



# 2020 Interim Results Announcement

July 18, 2020



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

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# 2020 Interim Results Highlights



## Sales

- **Cipterbin (Inetetamab)** was successfully launched to sale in June 2020. In the first **12 days**, first prescription was issued in **5 cities** domestically.
- **TPIAO** sales reached **CNY 1.3 billion** in 2020H1, **YoY increased 15.2%**, Rank climbed from 24<sup>th</sup> in 2019H1 to **14<sup>th</sup>**, **production patent was honored in Liaoning Province as the second prize**.
- **NRDL updates: Fluticasone Propionate Cream (Shinuo)**, Severe plaque psoriasis in adult patients, one of the **rhTNFR-Fc's (Yisaipu)** indications 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 Category B to A; **Byetta** succeeded in the negotiation with the National Healthcare Security Administration
- **Yisaipu** won **the 1st Shanghai Intellectual Property Innovation Award**
- **Subsidiary Sunshine Guojian** was awarded as **Grade A Quality Credit Unit of Shanghai Pharmaceutical Manufacturers** in 2019

## R&D

- **Cipterbin (Inetetamab)** was firstly approved by NMPA for treatment of HER2-positive metastatic breast cancer combining with chemotherapy in China in June 2020
- **611 (Anti-IL-4Ra antibody)** IND approval by FDA and reviewing by NMPA
- **610 (Anti-IL-5 antibody)** IND approval by NMPA to conduct Phase I trials and patient enrollment was initiated.
- **609A (Anti-PD1 antibody)** completed patient enrollment in U.S. Phase I trial and had initiated patient enrollment in China
- **608 (Anti-IL-17A antibody)** completed patient enrollment in Phase I trial and plan for Phase II trials
- **601A (Anti-VEGF antibody)** completed patient enrollment in Phase I trial to treat AMD and patient enrollment for Phase I trial to treat DEM is ongoing.
- **TRK-820 (Remitch)** completed Part I study of bridging Phase III trial of nalfurafine hydrochloride
- **SSS17 (HIF117)** had initiated patient enrollment in Phase I trial
- **MN709 (Minoxidil Foam)** had initiated patient enrollment in Phase III trial
- **SSS06 (Long-acting EPO)** patient enrollment in Phase II trial is ongoing smoothly

## Finance

- Revenue increased by **2.0%** to **RMB2,695.2 million**
- Gross profit increased by **1.5%** to **RMB2,217.1 million**
- Net profit attributable to owners of the parent increased by **118.6%** to **RMB702.5 million**
- Net cash flows from operating activities increased by **1.2%** to **RMB708 million**
- Gearing ratio excluding bonds decreased to **4.1%** from 13.7%



# Industry Policy Reformation was Fully Rolled Out and Continues to Encourage Innovation



- Encourage the development and sales of innovative drugs
- Improve the generic quality and standardize market competition

## Continues to Accelerate New Drug Application

- In 2019, 6,199 registration applications requiring technical review were accepted, an increase of **11.2%** compared with 2018. Among them, 1,005 registration applications are biological products, an increase of **23.3%** compared with 2018
- Accepted 127 applications for the registration of innovative drugs for category 1 biological products (100 varieties), an increase of **3.3%** compared with 2018
- In 2019, CDE approved 16 urgently needed drugs for the treatment of rare diseases, an increase of **60%** over 2018

## Implementation of Provisions for Drug Registration

- On 30 March 2020, the State Administration for Market Regulation announced *the new Provision for Drug Registration*, which was officially implemented on 1 July 2020
- *The Provision* redefines the classification of chemical drugs, traditional Chinese medicines, and biological products, and clarified the concept of innovative drugs to be more scientific and standardized
- Clarified the four accelerated channels of **breakthrough treatment drugs, conditional approval, priority review and approval, and special approval**, and defined the requirements for the scope, procedures, and supporting policies of each channel

## Biological Products was Included in the Centralized Procurement

- The National Healthcare Security Administration held a symposium on the centralized procurement of **biological products (including insulin)** and Chinese traditional drugs on July 15-16, 2020. Experts opinions and suggestions were provided, procurement policies in related fields would be improved, and procurement methods were promoted.
- In earlier 2020, Wuhan took the lead in piloting the centralized procurement of insulin varieties. Insulin is also considered to contain sufficient "conditions" to enter the national procurement. **Biosimilars** are generally believed to be the most likely to enter the field of centralized procurement.

## Deepen Centralized Procurement

- On 21 July 2020, Shanghai Sunshine Pharmaceutical Purchasing Network announced the Joint Purchasing Office's Notice on Carrying out the Collection of Certain Drug-Related Basic Information. In order to optimize the work process, all drug-related companies are required to performance smoothly in the collection of basic drug information.
- On 29 July 2020, Shanghai Sunshine Pharmaceutical Purchasing Network released the National Drug Centralized Procurement Documents to launch the 3rd batch of national centralized procurement. Among them, 56 generic drugs and 86 specifications are involved, which is a significant increment compared with the 2nd batch of national procurement



# Strong Sales Capability and Country-Wide Sales Network



## Sales Network Construction



Reached **all** provinces, autonomous regions and special municipalities in China



Covered over **2,500** top tier core (Grade III) hospitals



Covered over **14,000** Non-core (Grade II or lower ranking) hospitals and medical institutions

## Sales Team Construction



Robust marketing team with nearly **30** years proven record



**3,378** sales and marketing employees, **668** distributors and **2,124** third-party promoters



# 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



Hangzhou



Shenyang

- 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



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



Shenzhen



Shanghai






- 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





# 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			



# Integrated International Strategic Collaborations



## Mature Products and Platforms



Exclusive license for the commercialization of GLP-1 products in China



Exclusive license for the distribution and promotion of insulin products



Exclusive partnership to commercialize liposomal products utilizing NanoX™ in Mainland China



Exclusive right to develop and commercialize Remitch in China



Collaboration for clinical development and commercialization of multiple biosimilars in China



3SBio will obtain milestones and sales royalty and provide the bulk production

## Innovative Products and Platforms



Exclusive license to develop and commercialize programmed therapeutic cells in Greater China



Collaboration for clinical development and commercialization of MCM<sup>1</sup> in China



Priority for potential licensing or development of two ophthalmic-related disease products



Partnership focused on the development and commercialization of novel bi- and multi-specific antibodies in the field of immuno-oncology



Potential licensing priorities for four inner ear disease related research products



Investment to research and develop early stage cancer drugs





# Core Products Revenue is Generally Stable Under the Impact of COVID-19 Pandemic



Unit: RMB mm

	2015	2016	2017	2018	2019	1H 2019	1H2020	Ratio(%)	Market Share (%) <sup>1</sup>
<b>TPIAO</b>	605	765	975	1,670	2,323	1,194	<b>1,375</b>	<b>51.0</b>	<b>72.8</b>
<b>Yisaipu</b> <sup>2</sup>	842	925	1,013	1,111	1,144	501	<b>331</b>	<b>12.3</b>	<b>54.5</b> <sup>3</sup>
<b>EPIAO/SEPO</b>	727	773	855	897	749	452	<b>462</b>	<b>17.1</b>	<b>41.2</b> <sup>4</sup>
<b>Mandi</b>	24	65	94	127	250	108	<b>129</b>	<b>4.8</b>	-
<b>Others</b>	317	408	797	779	852	388	<b>387</b>	<b>14.8</b>	-

\*注:

1 IQVIA 2020H1MAT Data

2 Yisaipu was consolidated since 1 April 2016

3 Yisaipu indicated the TNFa market share

4 EPIAO/SEPO indicated the rhEPO market share



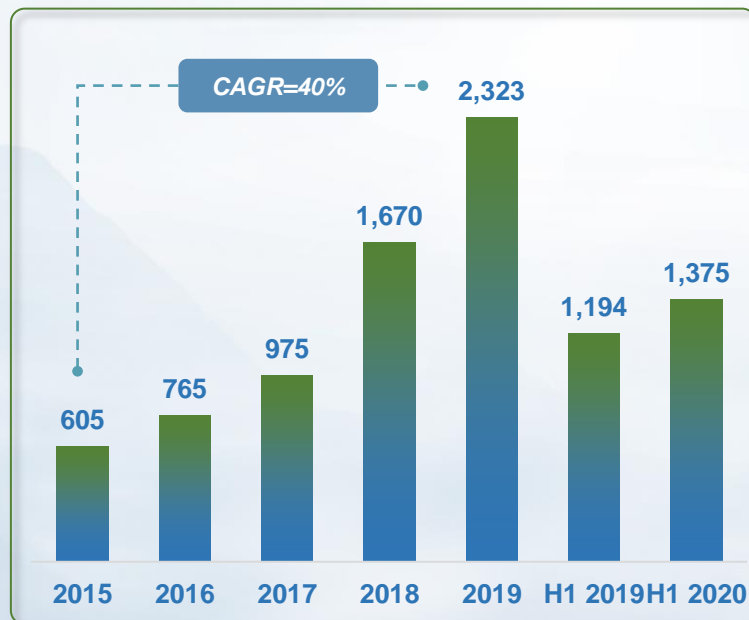
# Market-Leading Products with Significant Growth Potential

## TPIAO

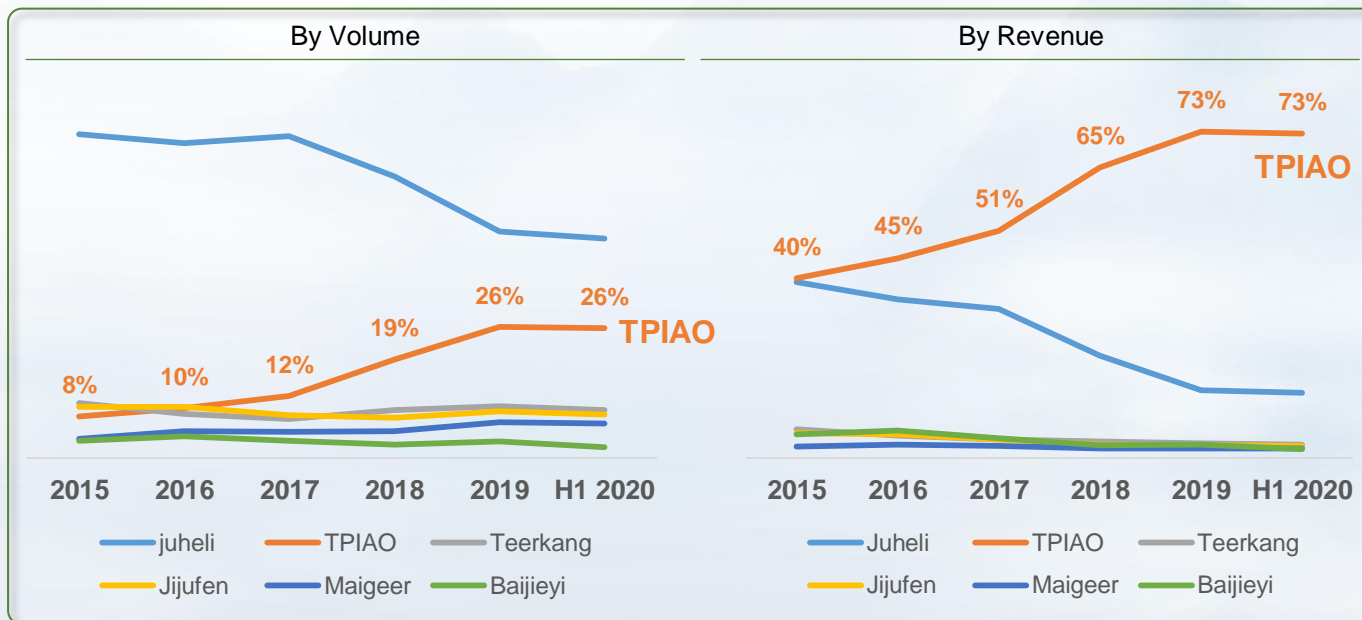


- First-to-market and the only commercialized rhTPO product in the world
- Market is still under-penetrated with significant growth potential
- Phase I in surgery patients with hepatic dysfunction at the risk of thrombocytopenia has been completed
- Phase III in pediatric ITP is ongoing
- One of the treatments for lymphoma CIT <sup>1</sup>
- The first-choice recommendation for boosting platelet production <sup>2</sup>
- Recommended to treat myelosuppressive thrombocytopenia <sup>3</sup>
- Deploy small molecule products to improve synergy in the field of indications

### The sales increased by 40% annually



### Market is still under-penetrated <sup>4</sup>



1. Recommended by Chinese Expert Consensus on Prevention and Treatment of CIT in Malignant Lymphoma
2. Recommended by The Expert Consensus for Diagnosis and Treatment of Thrombocytopenia in China
3. Recommended by The Expert Consensus for Diagnosis and Treatment of Thrombocytopenia in Adult Critical Illness in China
4. Source: IQVIA



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

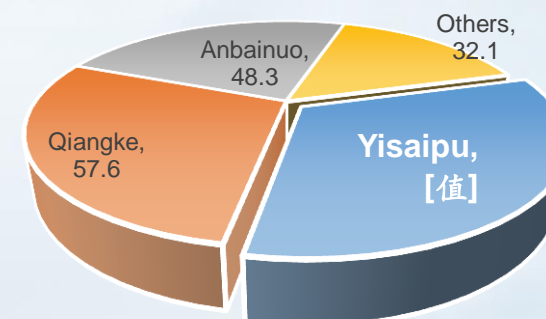
## Yisaipu



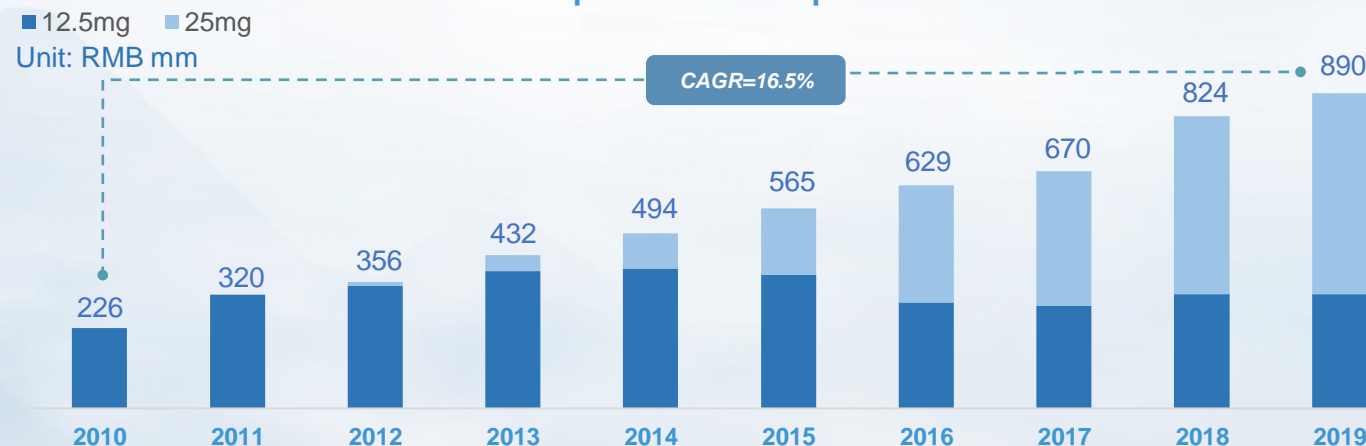
- **First-to-market** TNF $\alpha$  inhibitor product
- The indication of the treatment for adult patients with **severe plaque psoriasis** was newly covered by 2019 NRDL
- Penetration rate may be in the range of approximately **5% to 9%**
- Submitted the application for manufacturing approval for Yisaipu **pre-filled aqueous injection solution** and the application was accepted for review by the NMPA
- Approved by **15 countries** including Colombia, Thailand, Philippines, Pakistan

### Contributes most to overall category growth

The increment of Anti-TNF $\alpha$  in 2019 <sup>1</sup>  
(RMB mm)



### Yisaipu Sales in Hospital Market <sup>1</sup>





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

Yisaipu

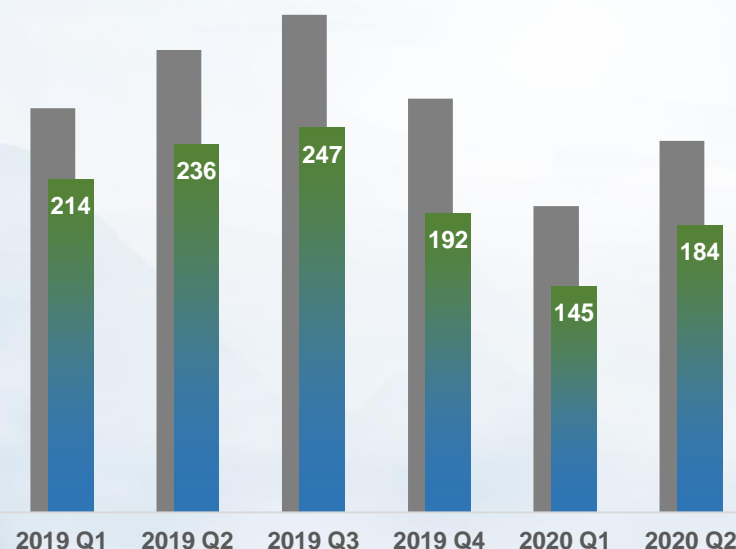


Price is under pressure, but growth potential is still significant

## Comparison of Etanercept and Adalimumab

### Sales of TNF $\alpha$ and Yisaipu<sup>1</sup> fusion protein in 2019&2020H1

■ All products (Yisaipu, Qiangke, Anbainuo and Enbrel)  
■ Yisaipu



	Etanercept	Adalimumab
TB infection rate <sup>2</sup>	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 <sup>2</sup>	0.39 per 100 person-years	0.75 per 100 person-years p<0.0035
Incidence of anti-drug antibodies <sup>3</sup>	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	1998 (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. 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

In H1 2020

- EPIAO and SEPO sales increased to RMB462.1 million, as compared to approximately RMB451.7 million, representing an increase of 2.3%.

In the future

1. The tendering price was stable in 2019, influencing factors were removed
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
6. Phase II clinical trial of the second generation, long-acting products has started



**Will continue to maintain stable growth in the future**



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

Mandi



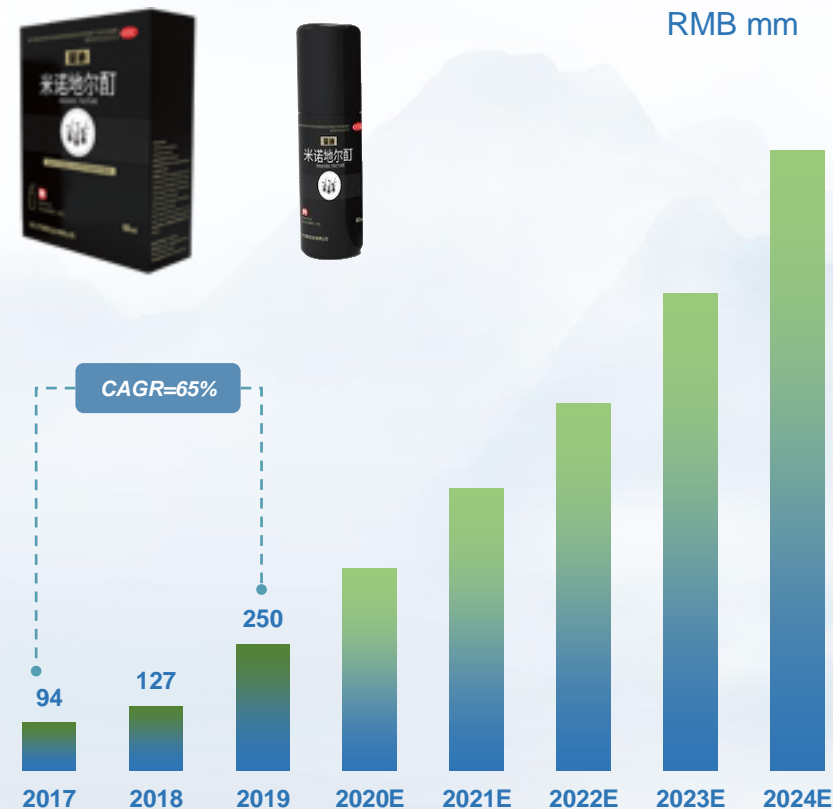
- Used in the treatment of androgenetic alopecia
- The only topical drug recommended by the guideline for diagnosis and treatment of androgenetic alopecia
- Sales grew strongly in the past three years, with sales expected to reach RMB 1 billion in the future

## Sales in the eCommerce channels have become emerging growth points

■ eCommerce  
■ Hospital  
■ OTC



RMB mm





# New Product Launch



## Cipterbin (Inetetamab)



- Approved by NMPA for treatment of HER2-positive on June 19, 2020
- Self-developed, China first innovated with engineered Fc region and optimized production process
- Stronger ADCC effect as proved to be capable of delaying the disease progression and bringing survival benefits to HER2-positive metastatic breast cancer patients

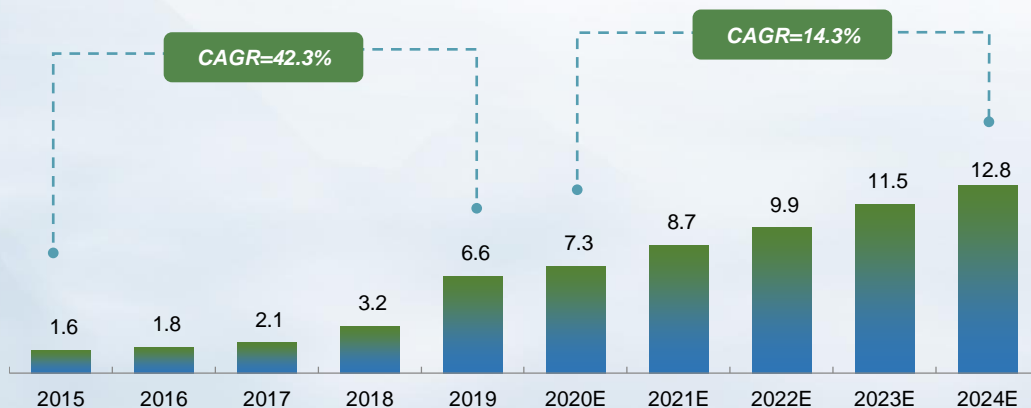
## Xenopax (Anti-CD25 antibody)



- Only approved Anti-CD25 antibody in domestic China
- Launched to sale in the market since October 2019
- Antibody humanization is greater than 90% with lower immunogenicity and higher safety result
- Used to prevent acute rejection caused by kidney transplantation, which could be used in combination with conventional immunosuppressive programs

### Anti-HER2 Antibody Estimated Market Scale in China

Unit: RMB BN



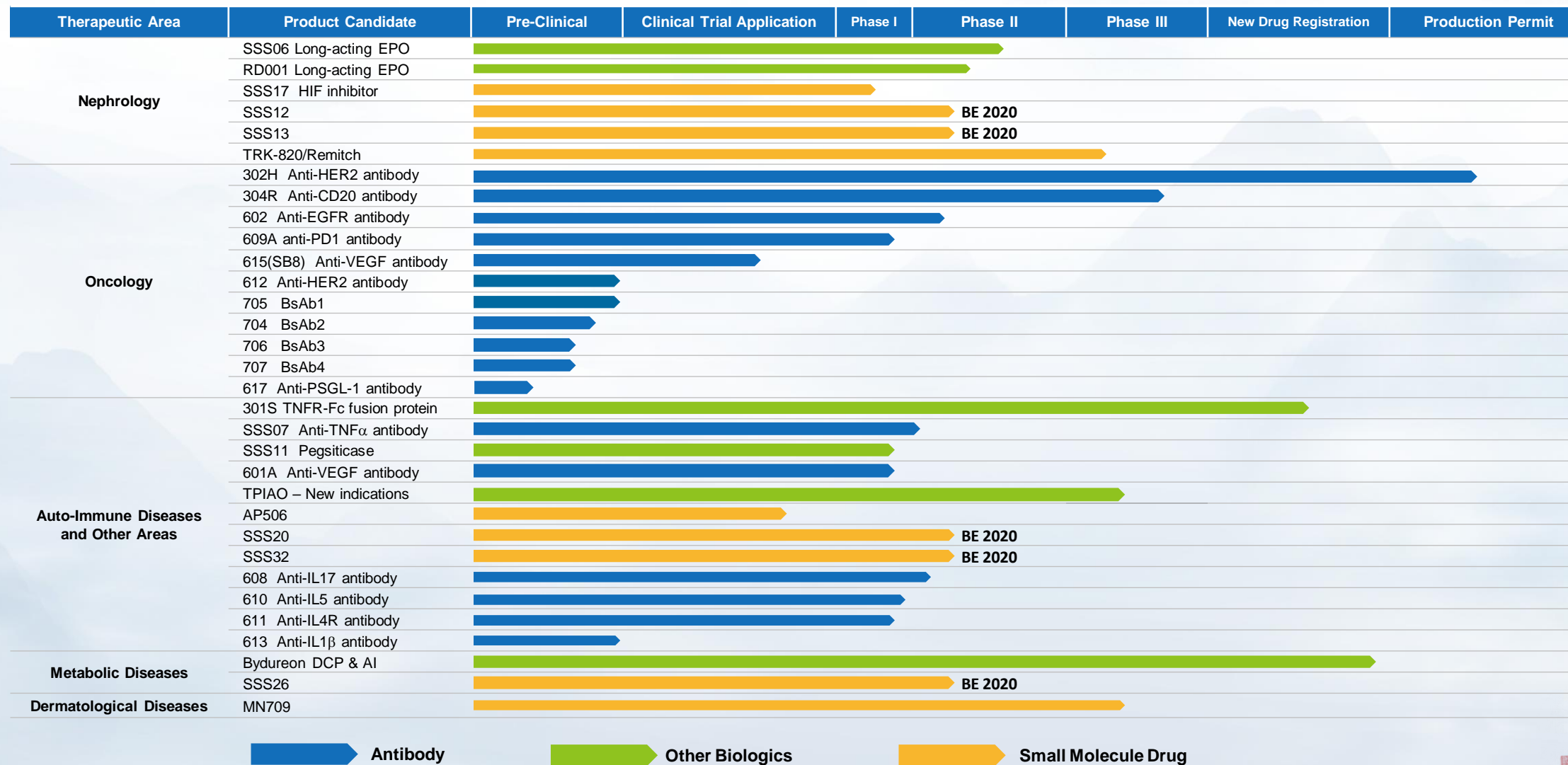
### Anti-CD25 Antibody Maintains Estimated 23% Growth in China within 5 Years

Unit: RMB mm



# Robust and Innovative Product Pipeline

## 32 product candidates, including 22 National New Drugs



# Major Progress in R&D in 2019-2020H1

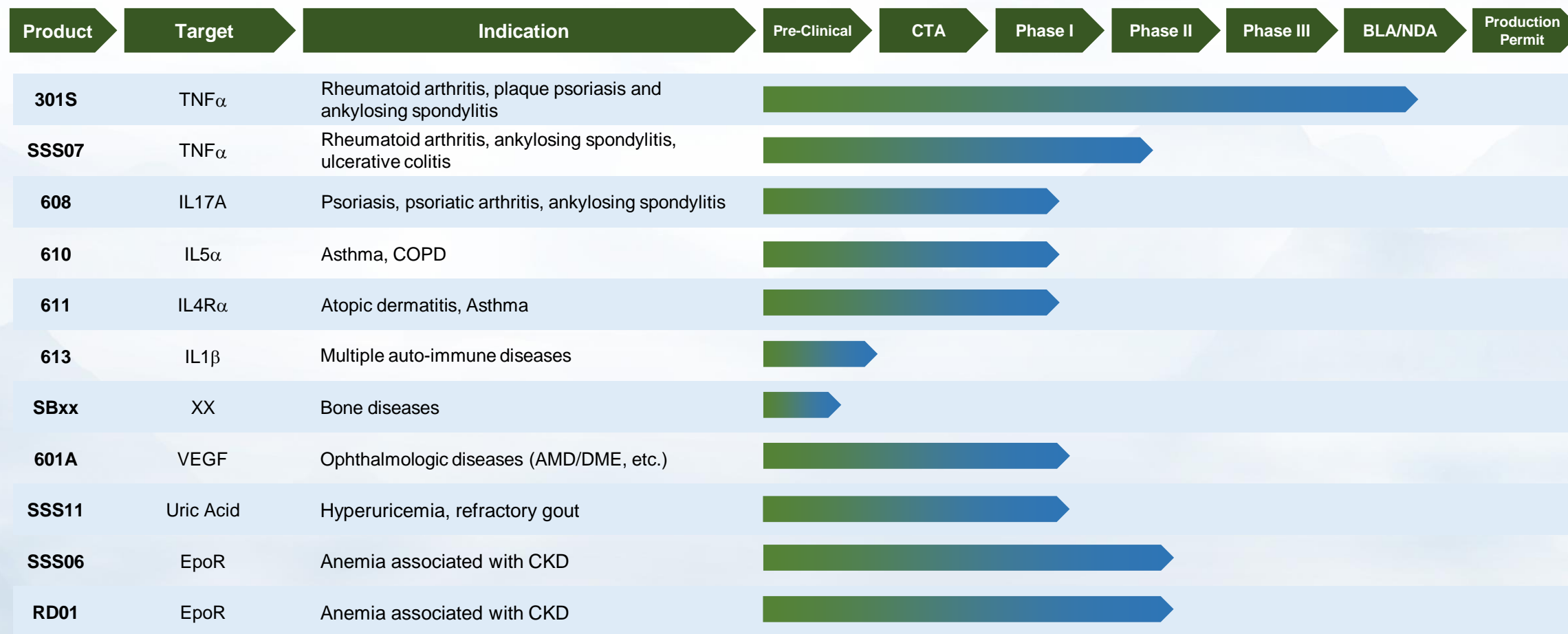


Area	Code	Target	Name	Indication	Situation
Nephrology	SSS06	Long Acting EPO	Second-generation rhEPO	Renal Anemia	• Completed multiple Phase I trials and initiated patient enrollment in Phase II
	RD001	PEG-EPO	Long-acting rhEPO	Renal Anemia	• Completed Phase I trials and initiated patient enrollment in Phase II
	SSS17	HIF-PHI	Small molecule inhibitor to HIF-PH	Renal Anemia	• Initiated patient enrollment in Phase I
	TRK-820	k-opioid	REMITCH	Pruritus in hemodialysis patients	• completed the part I study of a bridging phase III trial
Oncology	302H	HER2	Inetetamab	HER2+ Metastatic Breast Cancer	• Successfully launched to sale in June 19, 2020
	304R	CD20	Anti-CD20 monoclonal antibody	NHL	• Completed a Phase I comparing head-to-head with Rituxan®; Phase III trial site inspection
	602	EGFR	Anti-EGFR monoclonal antibody	Metastatic Colorectal Cancer	• Completed 2 Phase I trials and is planning advanced trials in patients with colorectal cancer
	609A	PD-1	Anti-PD-1 monoclonal antibody	Solid Tumor	• IND approval by NMPA, initiated patient enrollment in Phase I • IND approval by FDA, completed patient enrollment in Phase I
	617	PSGL-1	Anti-PSGL-1 monoclonal antibody	Solid Tumor	• Obtained the license in Great China
Auto-Immune Diseases	301S	TNF $\alpha$	Recombinant human type II tumor necrosis factor receptor - antibody fusion protein	Rheumatoid arthritis, plaque psoriasis and ankylosing spondylitis	• NDA was accepted for review by the NMPA.
	608	IL-17A	Anti-IL-17A monoclonal antibody	Plaque psoriasis	• Completed healthy volunteer subject enrollment of a phase I trial and is planning for phase II trials
	TPIAO	MpIR	Recombinant human thrombopoietin	Idiopathic Thrombocytopenic Purpura	• Phase III in pediatric ITP is ongoing • Phase I in surgery patients with hepatic dysfunction at the risk of thrombocytopenia has been completed
	SSS07	TNF $\alpha$	Anti-TNF $\alpha$ monoclonal antibody	Rheumatoid arthritis and other auto-immune diseases	• Completed Phase I and is planning for Phase II
Ophthalmology	601A	VEGF	Anti-VEGF monoclonal antibody	AMD, DME	• Completed Patient enrollment in AMD Ib and the enrollment in DME I/Ib is ongoing smoothly
Other Areas	610	IL-5	Anti-IL-5 monoclonal antibody	Severe eosinophilic asthma	• Patient enrollment has been initiated
	611	IL-4R $\alpha$	Anti-IL-4R $\alpha$ monoclonal antibody	Atopic dermatitis, Asthma	• Approved by USFDA for clinical trial and the application for its domestic clinical trials has also been accepted by the NMPA
	SSS11	Uric acid	Pegsiticase	Refractory gout patients with high uric acid level	• Patient enrollment in Phase I
	MN709	-	Minoxidil foam	Hair loss and alopecia areata	• Phase III was initiated

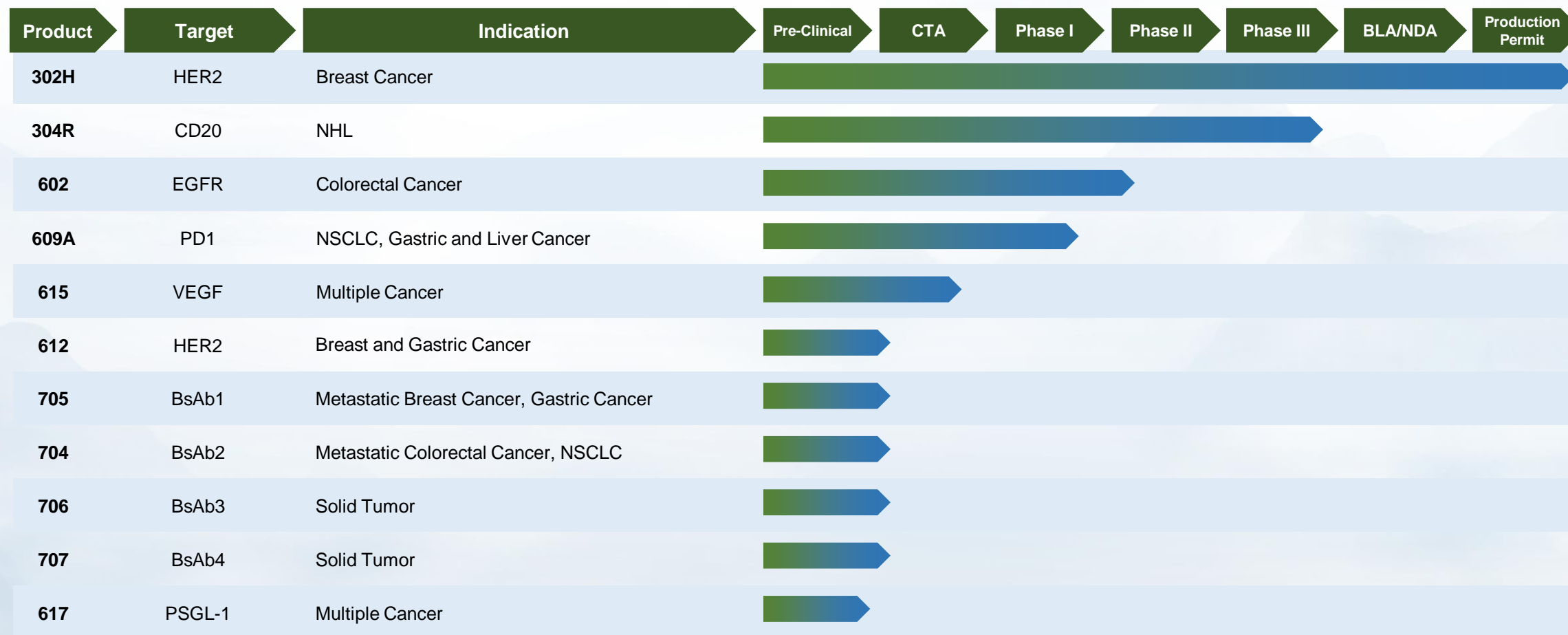




# Biologics Pipeline in Nephrology, Auto-immune and Other Diseases



# Biologics Pipeline in Oncology



# 2020-2022 R&D Outlook



<b>Production Permit (2020-2021)</b>	<ul style="list-style-type: none"> <li>• 302H (H1 2020) <sup>7</sup></li> <li>• 301S (H1 2021)</li> </ul>	<b>New IND / Phase I (2020-2022)</b>	<ul style="list-style-type: none"> <li>• IND of 10-15 new mAbs and bispecific antibodies (China and US)</li> </ul>
<b>Initiation of Registration Clinical Trials (2020-2021)</b>	<ul style="list-style-type: none"> <li>• 615</li> <li>• TPIAO <sup>1</sup></li> <li>• 304R <sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>• TRK-820</li> <li>• 601A <sup>3</sup></li> <li>• MN709</li> </ul>	<div> <div><b>Autoimmune and Inflammation</b></div> <ul style="list-style-type: none"> <li>• SSS20</li> <li>• AP506</li> </ul> </div> <div> <div><b>Nephrology</b></div> <ul style="list-style-type: none"> <li>• SSS32</li> <li>• TK805</li> </ul> </div>
<b>Phase II - III (2020-2022)</b>	<ul style="list-style-type: none"> <li>• SSS06</li> <li>• RD01</li> <li>• 602</li> </ul>	<ul style="list-style-type: none"> <li>• 608</li> <li>• 609A</li> <li>• 601A <sup>4</sup></li> </ul>	
<b>Phase I-II (2020-2022)</b>	<ul style="list-style-type: none"> <li>• 610 <sup>5</sup></li> <li>• 611 <sup>6</sup></li> <li>• 612</li> </ul>	<ul style="list-style-type: none"> <li>• 613</li> <li>• 705</li> <li>• SBxx</li> </ul>	<div> <div><b>BLA/NDA (2021-2022)</b></div> </div> <div> <ul style="list-style-type: none"> <li>• TPIAO <sup>1</sup> (2021)</li> <li>• TRK-820 (2021)</li> <li>• MN709 (2021)</li> <li>• SSS12 (2021)</li> <li>• SSS13 (2021)</li> <li>• SSS20 (2021)</li> <li>• SSS32 (2021)</li> </ul> </div> <div> <ul style="list-style-type: none"> <li>• TK805 (2021)</li> <li>• 615 (2022)</li> <li>• SSS34 (2022)</li> <li>• SSS38 (2022)</li> <li>• AP506 (2022)</li> <li>• 601A (2023)</li> <li>• 304R (2023)</li> </ul> </div>

**\*Note**

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

5. Completed the first patient enrollment on June 23, 2020
6. Approved by USFDA for clinical trial on June 28, 2020. In addition, the application for its domestic clinical trials has also recently been accepted by the NMPA
7. Successfully launched to sale on June 19, 2020





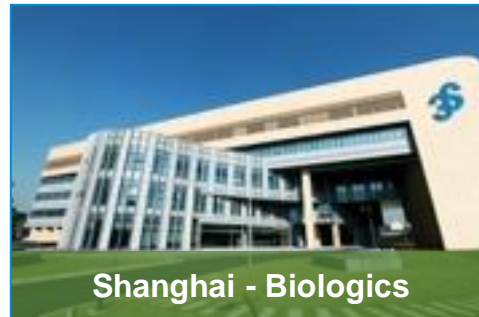
# Extensive Coverage of Key Targets and Next-Generation Biologic Therapies



## 4 R&D Centers and over 420 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 <sup>1</sup>

Programmed CAR-T

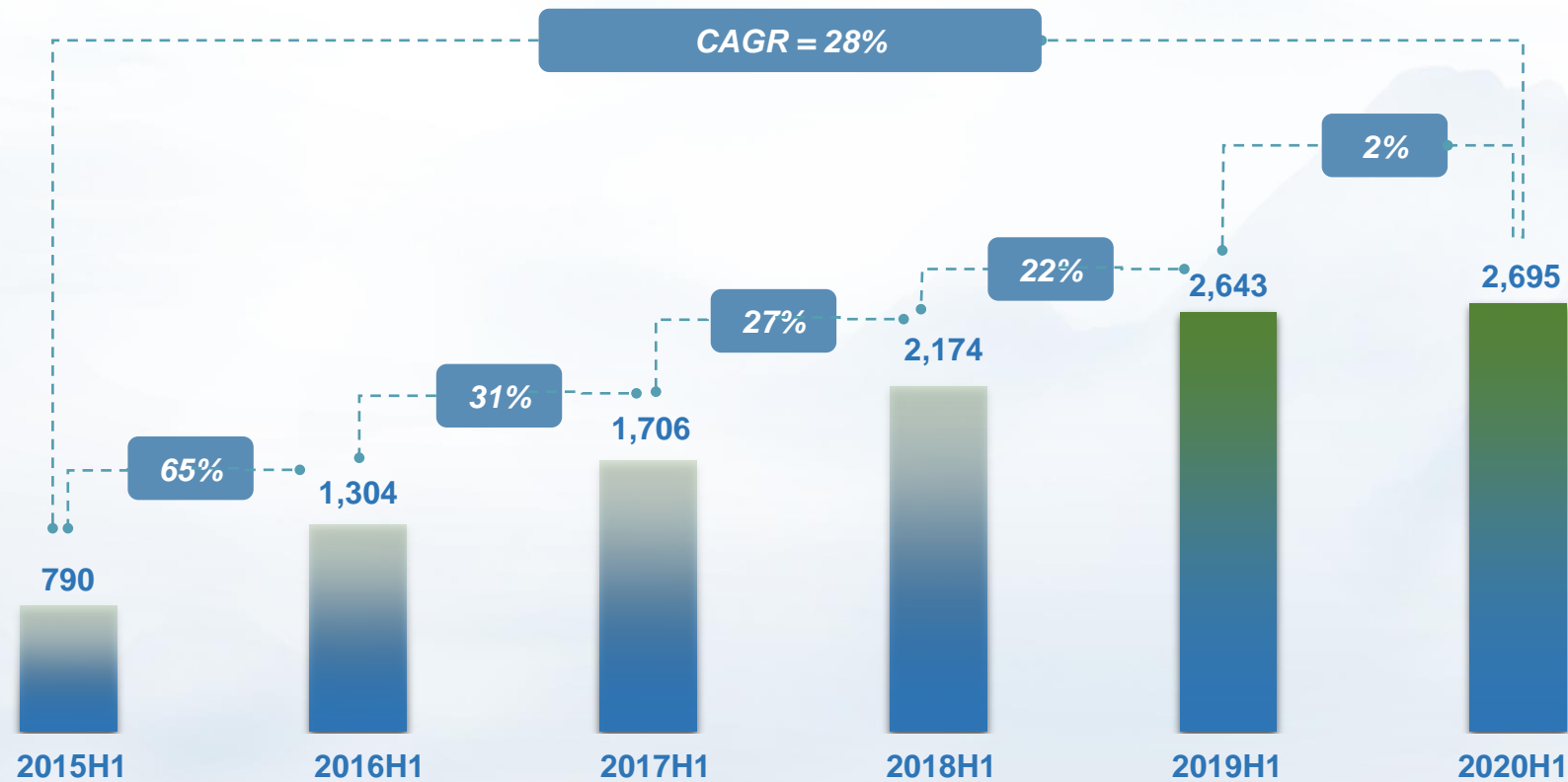
Multi-specific Antibody

Bi-specific Antibody



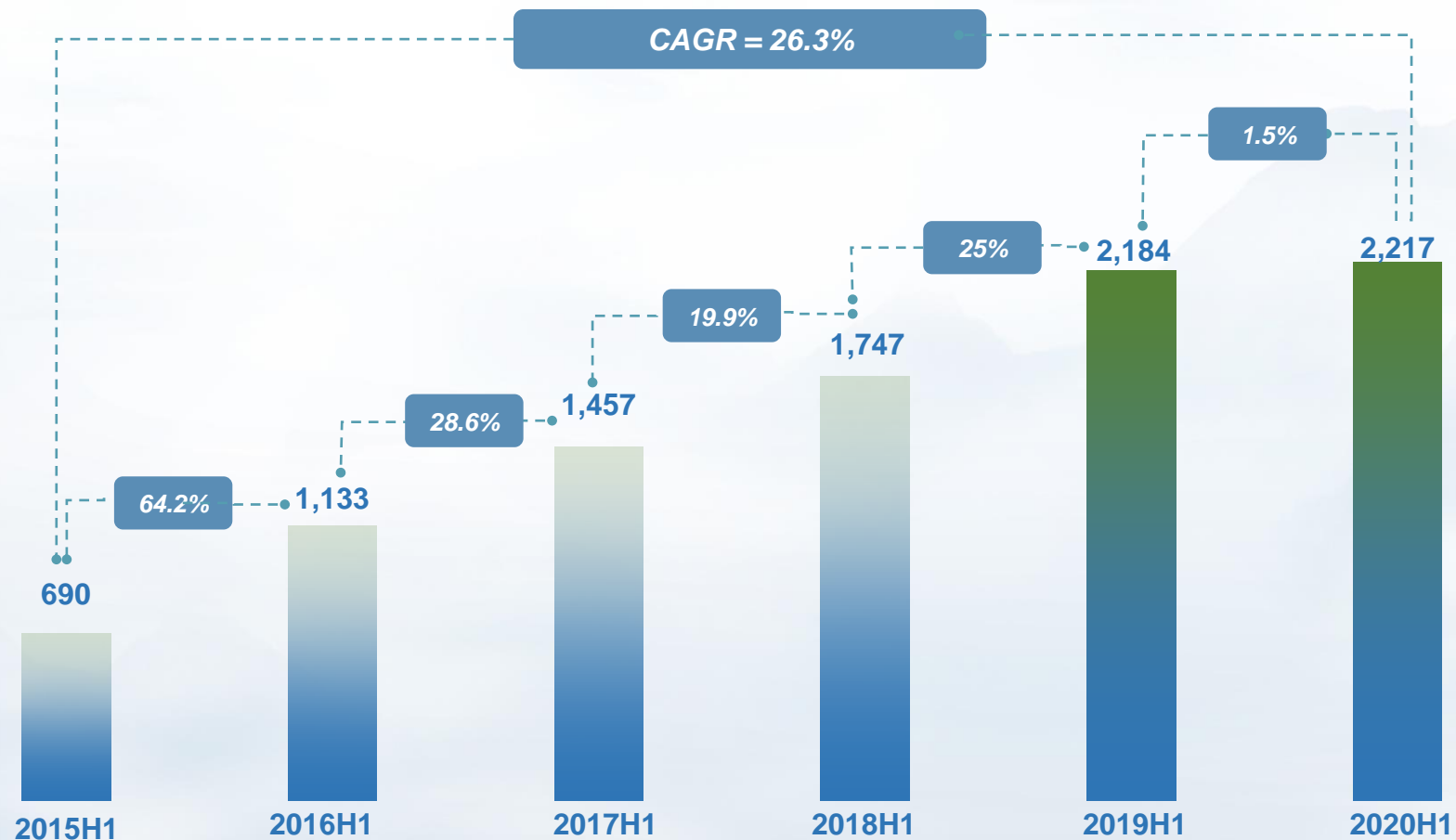
# Major Income was Effectuated by Covid-19 Pandemic in 2020H1, but Maintains an Overall Steady Growth

Unit: RMB mm



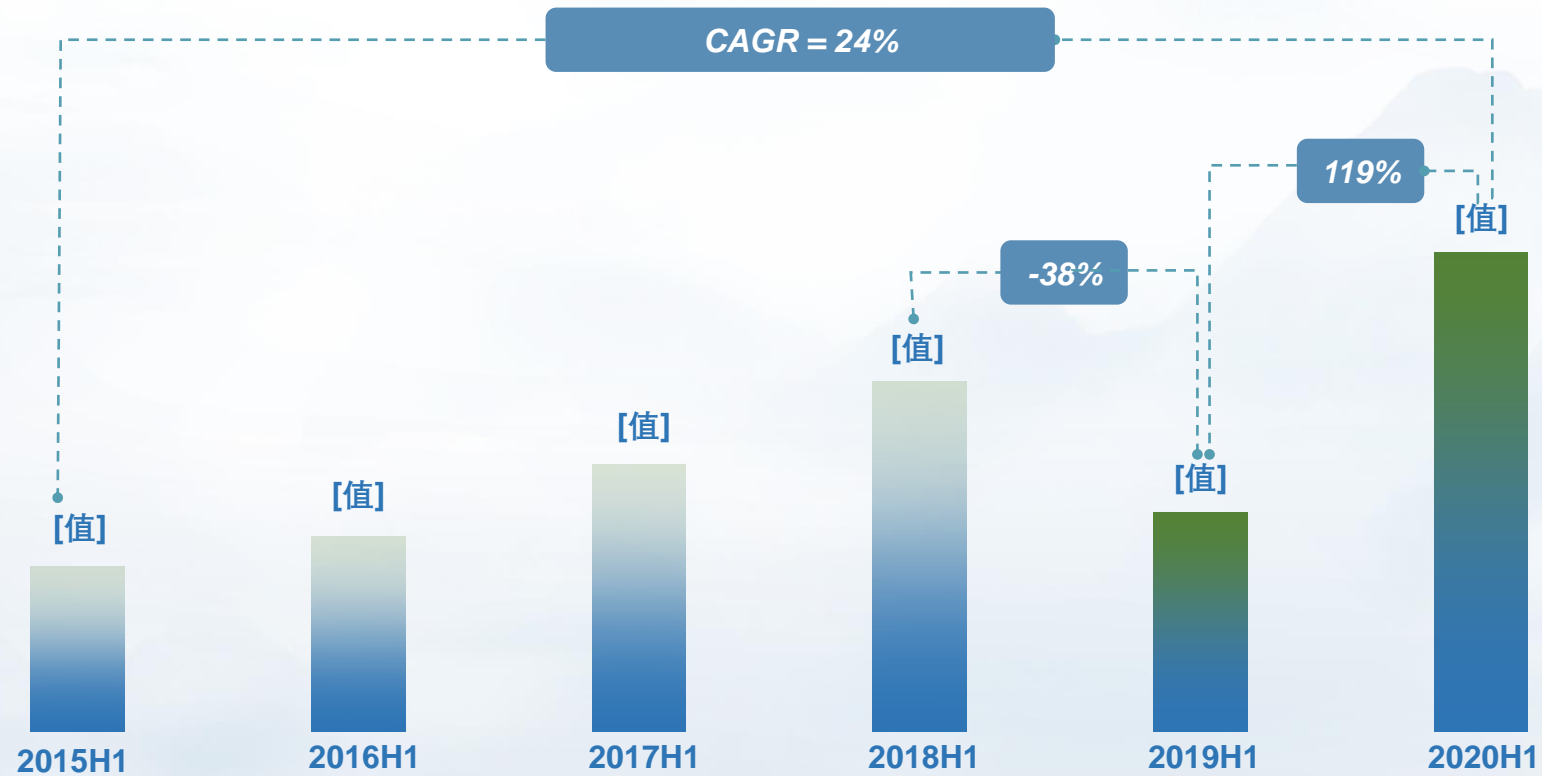
# Gross Profit Remains Steady Growth even under the Impact of Covid-19 Pandemic in 2020H1

Unit: RMB mm



# Net Profit Attributable to the Parent Soared for 119% with Strong and Sustained Profitability in 2020H1

Unit: RMB mm

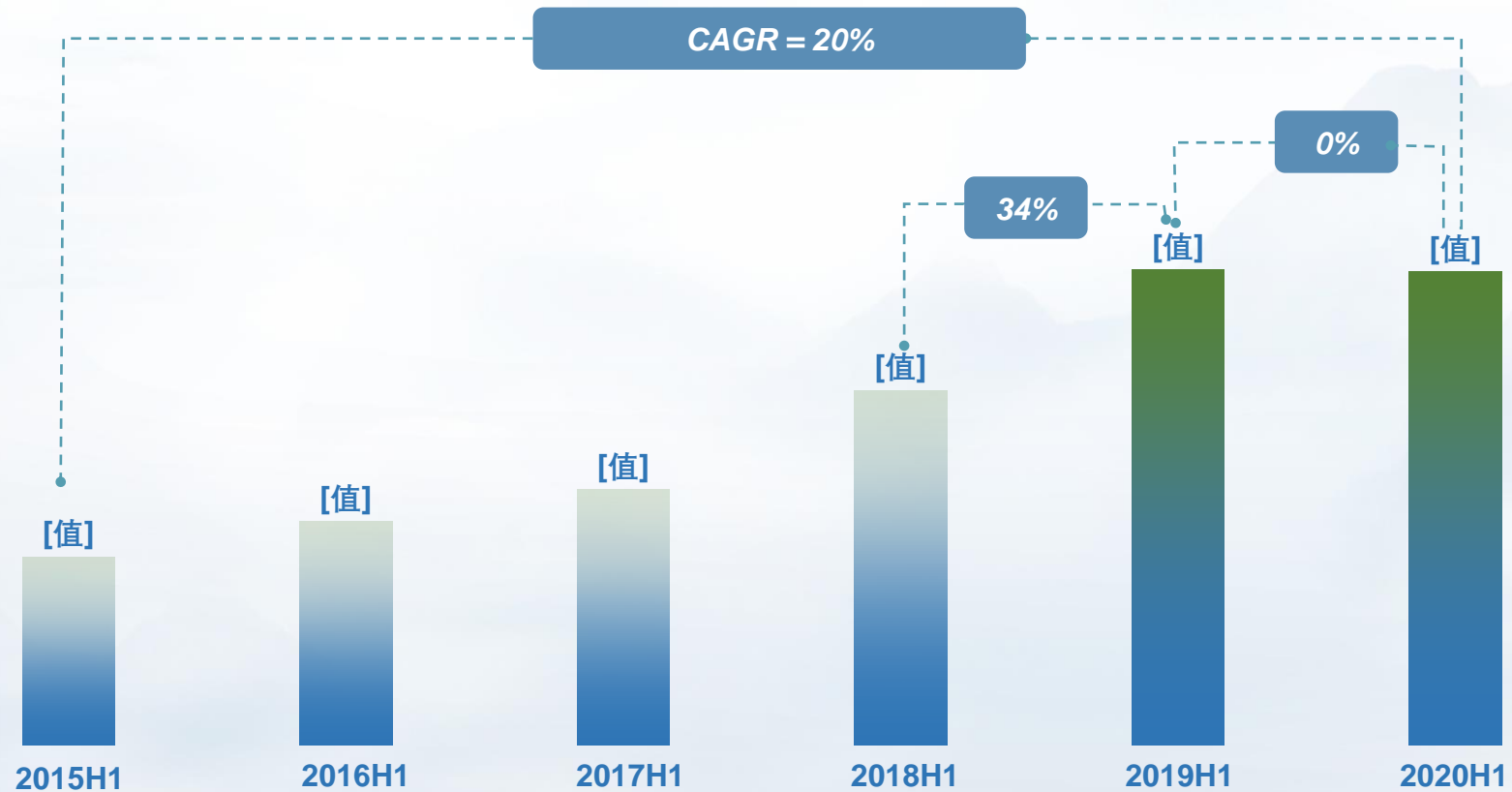




# Normalized Net Profit Attributable to the Parent is Flat with Stable Profitability in 2020H1



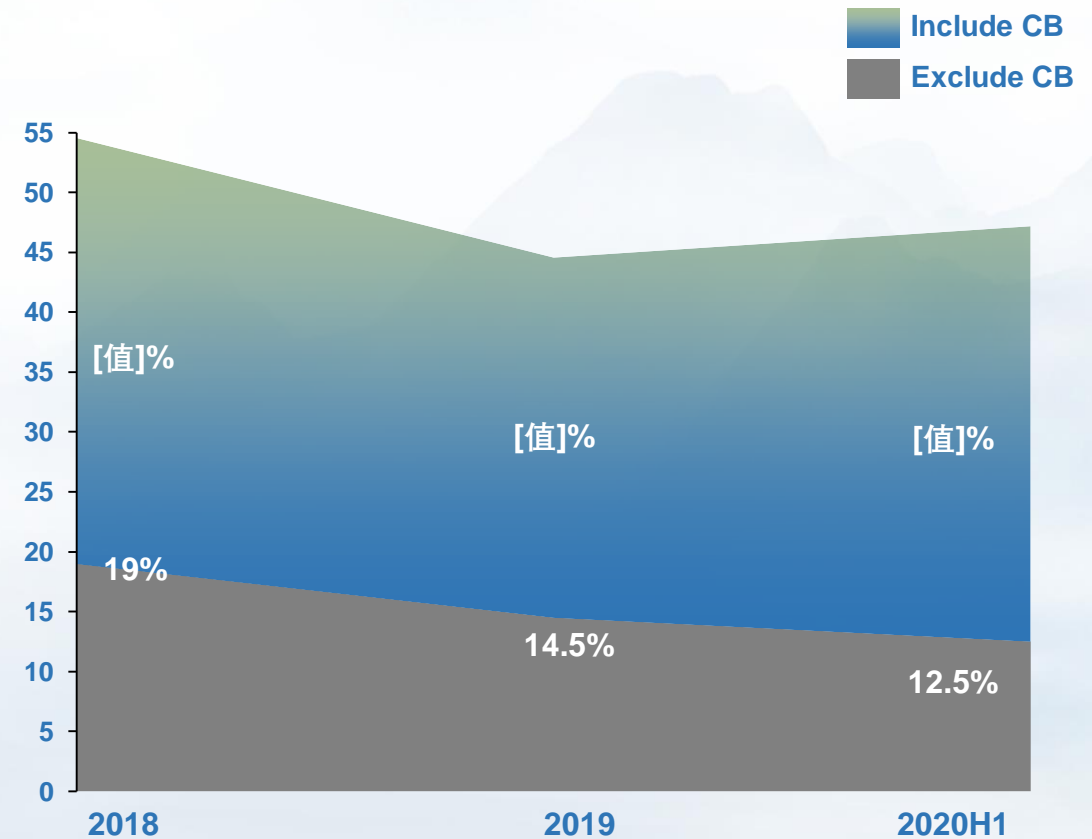
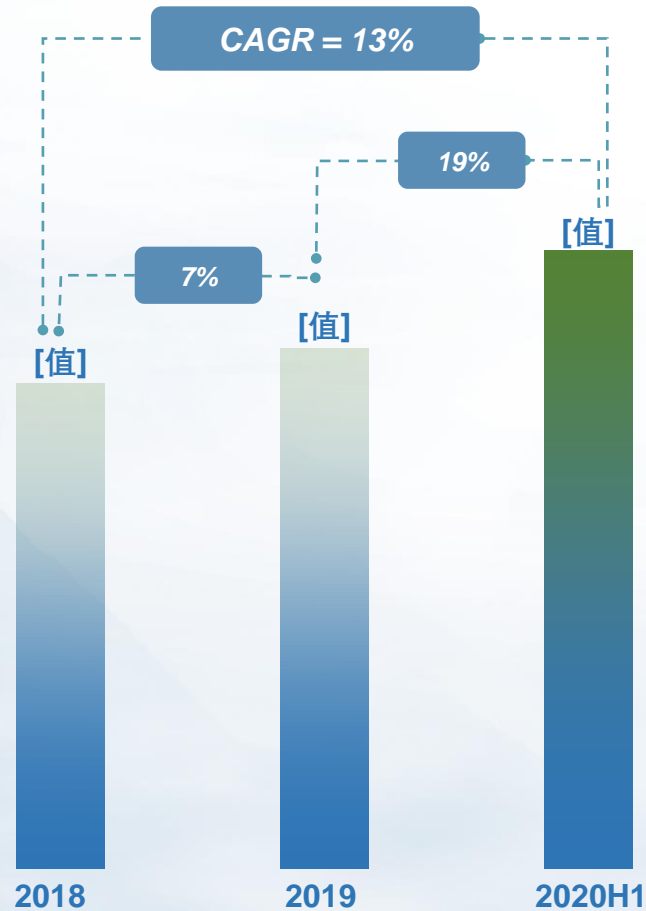
Unit: RMB mm



# Total Assets Increased Significantly in 2020H1 While the Debt Ratio is Relatively Low



Unit: 100 million RMB

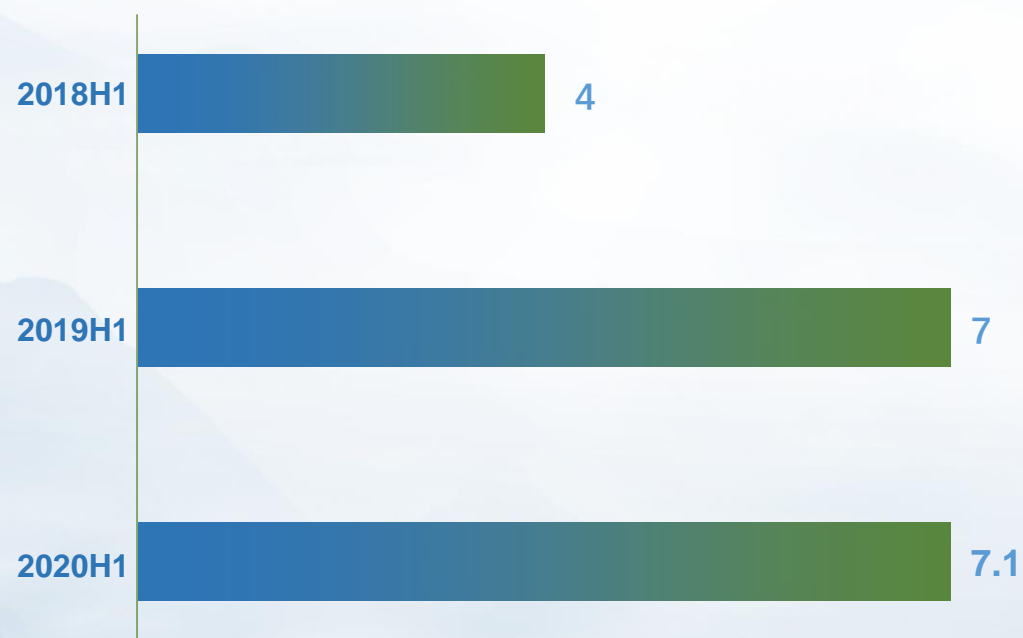


# Excellent Cash Flow with Sufficient Funds in 2020H1

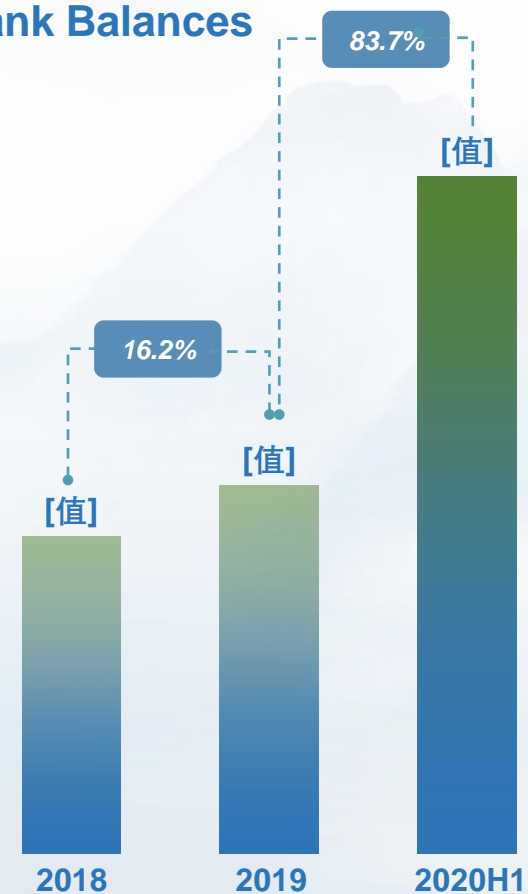
Unit: 100 million RMB



## Cash Flows from Operating Activities



## Cash and Bank Balances

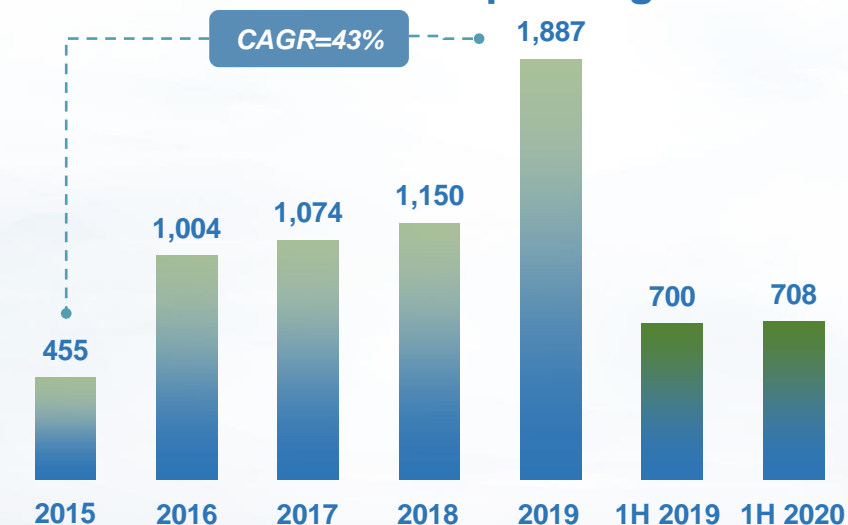


# Excellent Operations Management Capabilities

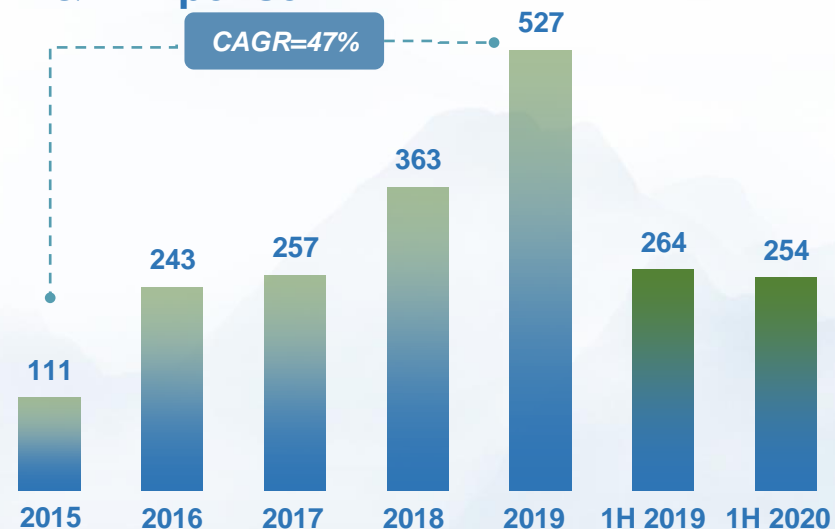
Unit: RMB mm



## Net Cash Flows from Operating Activities



## R&D Expense



## Sales and Marketing Expense



## Financial Expense





# Outlook



Operation	❖ Operating indicators and revenue of key products will continue to grow steadily
New Products	❖ Launch of new products (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





**THANKS**

**Q & A**



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CHERISH LIFE CARE FOR LIFE CREATE LIFE