manufacturing and quality control, taking leading roles in MNCs and engaging in drafting national pharmaceutical guidelines and standards

- Serves world-renowned companies such as Mylan and Sanofi
- QA personnel represent nearly 40% of all manufacturing employees at the site
- EU GMP certified production lines in Italy

- All existing and new production lines were granted GMP certification in 2013 and in 2016
- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 10 years' experience of pharmaceutical R&D, manufacturing and quality control



- Plant certified by countries including Colombia, Brazil, Mexico and Ukraine
- Passed EU QP audit
- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 30+ years' experience of pharmaceutical R&D, manufacturing and quality control

Integrated Cell Expression Systems and Sufficient Production Capacity

	Expression System			Present Production Capacity
	Prokaryotic Cell	Eukaryotic Cell	Chemical	
 Shenyang	★	★		Annual capacity of 50 million injections, in accordance with EU standard
 Shanghai		★		Commercialized manufacturing base with more than 38,000 liters, ranked number one among biopharmaceutical companies in China
 Shenzhen		★	★	Annual capacity of 40 million injections
 Hangzhou			★	Annual capacity of 500 million tablets, 25 million capsules, 62 million injections, 10 million tubes of creams and 5.6 million bottles of tincture and spray
 Italy	EU GMP certified small volume injection (both aqueous and powder) production lines in Italy serve world-renowned companies such as Mylan and Sanofi			

Core Products Maintained Dominant Market Share

	2015	2016	2017	2018	2019	Market Share (%)[1]
TPIAO	605	765	975	1,670	**2,323**	73.2
Yisaipu [2]	842	925	1,013	1,111	**1,144**	60.9
EPIAO/SEPO	727	773	855	897	**749**	41.6
Mandi	24	65	94	127	**250**	66.3

** Note：*

1 The Market shares of TPIAO, Yisaipu and EPO franchise comes from IQVIA 2019MAT; the one of Mandi from CPA

2 Yisaipu was consolidated since 1 April 2016

Indications and Products Newly Included in 2019 NRDL

Fluticasone Propionate Cream (Shinuo)	A product with broad applications in the treatment of a variety of dermatological disorders was newly included in the 2019 NRDL
rhTNFR-Fc (Yisaipu)	The indication for severe plaque psoriasis in adult patients was newly covered
rhEPO (EPIAO/SEPO)	Chemotherapy-induced anemia in patients with non-hematological malignancies was included
Protamine Zinc Recombinant Human Insulin (Humulin NPH)	Reclassified from Class B to Class A
Exenatide (Byetta)	Succeeded in the negotiation with National Healthcare Security Administration

Strong Sales Capability and Country-Wide Sales Network

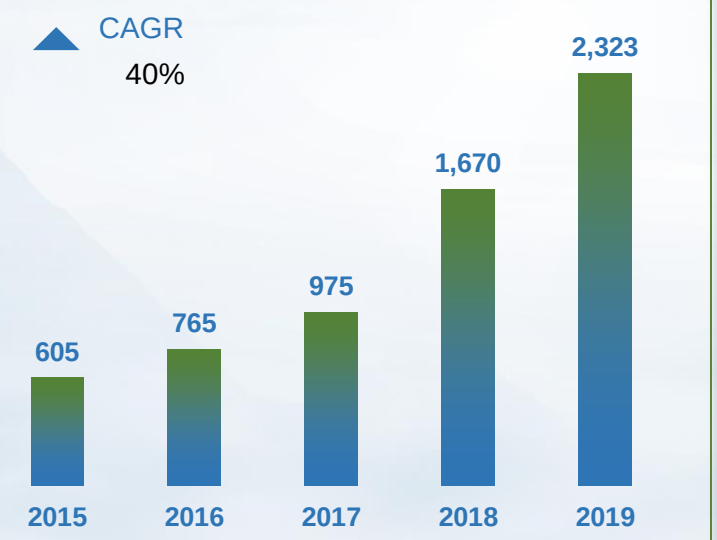
- Proven marketing team with nearly **30** years of market validation
- Reached **all** provinces, autonomous regions and special municipalities in China
- **3,372** sales and marketing employees, **660** distributors and **2,079** third-party promoters
- Covered over **2,000** Grade III hospitals
- Covered over **14,000** Grade II or lower ranking hospitals and medical institutions

Market-Leading Products with Significant Growth Potential

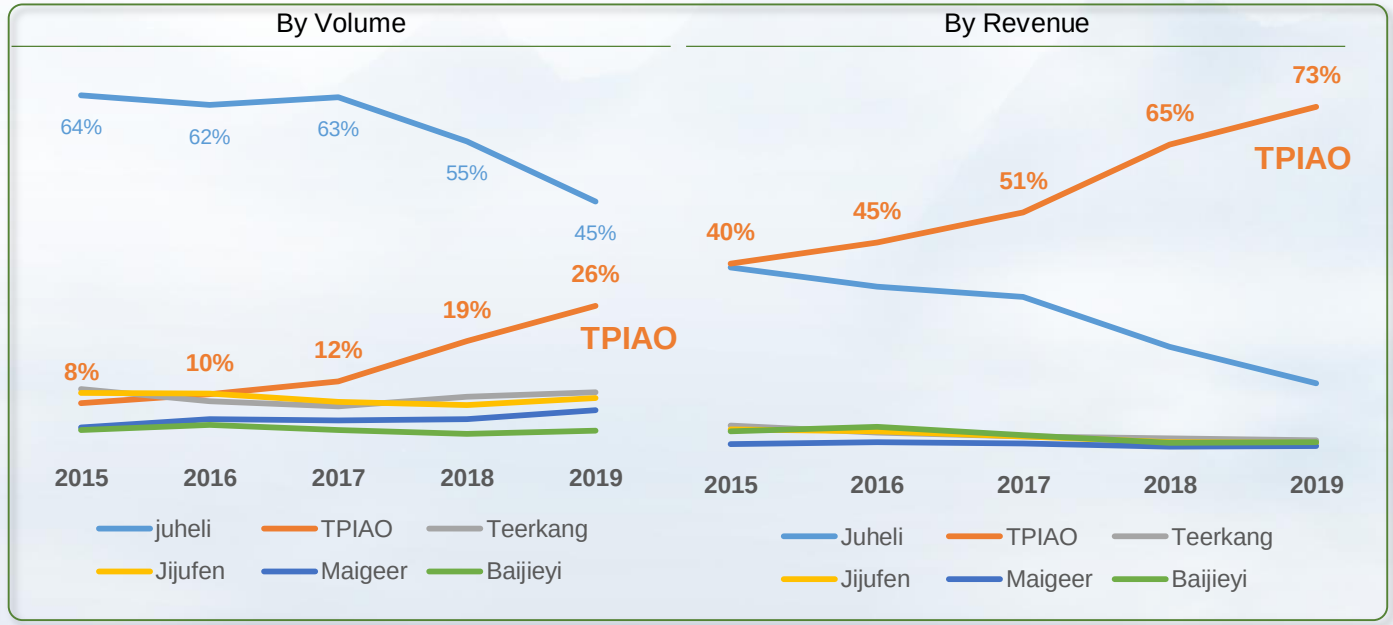
TPIAO

- First-to-market and the only commercialized rhTPO product in the world
- Market is still under-penetrated with significant growth potential
- Extended new indications for the surgery patients with hepatic dysfunction at the risk of thrombocytopenia and pediatric ITP
- Developing small molecule product with ITP indication

The sales increased by 40% annually



Market is still under-penetrated



Source: IQVIA

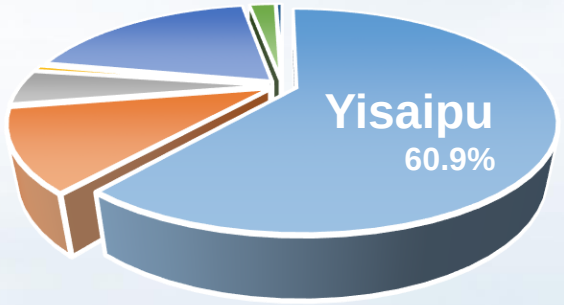
Market-Leading Products with Significant Growth Potential (con'd)

Yisaipu

- First-to-market TNFa inhibitor product
- The indication of the treatment for adult patients with severe plaque psoriasis was newly covered by 2019 NRDL
- Penetration rate may be in the range of approximately 5% to 9%
- Submitted the application for manufacturing approval for Yisaipu pre-filled aqueous injection solution and the application was accepted for review by the NMPA
- If approved, it may likely be the only TNFa inhibitor product in pre-filled format among Chinese peers
- Approved by 15 countries including India, Thailand, Philippines, Mexico

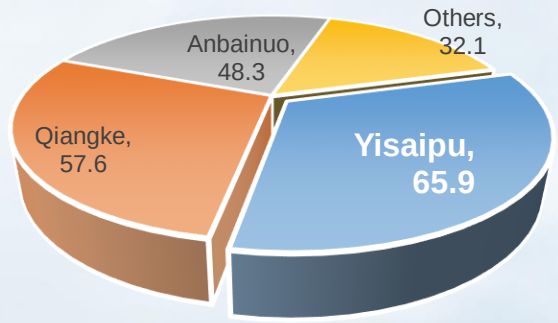
Anti-TNFα Leadership in China

Market share of Anti-TNFα in 2019 [1]



Contributes most to overall category growth

The increment of Anti-TNFα in 2019 [1]
(RMB mm)



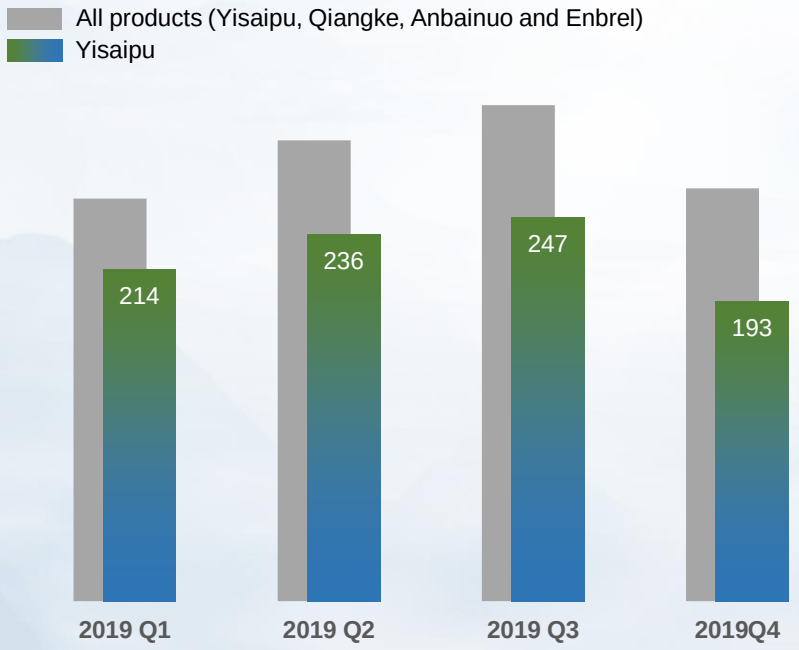
Source: IQVIA

Market-Leading Products with Significant Growth Potential (con'd)

Yisaipu

Price is under pressure, but growth potential is still significant

Sales of TNFα and Yisaipu[1] fusion protein



Comparison of Etanercept and Adalimumab

	Etanercept	Adalimumab
TB infection rate [2]	0.57 per 100 person-years （44/7690 person-years）	1.62 per 100 person-years （86/5317 person-years） P<0.0001
Serious hepatic events that led to hospitalization[2]	0.39 per 100 person-years	0.75 per 100 person-years p<0.0035
Incidence of anti-drug antibodies[3]	0 % (200 cases)	31.2% (199 cases)
Dosing Frequency	Twice a week x 25mg	Once every two weeks x 40mg
Dosage Form	Powder injection	Aqueous injection
Launch Year in US	2004 (Enbrel)	2002 (Humira)
Launch Year in China	2005 (Yisaipu)	2010 (Humira)

1. *Source: IQVIA*
2. *Chiu YM., et al., A real world risk analysis of biological treatment (adalimumab and etanercept) in a country with a high prevalence of tuberculosis and chronic liver disease: a nationwide population-based study. Scand J Rheumatol., 46: 236-240. 2017.*
3. *2. Moots RJ, et al., The impact of anti-drug antibodies on drug concentration and clinical outcomes in rheumatoid arthritis patients treated with adalimumab, etanercept, or infliximab: Results from a multinational, read-world clinical practice, non-interventional study. PLoS One, 12 (4): e0175207， DOI:10.1371.*

Market-Leading Products with Significant Growth Potential (con'd)

EPIAO and SEPO

- **Still the only rhEPO product approved by the NMPA for all three indications**
- **Consistently been the dominant market leader in Mainland China rhEPO market since 2002**

Reasons for negative growth in 2019

- The tendering prices in many provinces decreased by at least 10% in 2018
- Specification change

2020 and After

1. The tendering price was stable in 2019
2. Continue to advance the dual-brand collaboration strategy and maintain stable pricing
3. Chemotherapy-induced anemia in patients with non-hematological malignancies, one of the indications of rhEPO (EPIAO and SEPO), was newly included in the NRDL
4. Increased dialysis penetration rates among stages IV and V CKD patients, which the Group believes is substantially lower in Mainland China compared with other countries
5. The increase in the applications of EPIAO in reducing allogeneic blood transfusion and in CIA oncology indication in Mainland China, which the Group believes is at a very early stage of growth

Will continue to maintain stable growth in the future

Market-Leading Products with Significant Growth Potential (con’d)

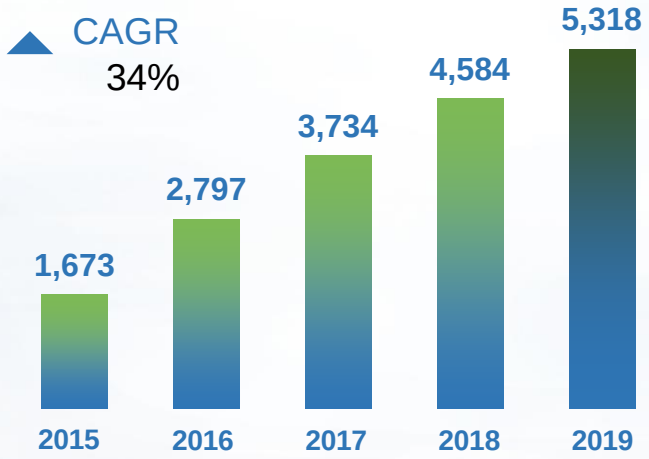
Mandi

- Used in the treatment of androgenetic alopecia
- The only topical drug recommended by the guideline for diagnosis and treatment of androgenetic alopecia
- Sales grew strongly in the past three years, with sales expected to reach RMB 1 billion in the future

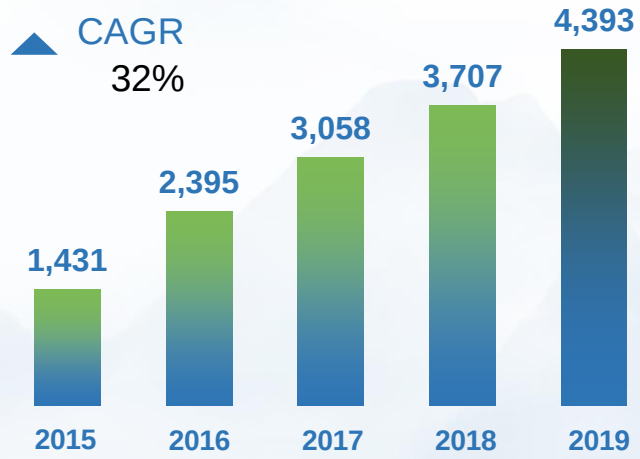
Consistent Strong Growth

Unit: RMB mm

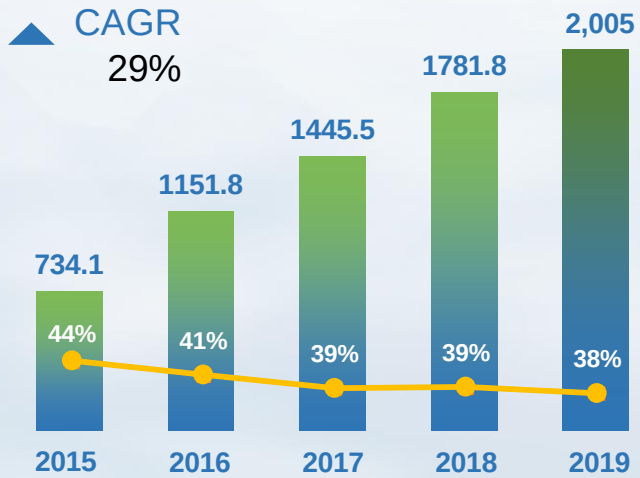
Revenue



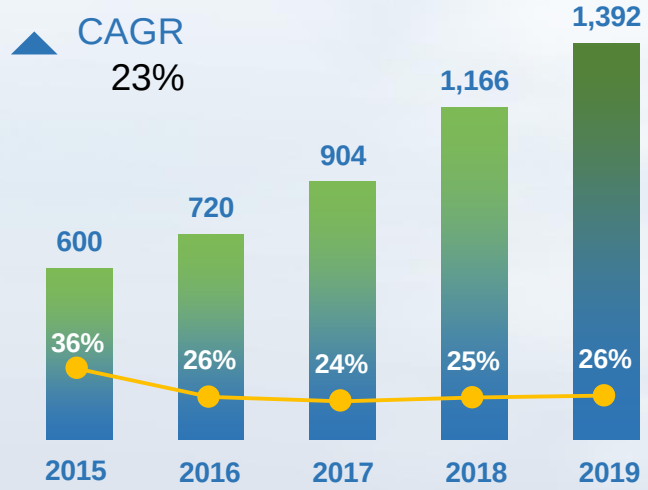
Gross Profit



Normalized EBITDA



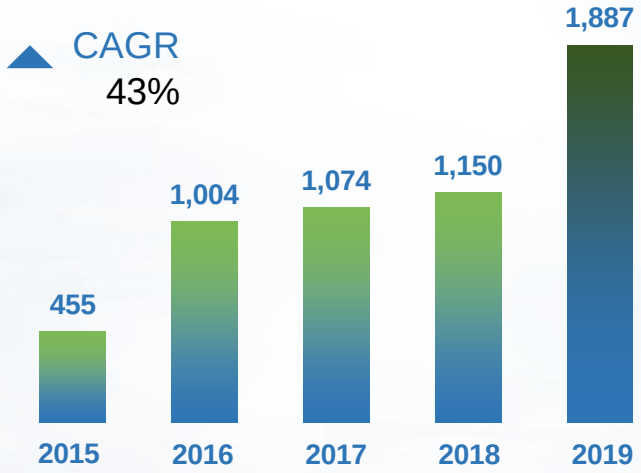
Normalized Net Profit Attributable to Owners of the Parent



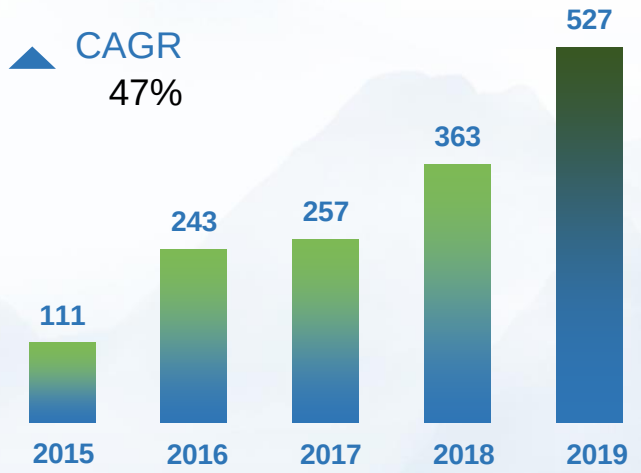
Strong Management and Operational Capabilities

Unit: RMB mm

Net Cash flows from operating activities



R&D Expense



Sales and Marketing Expense

Financial Expense

Impacts from COVID-19

Impacts	Risks and Challenge for Company	Responses
• Work resumption was delayed • Transportation was affected • Flow of goods and people were restricted • The number of patients going to hospital reduced	• Minimal impact on manufacturing and R&D • Impacted sales and marketing of some products which will take time to recover	• Close follow-up and careful analysis of the risks posed by the outbreak • Reduce expenses, focus on priorities, and maintain a steady and sufficient cash flow

Outlook

Operation	✤ Operating indicators and revenue of key products will continue to grow steadily
New Products	✤ Launch of new products (Cipterbin, Pre-filled injection of Yisaipu)
R&D	✤ Increase the investment in R&D, continue to accelerate clinical trials and IND of pipeline products
Collaboration	✤ Continue to seek business development and in-licensing opportunities
Manufacturing	✤ Continue to expand production capacity

Company Strategy

Vision	China-based Global Leader in Biologics
Position	Innovative Biologics & Core Product Portfolio
Focused Therapeutics	Oncology; Autoimmune; Nephrology; Metabolic; Dermatology
Platforms	R&D; Manufacturing; Sales and Marketing; Collaboration

THANKS

珍 爱 生 命 • 关 注 生 存 • 创 造 生 活

CHERISH LIFE CARE FOR LIFE CREATE LIFE