石藥集團有限公司
CSPC PHARMACEUTICAL GROUP LIMITED

# 2023 Q3 Results

November 2023

# China’s Leading Innovative Pharmaceutical Enterprise

## R&D Capabilities

- **8** R&D platforms
- **5** R&D centres located in China & the U.S.
- **~ 2,000** R&D staff
- **~ 300** R&D projects (~**130** innovative projects)
- R&D expenses in YTDQ3 2023: RMB3.68B

## Commercialization Capabilities

- **10,000+** professional sales personnel
- Covered **35,000+** medical institutions across the country, of which **2,900+** Class 3 hospitals (more than 90%), **7,000+** Class 2 hospitals (more than 70%), **26,000+** other terminals and **350,000+** drug stores
- Products exported to **114** countries/regions in 6 continents, including the U.S. and Europe; marketing centers established in the U.S., Germany and Brazil

## Manufacturing Capabilities

- **10+** pharmaceutical production bases
- Nano formulation： **27** production lines built with production capacity of **20M** doses/year; **2** production lines under construction with production capacity of **2M** doses/year
- Biologics: fermentation capacity of **40,000L**
- Chemical drugs: production capacity of OSD~**30B** tablets/year, production capacity of injection ~**3B** doses/year
- mRNA vaccines： GMP-compliant production plant has been built
- siRNA: 2 pilot scale production lines has been built; commercial scale production line is under construction

# 2023 YTD Q3 Highlights

## R&D

**4 new drug approvals:**
Covid-19 mRNA vaccine (EUA)
Desvenlafaxine succinate extended-release tablets
Narlumosbart for injection
Irinotecan liposome injection

**5 applications for marketing approval:**
Enlonstobart （PD-1)
Amphotericin B liposome
Prugliptin tablets （DPP-4)
Omalizumab
Batoclimab

**28 IND approvals in China：**
15 for the first indication
13 for additional indications

**North America：**
CPO301 obtained IND approval and granted fast track in the U.S.
CPO301 obtained IND approval in Canada

## Business

- Revenue increased by **1.6%** to **RMB23.87B**
- Underlying profit attributable to shareholders* (see page 6) increased by **2.0%** to **RMB4.72B**

## BD

- Nectin-4ADC: licensed-out the rights in the US, EU, UK, Canada, Australia, Iceland, Liechtenstein, Norway and Switzerland to Corbus, with **US$7.5M** upfront payment, potentially **US$685M** milestone payment and royalty.
- Obtained the exclusive promotion rights of Glumetinib (c-MET inhibitor) from Haihe Biopharma. The product has been approved for marketing in March 2023
- Signed a strategic partnership agreement with Pfizer to launch a local brand of the COVID-19 oral therapeutic treatment Nirmatrelvir/Ritonavir in China

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Part 01

# Financial Highlights

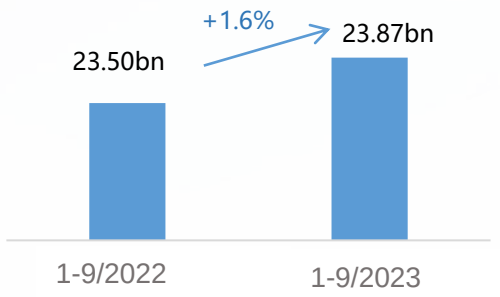
# Financial Highlights

Unit: RMB '000

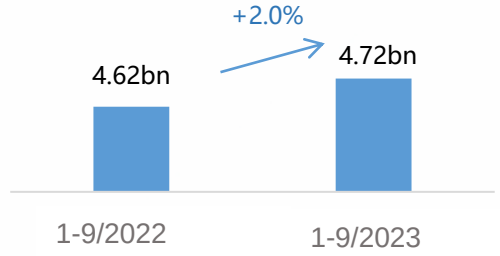
| | 1-9/2023 | 1-9/2022 | Change |
|---|---|---|---|
| Revenue | 23,865,076 | 23,495,518 | +1.6% |
| Gross profit | 16,792,100 | 17,082,304 | -1.7% |
| Gross profit margin | 70.4% | 72.7% | -2.3pp |
| R&D expenses | 3,677,949 | 2,920,249 | +25.9% |
| Underlying profit attributable to shareholders* | 4,715,187 | 4,623,720 | +2.0% |
| Profit attributable to shareholders | 4,494,641 | 4,467,837 | +0.6% |
| Basic earnings per share (RMB cents) | 37.84 | 37.49 | +0.9% |

*Note:
Underlying profit attributable to shareholders, a non-HKFRS measure, represents profit before taking into account fair value loss on financial assets measured at fair value through profit or loss, employee share-based compensation expense and gain on deemed disposal of partial interest in an associate.

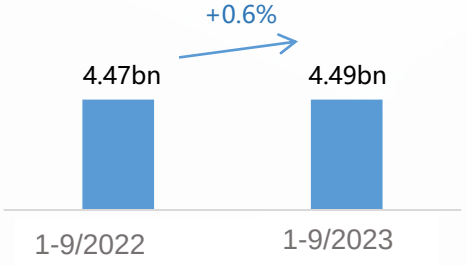
**Revenue**




**Underlying profit attributable to shareholders**




**Profit attributable to shareholders**



# Revenue

## Revenue by product category

Unit: RMB MM

| | 1-9/2023 | 1-9/2022 | Change |
|---|---|---|---|
| **Finished drugs** | 19,338 | 18,613 | +3.9% |
| **Bulk vitamin C** | 1,513 | 1,978 | -23.5% |
| **Bulk antibiotics** | 1,362 | 1,155 | +17.9% |
| **Functional Food and Others** | 1,652 | 1,750 | -5.6% |

## Finished drug revenue

Unit: RMB MM

| | 1-9/2023 | 1-9/2022 | Change |
|---|---|---|---|
| **Nervous system** | 6,926 | 6,012 | +15.2% |
| **Oncology** | 4,624 | 5,866 | -21.2% |
| **Anti-infective** | 3,143 | 2,646 | +18.8% |
| **Cardiovascular** | 1,836 | 2,173 | -15.5% |
| **Respiratory system** | 1,159 | 440 | +163.5% |
| **Digestion & metabolism** | 662 | 564 | +17.4% |
| **Others** | 953 | 726 | +31.3% |
| **Licence fee income** | 35 | 186 | -81.3% |

# Operating Profit

Unit: RMB MM

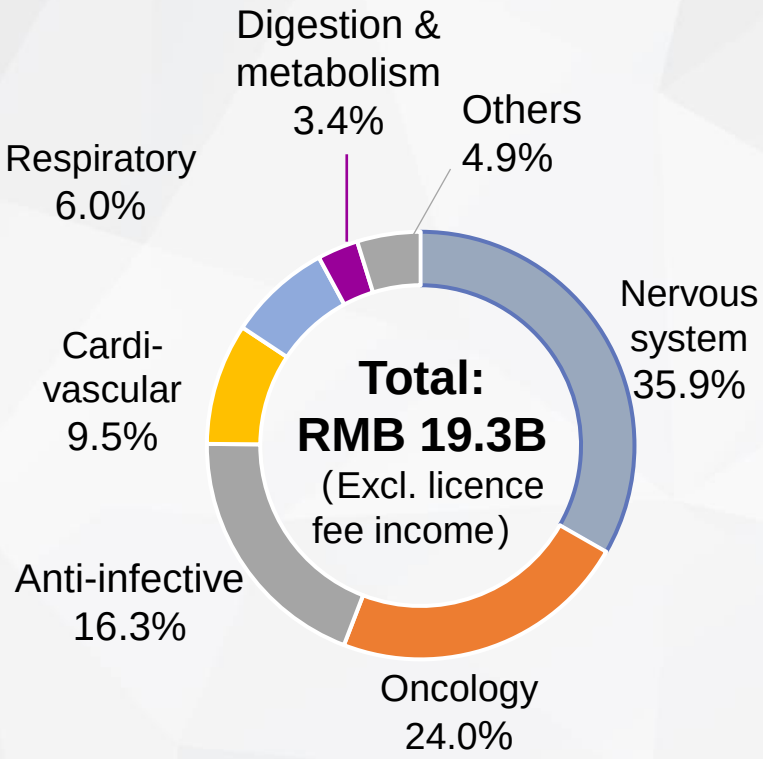
| | 1-9/2023 | 1-9/2022 | Change | 1-9/2023 OPM | 1-9/2022 OPM | Change |
|---|---|---|---|---|---|---|
| **Finished drug** | 4,959 | 4,587 | +8.1% | 25.6% | 24.6% | +1.0pp |
| **Bulk vitamin C** | 52 | 403 | -87.2% | 3.4% | 20.4% | -17.0pp |
| **Bulk antibiotics** | 104 | 89 | +16.1% | 7.6% | 7.7% | -0.1pp |
| **Functional Food and Others** | 440 | 476 | -7.6% | 26.6% | 27.2% | -0.6pp |

Note: certain percentage changes of financial figures contained in this material are calculated based on the corresponding financial figures in RMB for two periods/years, rounded to the nearest thousand. Therefore, the percentage changes listed in certain tables may differ from those calculated based on the financial figures in RMB for two periods/years, which are presented in million.

Part 02

# Business Review

# Finished Drug Overview by Therapeutic Areas




| | |
|---|---|
| **Nervous system** | • Major products include NBP (butylphthalide soft capsules, butylphthalide and sodium chloride injection), Ouyuexin (desvenlafaxine succinate extended-release tablets),Shuanling (pentoxifylline extended-release tablets, pentoxifylline injection), Oulaining (oxiracetam capsules, oxiracetam for injection), Enxi (pramipexole dihydrochloride tablets), Enliwei (lacosamide injection, lacosamide tablets and Oushuan (paliperidone extended-release tablets) |
| **Oncology** | • Major products include Duomeisu (doxorubicin hydrochloride liposome injection), Jinyouli (PEG-rhG-CSF injection), Keaili (paclitaxel for injection (albuminbound)) Duoenda (mitoxantrone hydrochloride liposome injection), Duoenyi (irinotecan hydrochloride liposome injection), Jinlisheng (Narlumosbart for injection), Copiktra (duvelisib capsules) and Geruite (lenvatinib mesilate capsules) |
| **Anti-infective** | • Major products include Anfulike (amphotericin B cholesteryl sulfate complex for injection), Shuluoke (meropenem for injection), Nuomoling (amoxicillin capsules), Weihong (azithromycin capsules, azithromycin for injection), and Zhongnuo Eta (Ertapenem for injection) |
| **Cardio-vascular** | • Major products include Xuanning (levamlodipine maleate tablets and dispersible tablets), Mingfule (recombinant human TNK tissue-type plasminogen activator for injection), Encun (clopidogrel bisulfate tablets), Daxinning (dronedarone hydrochloride tablets) and Yishuning (nifedipine controlled-release tablets) |
| **Respiratory system** | • Major products include Yiluoda (nintedanib capsules), Qixin (oseltamivir phosphate capsules), Qixiao (arbidol hydrochloride tablets), Nuoyian (montelukast sodium tablets/chewable tablets), Zhongnuo Like (ambroxol hydrochloride oral solution) and Zhongnuoping (ambroxol hydrochloride extended-release tablets) |
| **Digestion & metabolism** | • Major products include Debixin (omeprazole enteric capsules), Linmeixin (glimepiride dispersible tablets), Shuanglexin (metformin hydrochloride tablets/extendedrelease tablets) and Xinweiping (acarbose tablets) |
| **Others** | • Major products include Gubang (alendronate sodium tablets/enteric tablets), Xianpai (omeprazole sodium for injection) and Qimaite (tramadol hydrochloride tablets) |

# Key Products Overview

## NBP

**Butylphthalide soft capsules and injections**

- 1st Class 1 new drug of cardio-cerebrovascular field in China
- Price cut after negotiation improves affordability and accessibility, benefiting more patients
- Significant growth in OTC and E- channels
- New indication - vascular dementia (VaD) under clinical trails

## Mingfule

**Recombinant human TNK tissue-type plasminogen activator for injection**

- Mainly used for the thrombolysis treatment in patients with acute myocardial infarction
- Recommended by ***Chinese Expert Consensus on Pre-hospital Thrombolysis*** and ***Guidelines for Rational Use of Drugs for STEMI*** and other authoritative guidelines
- BLA accepted by CDE for the treatment of acute ischemic stroke

## Ouyuexin

**Desvenlafaxine succinate extended-release tablets**

- The third-generation antidepressant
- First generic drug of its kind that has been approved in China
- Convenient to use without dosage titration
- Patients with liver injuries are able to use recommended dosage, widening its target audience

## Xuanning

**Levamlodipine maleate tablets and dispersible tablets**

- Exclusive product in China and the 1st new drug fully approved by the U.S. FDA from China
- Leverage its integrated sales model of direct, cooperative and retail sales to drive a steady growth

## Anfulike

**Amphotericin B cholesteryl sulfate complex for injection**

- Exclusive formulation, obtained marketing approval in March 2021; included in the NRDL in December 2021
- Covered approx.1300 hospitals
- Significantly decrease nephrotoxicity and increase dosage

# Key Products Overview

## Jinyouli

**PEG-rhG-CSF**

- 1st long-acting white blood cell booster drug in China
- Expanding coverage in major municipal hospitals and county-level markets
- Included in the centralised procurement of the Guangdong Alliance of 11 provinces, enhanced accessibility of the drug will expedite a broader clinical use

## Duomeisu

**Doxorubicin Hydrochloride liposome injection**

- No.1 in market share in China
- The first player passed consistency evaluation

## Duoenda

**Mitoxantrone hydrochloride liposome injection**

- Exclusive new preparation worldwide with various patent granted in many countries; Obtained marketing approval in January 2022
- Various clinical trails in solid tumors undergoing, blockbuster potential

## Duoenyi

**Irinotecan hydrochloride liposome injection**

- In combination with 5-fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic pancreatic cancer after disease progression following gemcitabine-based therapy
- Grade I recommendation (Level 1A evidence) in CSCO Guidelines in 2020, which is the therapy with the highest level of recommendation and evidence among current 2L therapies for pancreatic cancer

## Jinlisheng

**Narlumosbart for injection**

- The first IgG4 subtype fully human monoclonal antibody against RANKL obtaining marketing approval in the world
- Compared with denosumab, the Product has significant enhancement in uniformity and quality controllability, with favorable efficacy and safety profile
- New indications of tumor bone metastasis and osteoporosis are under development

# Bulk Product Business, Functional Food and Others

## Bulk vitamin C

- Major products: vitamin C, vitamin C - sodium, vitamin C - calcium and granular vitamin C
- Sales of vitamin C products decreased by 23.5% to RMB1,513 million, mainly due to the weakening price of vitamin C products

## Bulk antibiotics

- Major products: 7-ACA (intermediate), cefazolin sodium, penicillin potassium, penicillin sodium, azithromycin and ampicillin sodium
- Sales of antibiotic products increased by 17.9% to RMB1,362 million, driven by the growth in sales volume

## Functional food and others

- Recorded sales of RMB1,652 million for the period, a decrease of 5.6% year-on-year
- There was certain decline in the prices of caffeine products during the period, with sales volume maintaining a stable growth

Part 03

# R&D Capability

# R&D Overview

## R&D Centre

- 5 R&D centres located in China & the U.S.
- R&D expenses in YTDQ3 2023: RMB3.68B

## Technology Platform

- 8 national science & technology qualifications
- 2 state key labs
- 8 R&D technology platforms

## Project under Development & IPs

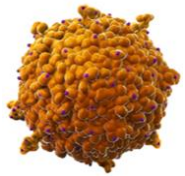
- Approx.300 projects under development (approx. 130 innovative drug projects)
- 1793 IPs applications
- 889 IPs authorised

## Science Projects& Government Support

- 87 national projects
- RMB890M government grant support
- 8 national prizes

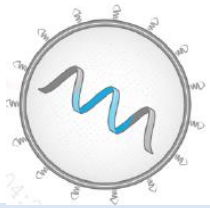
# Innovative R&D Platforms

## Nano-formulation



- Mitoxantrone liposome
- Albumin-bound docetaxel
- Paclitaxel cationic liposome
- Cisplatin micelle

## mRNA vaccine



- Covid-19 mRNA vaccine and various preventive and therapeutic vaccines

## siRNA

- PCSK9 siRNA and other chronic disease drugs

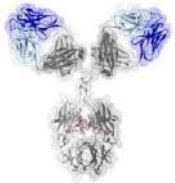
## ADC

- HER2 ADC
- CLDN18.2 ADC
- Nectin-4 ADC

## BsAb

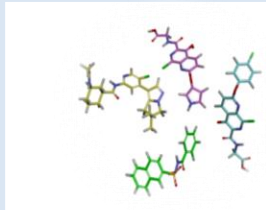
- JMT601 (CD47/CD20)
- JMT106 (GPC3/IFN)
- JMT108 (**/IL15)

## mAb



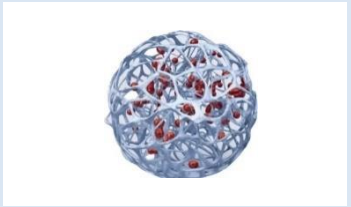
- JMT101 (EGFR)
- JMT103 (RANKL)
- ALMB0168 (CX43 agonist)
- ALMB0166 (CX43 antagonist)

## Small molecule



- Prugliptin (DPP-4)
- Amuxetine
- SKLB1028 (FLT3)
- SYHA1813 (VEGFR/CSF1R)

## Long-acting injection



- Octreotide Long-acting injection
- Paliperidone injection
- Leuprorelin microsphere injection

*Note：only shows the representative products on each platform*

# Nano-formulation Platform

## Nano-formulation development and manufacturing platform

### Novel drug carrier design

- Invented Albumin nanoemulsion
- Developed new cationic materials and new delivery system

### Novel drug delivery technology

- Invented ammonium salt gradient method of sulfobutylether-β-cyclodextrin and 5-sulfosalicylate
- Cholesterol PEGylation modification method and post single layer PEGylation

### Novel preparation method

- Invented single-phase solution lyophilization technology、O/W type Emulsification technology、crossflow mixing technology、continuous flow reaction technology, etc.
- Invented bottom up nanocrystal preparation technology, enabling continuous production

### Novel Industrialized production technology

- Invented continuous flow technology, employing linear amplifier，overcome barriers to industrialized production
- Illustrated that all nano drugs are able to be prepared by permutation and combination of four key processes

## Nano-formulation assessment system

### Particle characterisation method

- Developed nano-formulation assessment technology for lipsome, albumin nanoparticles, emulsion, micelles, etc.

### PK determination method

- Established multiple PK determination methods for nano drugs including lipsome, albumin nano-particle, micelles etc.

### Mature animal screening models

- Established multiple animal disease model for efficacy assessment
- Established animal models for evaluating ABC phenomenon、CARPA response and HFS, enabling quick screening

### Particle characterisation technique guided in vivo PK、PD、TOX evaluation

- Illustrated influence of drug release rate of lipsome, mode of administration and animal model on ABC phenomenon
- Detailed study of CARPA and HFS laid the foundations for rational design of nanoparticles

# mRNA Vaccine platform

## 1 Advantages of antigen design

- Mutation prediction platform
- The combination of bioinformatics and structural biology to obtain effective epitopes
- Superior immunogenicity from site-specific mutation of antigen

## 2 mRNA vaccine design

- Base modification, UTR screening, codon optimization and structural elements inclusion
- Structural energy optimization to enhance antigen expression

## 3 Manufacturing capabilities

- Manufacturing capabilities of CSPC
- Top tier LNP R&D platform
- Manufacturing capacity reaches to 1.5 billion doses per year

## 4 Excellent safety profile

- No observed SAE in clinical trials
- Excipients proven to be low toxicity by launched products
- Base modification mitigates innate immunogenicity
- Formulation ensures long-term stability

## 5 Streamlined CMC Strategy

- One-step API manufacturing process
- API purification process: up to 99% purity
- Highly scalable LNP manufacturing process
- Short turnaround time: ~2 days

## 6 Highly expandable platform

- Each individual component can be continuously upgraded
- Expansion from linear mRNA to circRNA; from liver-target delivery to extrahepatic delivery
- From preventive to therapeutic application; from vaccine to CGT

# siRNA Platform

## 1 HTS screening platform

- Rational sequence design based on bioinformatics and experienced scientists
- Comprehensive in vitro and in vivo PK/PD characterization

## 2 CMC platform

- Build strong oligonucleotides CMC platform based on QbD strategy
- Develop liquid synthesis technology

## 3 Manufacturing capabilities

- Manufacturing capabilities of CSPC
- Two GMP-compliant production lines have been built

## 4 Excellent safety profile

- Superior safety profile in pre-clinical study
- Build off-target risk assessment platform
- Chemical modification to mitigate immunogenicity
- Long-term stability

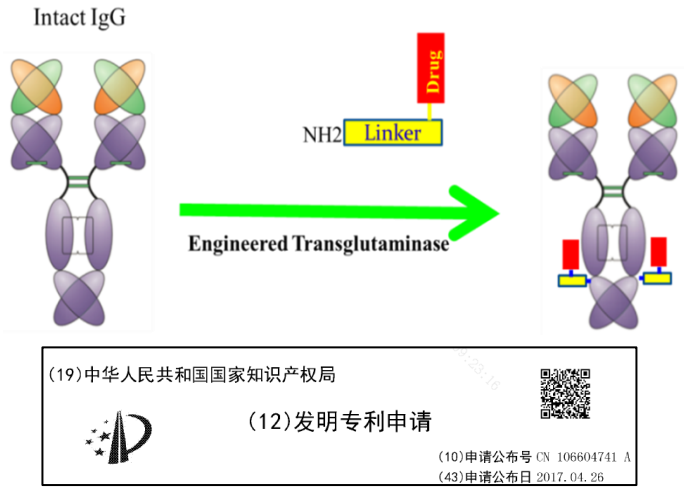
## 5 Nucleotides building blocks

- Develop novel building blocks
- Develop Galnac molecule with in-house IP
- Scalable building blocks manufacturing technology
- Manufacturing capability of key building blocks

## 6 Highly expandable platform

- Each individual component can be continuously upgraded
- Integrated manufacturing capabilities from building blocks, API and drug product

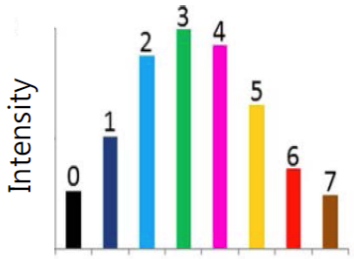
# ADC Platform

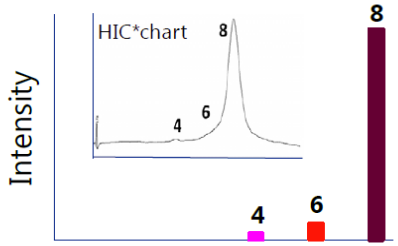



| ADC Design | Characteristics | Advantages |
|---|---|---|
| Conjugation Mode | Engineering TGase catalysis | The specific conjugation on the homogeneous glutamine residue in the Fc region catalyzed by engineering modified Tgase can produce highly purified ADC molecule with stable DAR ratio, excellent PK character and wide therapeutic index |
| Conjugation Spot | Conserved Q295 residue on the heavy chain of the antibody | |
| Form of Antibody | Intact homogeneous IgG | Avoid introducing mutation or deglycosylation that may lead to the increase of immunogenicity |

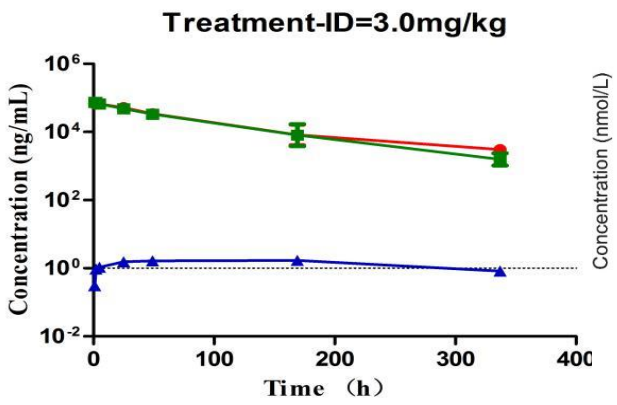
## Fixed-point conjugation produces highly homogeneous DAR2 product

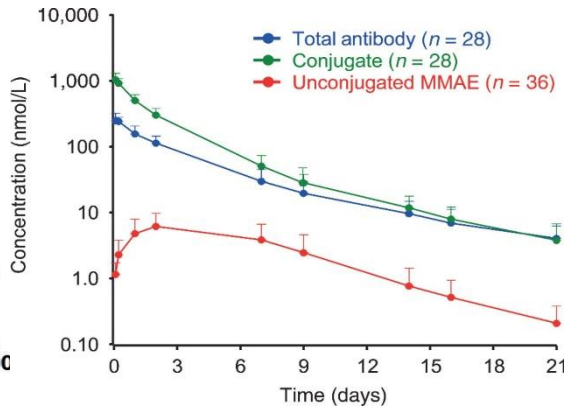
| | T-DM1 | DP303c |
|---|---|---|
| Antibody | Trastuzumab | Anti-HER2 Ab |
| Payload | Tubulin inhibitor (DM1) | Tubulin inhibitor (MMAE) |
| DAR | 3.5 | 2 |




## Extremely low proportion of free toxins in human plasma



# Bispecific Antibody Platform

## Antibody-interferon fusion protein platform

**Structural advantages**

- **Synergistic** binding effect when targeting the same cell
- **Smaller** molecular weight(smaller than that of conventional antibodies)

**Safer impurities**

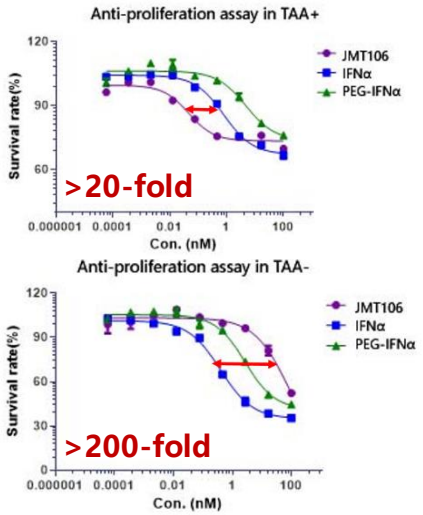
- The activity of interferon-containing impurities is **far lower** than that of conventional bispecific antibodies
- No serious safety risk of interferon-containing impurities from the production process

**Stronger target selectivity**

- Limited binding activity to receptors on TAA- cells, demonstrating a **better therapeutic window**
- The optimization of interferon mutation to further improve **target selectivity**

**More stable product**

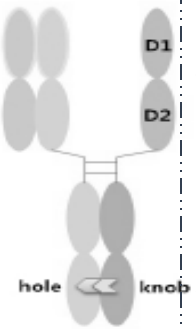
- **Lower difficulty** in pharmaceutical development
- Significantly reduce the interferon breakage during the production process and in the body, resulting in **high yield** and **low risk**




- ✓ The proliferation inhibitory activity in TAA+ cells is more than 20- fold higher than that of IFNα
- ✓ The proliferation inhibitory activity in TAA- cells is more than 200-fold lower than that of IFNα
- ✓ ADCC and tumor immunomodulatory effects
- ✓ In vivo anti-tumor efficacy in a dose-dependent manner
- ✓ in vivo anti-tumor effect is superior to TAA mAb, PEG-IFNα monotherapy and the combination therapy
- ✓ Cytokine release from human PBMCs is within a safe range
- ✓ No significant proliferative stimulation or inhibition on human PBMCs
- ✓ Good Serum stability, accelerated stability, and freeze-thaw stability

- High expandability
- stronger targeting ability
- Better safety profile
- Lower molecular weight
- More stable
- Simple production procedure
- Lower production cost

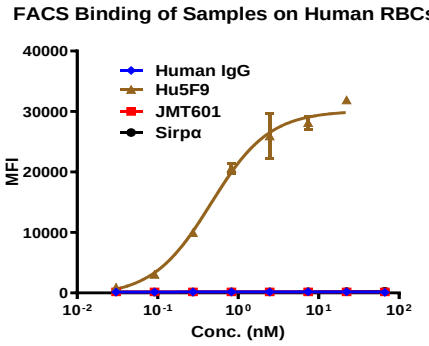
## CD47 targeting bifunctional fusion protein platform

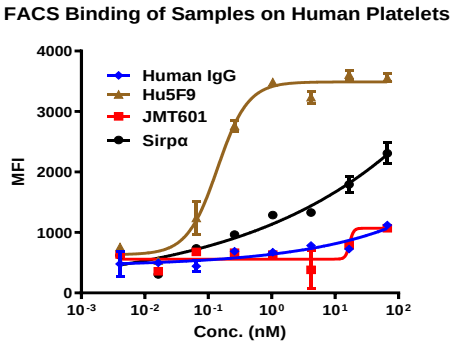


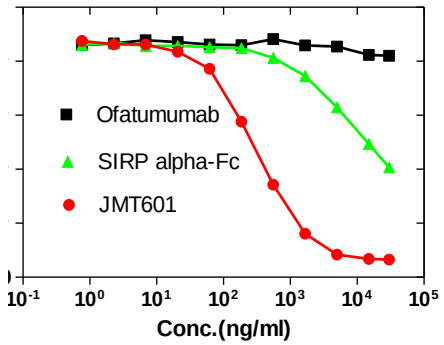

**Left-arm:**
high-affinity targeting of tumor semi-antibody

**Right-arm:**
Low-affinity targeting of SIRPα-Fc fusion protein

- ✓ Does not bind to TAA-/CD47+cells, including erythrocyte, platelet etc.
- ✓ TAA binds to CD47 with ADE




- High expandability: various types of tumor targeting antibody could be used as the left-arm
- Higher safety window.
- Lower molecular weight, better suits solid tumors
- Simple production process
- Possession of intellectual property right

Part 04

# Pipeline

# Candidates under Clinical Trial Stage

## PhI (26)

- NBL-012 IL23-P19
- NBL-015 CLDN18.2 mAb
- NBL-020 TNFR2
- NBL-028 CLDN6-CD137
- SYS6002 Nectin-4 ADC
- SYS6010 EGFR ADC
- SYS6011
- JMT203 GFRAL
- Secukinumab
- SYHA1801 BRD4
- SYHA1803 Pan-FGFR
- SYHA1805 FXRs
- SYHA1807 LSD1
- SYHA1811 BTK
- SYHA1815 FGFR/RET
- SYHX1903 CDK9
- SYHX2001 PRMT5
- SYHX2005 FGFR4
- SYHX2009 NTRK/ROS1
- SYH2038 SOS1
- SYH2043 CDK2/4/6
- SYH2045 PRMT5
- SYH2051 ATM
- SYH2053 PCSK9 siRNA
- SYHA1908
- Cisplatin micelle

## PhII (POC) (15)

- CLDN18.2 ADC
- CM326 TSLP
- ALMB0166 Cx43i mAb
- ALMB0168 Cx43s mAb
- JMT601 CD20/CD47
- SYHX1901 JAK/SYK
- Simmitinib TKI
- SYHA1813 VEGFR/CSF1R
- Amuxetine 5-HT/NE
- SYHA1402 ARi
- NBP Capsule (US PhII)
- Paclitaxel cationic liposome
- Albumin-bound Sirolimus
- Octreotide long-acting injection
- Alprostadil liposome

## PhII / III pivotal trial (17)

- JMT101 EGFR mAb
- CM310 IL4R
- KN026 Her2 BsAb
- TG103 Fc-GLP1
- Pertuzumab
- Ulsinumab
- DP303C HER2 ADC
- NBP Capsule (VaD) ☆
- SKLB1028 FLT3-TKI
- SYH2055 3CL
- SYHA121-28 RET-TKI
- Semaglutide
- Albumin-bound Paclitaxel II
- Albumin-bound Docetaxel
- Clevidipine injectable emulsion
- Meloxicam nanocrystal injection
- Daunorubicin cytarabine liposome

## NDA (7)

- rhTNK-tPA < 4.5h AIS☆
- SYSA1802 PD-1
- Omalizumab biosimilar
- Batoclimab
- DBPR108 DDP4
- Amphotericin B Liposome
- Bivalent covid mRNA vaccine

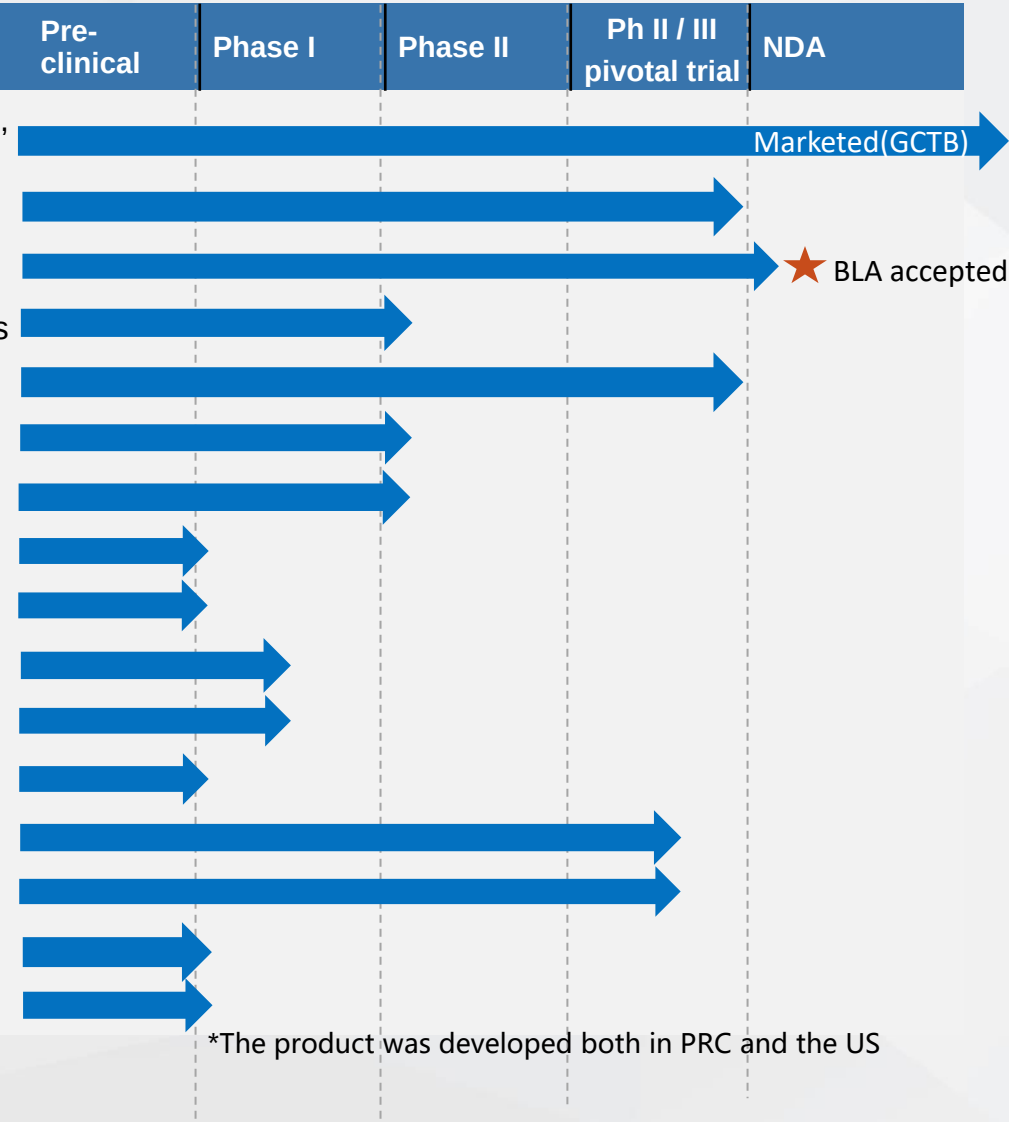
☆ Additional indications

- large molecule
- small molecule
- new preparation
- mRNA vaccine

# Pipeline – Large Molecule

Over 40 new biologic drugs under development: 4 filed BLA, 21 under clinical trial stage(7 under pivotal trial stage) and over 20 under pre-clinical stage

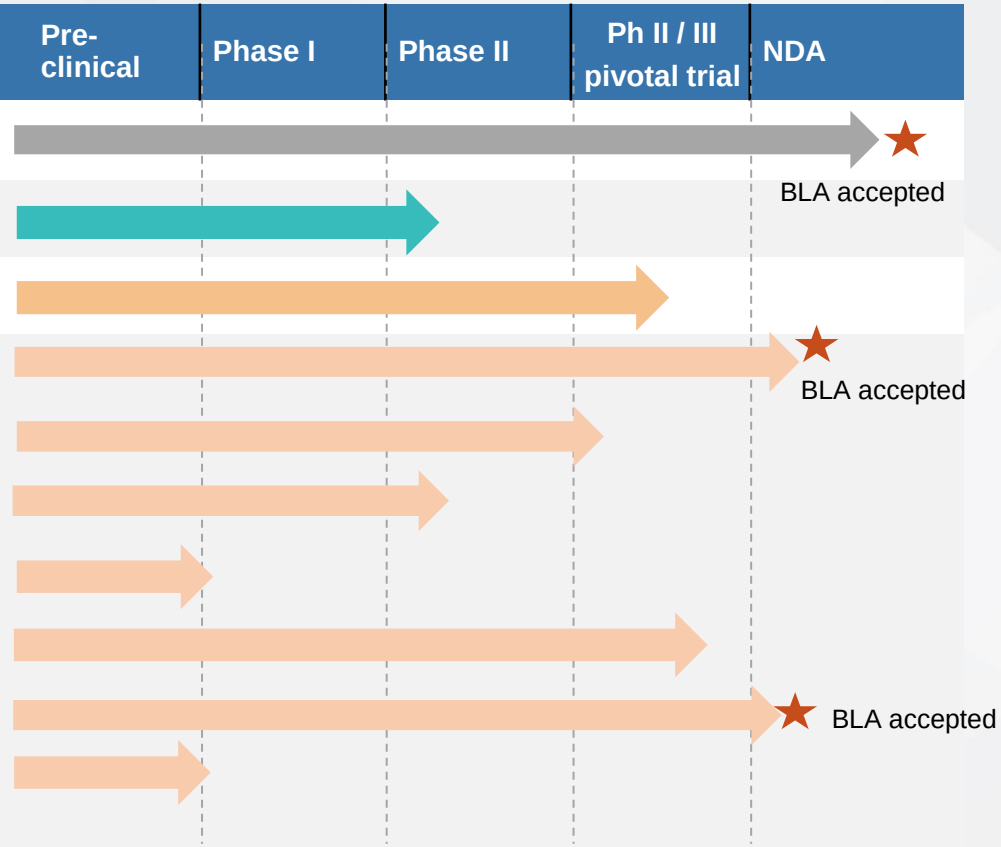
| TA | Major Candidates | Target | Indication (s) |
|---|---|---|---|
| Oncology | JMT103 | RANKL | Giant-cell tumor of bone, osteoporosis, bone metastasis |
| | JMT101 | EGFR | Multiple solid tumors |
| | SYSA1802（SG001） | PD-1 | Tumors |
| | JMT601* | CD47/CD20 | NHL& multiple hematologic neoplasms |
| | DP303c | HER2 ADC | Breast, gastric or ovarian cancer |
| | ALMB0168 | CX43 agonist | Bone cancer, cancer bone metastasis |
| | SYSA1801* | Claudin 18.2 ADC | Gastric cancer, pancreatic cancer |
| | NBL-015* | Claudin 18.2 mAb | Advanced solid tumor |
| | NBL-020* | TNFR2 | Advanced solid tumor |
| | SYS6002* | Nectin-4 ADC | Tumors |
| | SYS6010* | EGFR ADC | Tumors |
| | JMT203 | GFRAL | Cancer cachexia |
| | KN026 | HER2 BsAb | Gastric cancer, breast cancer |
| | Pertuzumab biosimilar | HER2 | Breast cancer |
| | SYS6011 | Undisclosed | Solid tumor |
| | NBL-028 | CLDN6-CD137 | Advanced tumor |




*The product was developed both in PRC and the US

# Pipeline – Large Molecule

| TA | Major Candidates | Target | Indication (s) |
|---|---|---|---|
| **Cardio-vascular** | Mingfule | rhTNK-tPA | Acute ischemic stroke (AIS) |
| **Psychiatry & Neurology** | ALMB0166 | CX43 antagonist | Spinal cord injury, AIS |
| **Digestion & Metabolism** | TG103 | GLP-1 | Obesity, Diabetes, NASH, AD |
| **Immune** | Omalizumab biosimilar | IgE | Allergic asthma, CIU |
| | CM310 | IL-4Rα | Asthma, COPD |
| | CM326 | TSLP | Asthma, COPD |
| | NBL-012* | IL-23p19 | Psoriasis, HS, IBD |
| | Ulsinumab | IL-12/IL-23 | Moderate to severe plaque psoriasis |
| | Batoclimab | FcRn | MG |
| | Secukinumab | IL-17A | psoriasis |

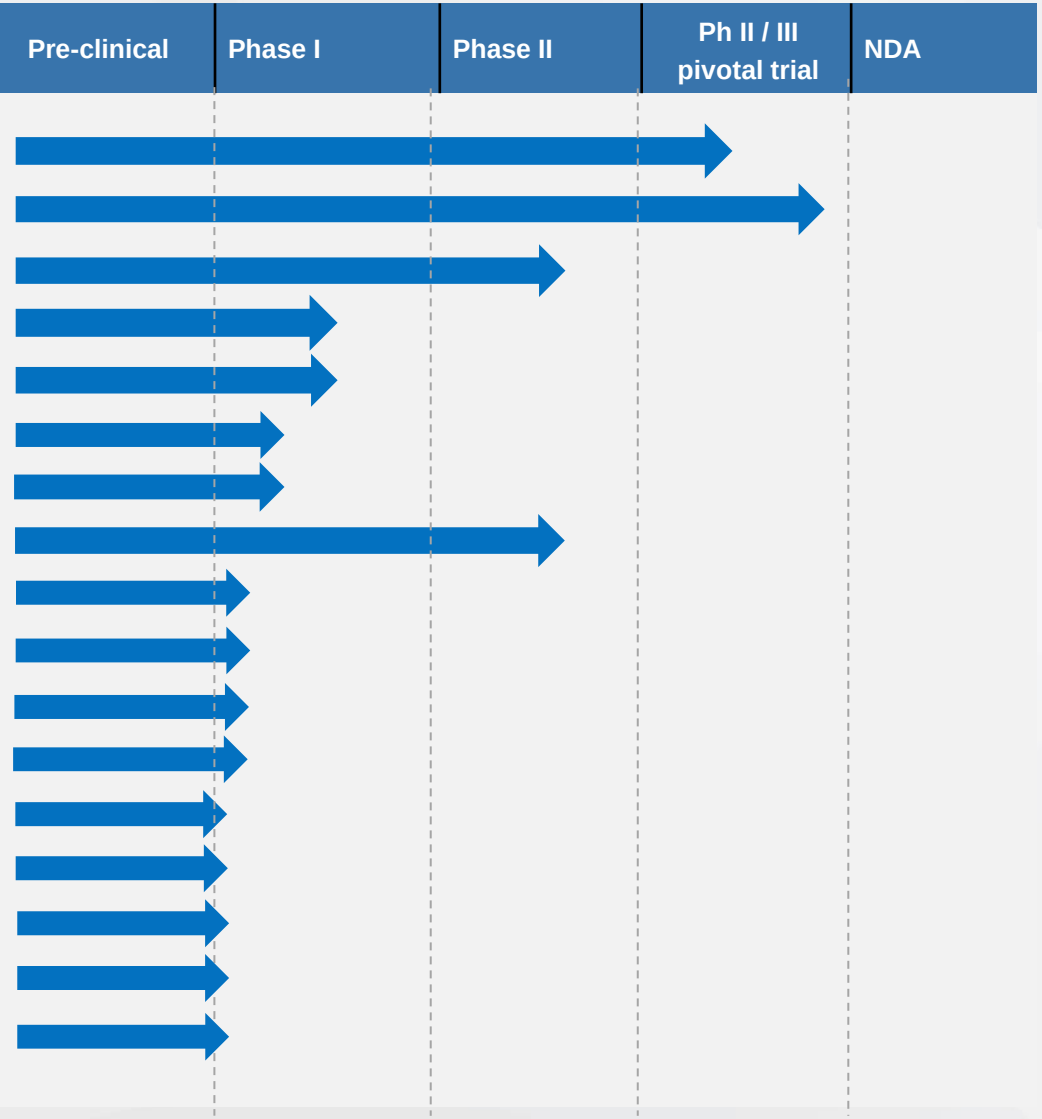



*The product was developed in both China and the US

# Pipeline - Small Molecule

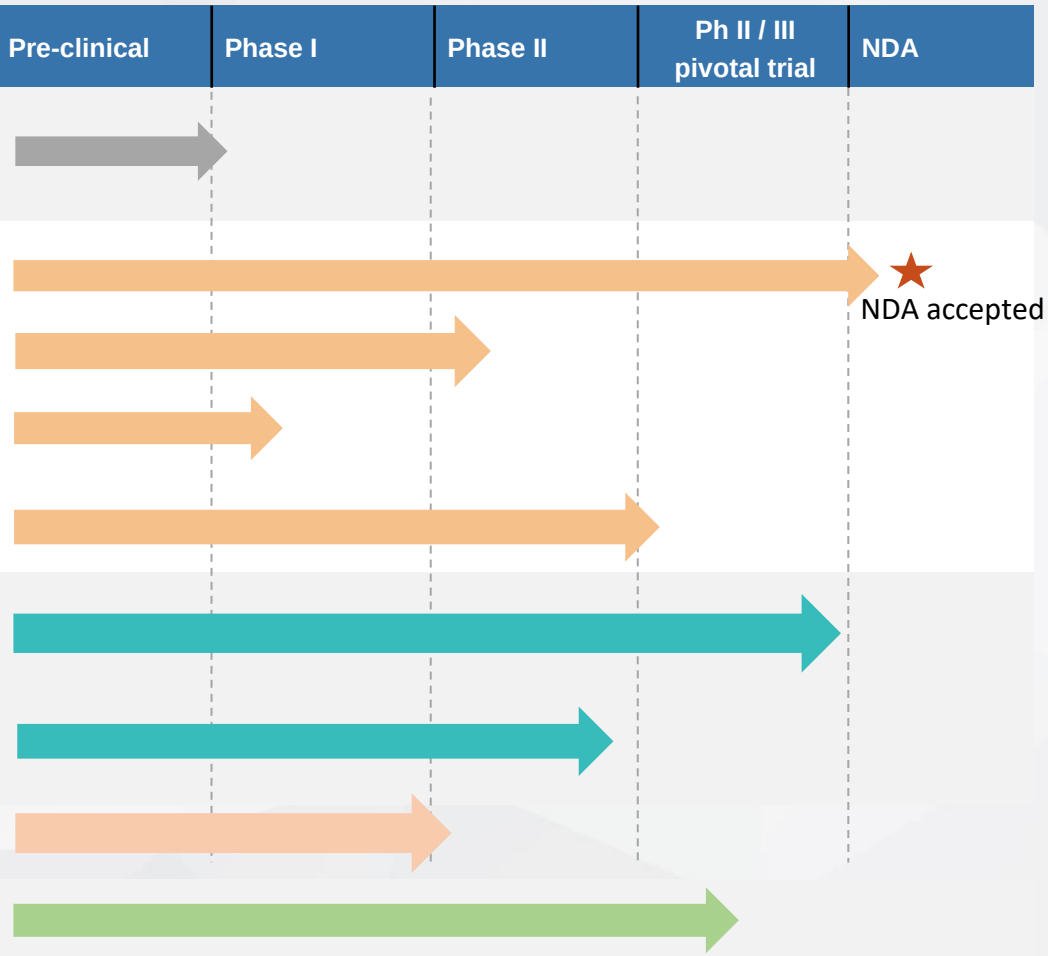
Over 40 small molecule new drugs under development: 1 filed NDA, 25 under clinical trial stage (5 under Phase III / pivotal trial stage) and over 20 under pre-clinical stage

| TA | Major Candidates | Target | Indication (s) |
|---|---|---|---|
| Oncology | SKLB1028 | FLT3、Abl、 Lyn 、EGFR | Acute myeloid leukemia |
| | SYHA121-28 | EGFR、VEGFR、FGFR、RET | Lung cancer |
| | Simmitinib | FGFR、KDR | Gastric cancer, cholangiocarcinoma, SQCC |
| | SYHA1801 | BRD4 | Advanced solid tumor |
| | SYHA1803 | Pan-FGFR | Intrahepatic cholangiocarcinoma, urothelial carcinoma |
| | SYHA1807 | LSD1 | Lung cancer |
| | SYHA1815 | RET、FGFR | Advanced solid tumor |
| | SYHA1813 | VEGFR/CSF1R | Relapsed or advanced solid tumour |
| | SYHA1811 | BTK | Leukemia, Lymphoma |
| | SYHX1903 | CDK9 | Hematological malignancies, solid tumors |
| | SYHX2001 | PRMT5 | Advanced solid tumor, r/r hematologic tumors |
| | SYHX2005 | FGFR4 | Advanced solid tumor |
| | SYHX2009 | NTRK、ROS1 | Solid tumor |
| | SYH2043 | CDK2/4/6 | Breast cancer |
| | SYH2045 | PRMT5 | Advanced malignant tumors |
| | SYH2051 | ATM | Solid tumor |
| | SYH2038 | SOS1 | Advanced solid tumor |



# Pipeline - Small Molecule

| TA | Major Candidates | Target | Indication (s) |
|---|---|---|---|
| **Cardio-vascular** | SYH2053 | PCSK9 siRNA | Primary hypercholesterolaemia or mixed dyslipidaemia |
| **Digestion & Metabolism** | DBPR108 | DPP-4 | Diabetes |
| | SYHA1402 | ARI | Diabetic neuropathy |
| | SYHA1805 | FXR Agonist | NASH |
| | Semaglutide | GLP-1 | Type2 diabetes |
| **Psychiatry & Neurology** | NBP soft capsule* | | VaD, Ischemic stroke(US) |
| | Amuxetine hydrochloride enteric tablets | 5-HT, SNDRI | Antidepressant |
| **Immune** | SYHX1901 | Syk-Jak | RA, SLE，COVID-19 |
| **Anti-infective** | SYH2055 | 3CL | COVID-19 |

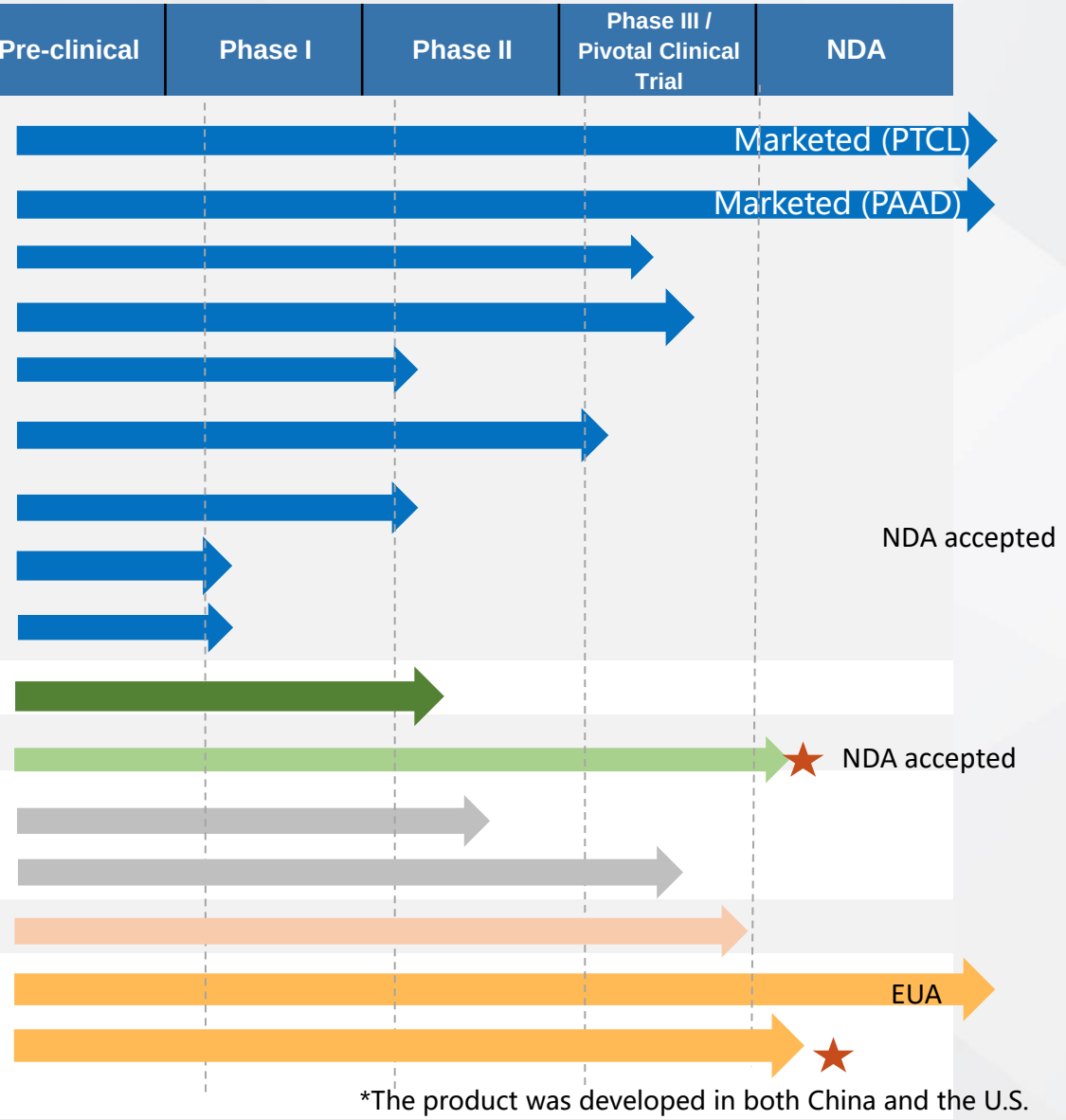



*The product was developed in both China and the U.S.

# Pipeline - New Preparation

Over 30 new preparations under development: 2 applied marketing approval, 11 under clinical trial, and over 20 under pre-clinical stage

| TA | Major Candidates | Indication(s) |
|---|---|---|
| Oncology | Mitoxantrone hydrochloride liposome injection * | Multiple hematologic neoplasms & solid tumors |
| | Irinotecan liposome * | Pancreatic cancer |
| | Daunorubicin cytarabine liposome | Leukemia |
| | Paclitaxel nanoparticles (fast dissolving) | Multiple solid tumors |
| | Paclitaxel cationic liposome | Advanced solid tumors |
| | Docetaxel for injection (albumin-bound) * | Multiple solid tumors |
| | Sirolimus for injection (albumin-bound) | Multiple hematologic cancers & solid tumors |
| | SYHA1908 for injection (class 1 new drug+nano drug) | Solid tumors |
| | Cisplatin micelle | Multiple solid tumors |
| Endocrinology | Octreotide long-acting injection | Acromegaly |
| Anti-infective | Amphotericin B liposome * | Invasive fungal infection |
| Cardio-cerebrovascular | Alprostadil liposome | Vasodilation |
| | Clevidipine injectable emulsion | Hypertension |
| Immune | Meloxicam nanocrystal injection | Moderate-to-severe pain |
| Vaccine | COVID-19 mRNA vaccine | COVID-19 |
| | Bivalent COVID-19 mRNA vaccine | COVID-19 |



# Pipeline Products Launch Plan

- 57 New Drugs /Indications approved in coming 6 years

Vaccine
Large molecule
Small molecule
New preparation
Non-oncology

## 2023

5

- mRNA vaccine COVID-19
- 3CL Pfizer licensed
- Desvenlafaxine Depression
- JMT103 (RANKL) GCTB
- Irinotecan lipsome Pancreatic cancer

## 2024

6

- Mingfule Acute ischemic stroke
- Omalizumab Urticaria
- Batoclimab MG
- Amphotericin B lipsome Invasive fungal infection
- DBPR108 (DPP4) Diabetes
- SYSA1802(PD-1) ≥2LCervical cancer

## 2025

10

- Meloxicam nanocrystal Postoperative analgesia
- Ulsinumab Plaque psoriasis
- NBP soft capsule VaD
- SYHA1402(Ari) Diabetic neuropathy
- Sirolimus for injection PEComa
- Docetaxel for injection (albumin-bound)) Pancreatic cancer
- JMT101(EGFR mAb) EGFR 20 ins NSCLC
- Clevidipine injectable emulsion Hypertension
- DP303C (HER2 ADC) Breast cancer
- Albumin-bound Paclitaxel II Breast cancer

## 2026

13

- mRNA vaccine RSV
- TG103 Obesity, Diabetes
- Semaglutide Diabetes
- Paliperidone palmitate (1M) Schizophrenia
- SYHA1813 Brain glioma
- SKLB1028（FLT3-TKI） r/r AML
- Pertuzumab biosimilar Breast cancer
- KN026 (Her2 BsAb) HER2 + Gastric cancer
- JMT601 (CD47/CD20) Lymphoma
- SYSA1801(CLDN 18.2 ) Gastric cancer
- Daunorubicin cytarabine liposome AML/AML-MRC
- Mitoxantrone liposome DLBCL
- Mitoxantrone liposome Nasopharyngeal carcinoma

## 2027

12

- mRNA vaccine Rabies
- SYHX1901 Psoriasis
- CM310 (IL-4Rα) Asthma
- Batoclimab TED
- Paliperidone palmitate (3M) Schizophrenia
- Dexmedetomidine Sedation
- Paclitaxel cationic liposome Solid tumors
- Simertinib (TKI) Solid tumors
- JMT 203 (GFRAL) Cancer cachexia
- KN026 (Her2 BsAb) HER2 + breast cancer
- NBL-020 (TNFR2) Advanced solid tumors
- ALMB0168(Cx43s) Osteosarcoma

## 2028

11

- mRNA vaccine VZV
- Tramadol celecoxib hydrochloride Pain
- Amoxetine Antidepressant
- Mitoxantrone liposome NMOSD
- Cisplatin micelle UC/pancreatic cancer
- SYHA1908 (C2 Docetaxel) Advanced solid tumors
- SYS6002 (Nectin4) Urothelial cancer
- NBL-015 (CLDN 18.2) Gastric cancer
- SYS6010 (EGFR ADC) Lung cancer/CRC/HNC
- SYH2051 (ATM inhibitor) Glioma
- SYHX2001 (PRMT5) Solid tumors

# Common Generics Launch Plan

**14 applications have been filed for marketing approvals，expecting to receive approval in 2024-2025；Over 20 candidates under pharmaceutical research，expecting to receive approval in 2026-2027**

| No. | Product | Therapeutic Area | Expected to be launched |
|---|---|---|---|
| 1 | Desvenlafaxine succinate extended-Release tablets (25mg) | Nervous system | 2024 |
| 2 | Dapagliflozin tablets | Digestion & Metabolism | 2024 |
| 3 | Rabeprazole sodium enteric-coated tablets | Digestion & Metabolism | 2024 |
| 4 | Olaparib tablets | Oncology | 2024 |
| 5 | Palbociclib tablets | Oncology | 2024 |
| 6 | Lenalidomide capsules (5mg, 10mg) | Oncology | 2024 |
| 7 | Peramivir injection | Anti-infective | 2024 |
| 8 | Aprepitant injection | Others | 2024 |
| 9 | Dexrazoxane for injection | Others | 2024 |
| 10 | Roxadustat capsules | Others | 2024 |
| 11 | Regorafenib tablets | Oncology | 2025 |
| 12 | Ilaprazole enteric-coated tablets | Digestion & Metabolism | 2025 |
| 13 | Tedizolid phosphate | Anti-infective | 2025 |
| 14 | Oseltamivir phosphate for oral suspension | Anti-infective | 2025 |

# IND Approvals Obtained as of November 30

| IND approval for the 1st indication (15+2) | |
|---|---|
| SYH2045 (solid tumors) | Meloxicam nanocrystal injection (moderate-to-severe pain for adults) |
| Clevidipine injectable emulsion (hypertension) | Octreotide long-acting injection (acromegaly) |
| NBL-020 (advanced solid tumors) | SYS6010 (advanced solid tumors) |
| SYH2051（solid tumors） | JMT203 (tumor cachexia) |
| Semaglutide injection(Type 2 diabetes) | NBL-028 (Advanced tumors) |
| SYS6006.32 （Bivalent COVID-19 mRNA vaccine） | Secukinumab injection (Psoriasis) |
| SYS6011 (Solid tumors) | SYH2038 (Advanced solid tunor) |
| SYH2053 （Primary hypercholesterolaemia or mixed dyslipidaemia in adults） | CPO301 (advanced solid tumors)（US& Canada) |
| **IND approval for additional indications (13)** | |
| KN026 for injection –in combination with docetaxel (albumin-bound) for the treatment of first-line HER2 positive recurrent and metastatic breast cancer | Docetaxel for injection (albumin-bound)-in combination with SG001 (PD-1) for perioperative treatment of NSCLC |
| Docetaxel for injection (albumin-bound)-in combination with SG001 (PD-1) and cisplatin with concomitant radiotherapy for the treatment of locally advanced esophageal cancer | Docetaxel for injection (albumin-bound)-in combination with SG001 (PD-1) and cisplatin with concomitant radiotherapy for the treatment of locally advanced unresectable NSCLC |
| Docetaxel for injection (albumin-bound)-neoadjuvant treatment for luminal breast cancer | SYH2055 tablets-prevention of COVID-19 |
| CM326-COPD | CM310（COPD） |
| Paclitaxel cationic liposome for injection- Arterial perfusion therapy in patients with advanced solid tumors who failed standard treatment | Simmitinib-in combination with SG001 (PD-1) for the treatment of solid tumors |
| SG001 (PD-1) -in combination with chemotherapy for first-line cervical cancer | JMT101-in combination with SG001 and Irinotecan for treatment of colorectal cancer |
| ALMB-0166（Acute ischemic stroke） | |

Part 05

# BD&ESG

# Strategic Layout and Roadmap in Business Development

**Focusing on strategic areas, deepening BD strategies, and establishing an international ecosystem in business development**

**Product Positioning:** Aligning closely with clinical needs, emphasizing clinical benefits, grasping international cutting-edge technology and product trends, strengthening the leading areas of the Group, focusing on key clinical stage products in the mid to late phases, and exploring the untouched fields of nephrology, ophthalmology and orthopedics

**Technology Platforms:** Actively exploring collaboration and development of early-stage products with AI pharmaceuticals, nucleic acid drug antigen screening platforms, gene therapy technologies, and novel vaccine development platforms

**Internationalization:** Pursuing a dual strategy of both licensing-in and licensing-out, expanding international projects with leading multinational pharmaceutical companies and the Belt-and-Road initiatives, reinforcing strategic relationships with investment funds having overseas resources, and advancing collaboration in global projects

**Ecosystem Construction:** Leveraging the advantages of the Group's clinical development, registration and commercialization, through "Pharma+Biotech" model, engaging in extensive and in-depth collaboration with Biotech companies or research institutions that possess innovative advantages in specific areas or technology platforms, meanwhile considering practical and feasible merger and acquisition, to continue supporting the Group's external innovation

## BD projects completed in Q1-Q3 of 2023

- **License-out:**
  - Granted Corbus Pharmaceuticals the development and commercialization rights for SYS6002 (Nectin-4ADC, Phase 1) in the United States, European Union countries, the United Kingdom, Canada, Australia, Iceland, Liechtenstein, Norway, and Switzerland.
- **License-in:**
  - Obtained Pfizer's exclusive authorization to locally market the oral antiviral COVID-19 treatment medication, Namatavir Tablets/Litoconavir Tablets, in China

# Key Therapeutic Area Strategy for 2023 in Business Development

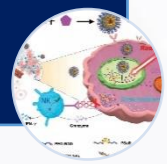
## Reinforce Leading Position in Established Areas

### Neurology Field

- Comprehensive Management of Stroke Disease, with a Focus on the Strategic Positioning and Collaboration of Innovative Drug Projects in Vascular Recanalization, Neuroprotection, and Anti-Inflammation that Synergize with the Company's Existing Resources
- Attention to Late-stage Clinical or Newly Approved Drugs in the Alzheimer's Disease (AD) Field, as well as Emerging Novel Targeted Therapeutics.

### Oncology Field

- Strengthen differentiation in hematologic malignancies, lung cancer, and breast cancer, focusing on targeted therapies, new immunotherapies, and combination treatments.
- Explore innovative drugs in areas such as digestive tract tumors, gynecological tumors, and urological tumors.



### Cardiovascular & Endocrinology Field

- Focus on challenging areas like refractory hypertension, hyperlipidemia, and heart failure.Pay attention to long-acting, oral diabetes/weight reduction innovative products.
- Address thyroid diseases and innovative treatments related to gout.

### Respiratory, Autoimmune & Anti-Infective Field

- Emphasize areas like idiopathic pulmonary fibrosis (IPF), COPD/asthma, and cough, exploring innovative targets, drug-device combinations, and drug delivery systems.
- Focus on high-end antibiotics effective against clinically resistant bacteria.
- Address conditions such as atopic dermatitis, systemic lupus erythematosus, and inflammatory bowel disease (IBD).

## Explore Novel Therapeutic Areas and Technology Platforms

### Nephrology Field

- Address primary and secondary kidney diseases like IgA nephropathy and diabetic nephropathy.
- Focus on complications of kidney diseases like renal anemia, hyperphosphatemic kidney disease, hypertension, and kidney-related itching.

### Ophthalmology Field

- Concentrate on well-established companies with mature late-stage ophthalmology pipelines.
- Focus on products for treating retinal diseases like AMD using new targets, long-acting formulations, nanomedicines, and gene therapies, with a special focus on geographic atrophy indications.

### Nuclear Medicine Field

- Focus on therapeutic nuclear medicine, breaking through new targets, new indications, and new isotopes while avoiding homogenization.
- Continuously research upstream isotope supply issues and address key problems related to downstream nuclear medicine construction and national regulatory dynamics.

### Psychiatry Field

- Expand into major population-based psychiatric disorders like depression and schizophrenia, focusing on the layout and collaboration of novel targeted drugs with improved efficacy, safety, and compliance.
- Emphasize fast-acting nasal spray formulations.

### Pain Management Field

- Chronic Pain: Focus on innovative drug projects that provide better pain relief, higher safety, and non-addictive properties.
- Acute Pain: Concentrate on innovative projects that extend postoperative pain relief duration while maintaining higher safety.

### Orthopedics Field

- Focus on unmet clinical needs in orthopedics, from completely innovative products to products that improve patient accessibility, and tap opportunities in orthopedics
- Focus on spine surgery-related drugs, osteoporosis iterations

# Aim to Become an ESG Leader in Pharmaceutical Industry

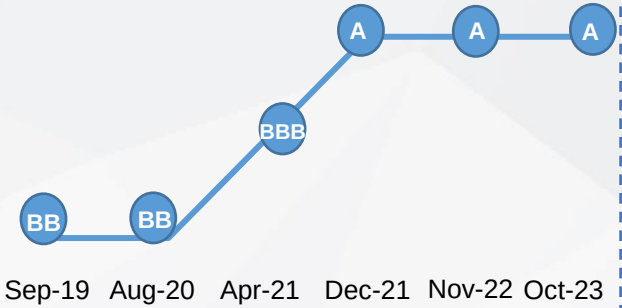
- Awarded “AAA Enterprise with Harmonious Labour Relations in Hebei Province” and “National Advanced Enterprise in Employment”
- Achieved “Five Zeros and One Low”*
- The major shareholder of the Group granted 220M conditional shares to over 300 employees in 2022
- Improving board diversity continuously

**People orientated, Win-win Future**

**Co-creation &Sharing, Hand-in-hand Development**

- Adhere to the procurement principle of “fair, impartial, green and transparent”
- Online bidding and procurement; supplier integrity commitment; *Blacklist Management System for Dishonesty*

**Continuous MSCI ESG rating upgrade**




**Environmentally-friendly, Carbon Emissions Reduction**

- Structural reduction of carbon emissions - the ratio of innovative drugs /formulations increasing and the ratio of APIs decreasing
- Invested RMB200m in upgrade of green factories in 2022
- A centralised process water system was put to use in No. 1 Manufacturing Centre in 2022, effectively reducing the use of water resources
- Ouyi and NBP (our subsidiaries) are recognized as “Green Factories” by the MIIT

**Mission-led, Responsibility taken**

- During the outbreak of Covid 19 in China, produced urgently needed drugs at full capacity to alleviate the market shortage; received gratitude from the MIIT
- CSPC Education Assistant Fund- helped 367 college students in 2022
- Medical care program for poor children- helped 63 children in 2022
- Cancer and critical illness patients assistant program- assisted 50 patients in 2022

## Environmental Protection Plan 2025

- ✓ Reduce greenhouse gas emissions per unit of revenue by 50%
- ✓ Reduce the emission of non-hazardous waste (general solid waste) per unit of revenue by 70%
- ✓ Reduce the discharge of hazardous waste per unit of revenue by 25%
- ✓ Reduce the comprehensive energy consumption by 47%
- ✓ Reduce the water consumption per unit of revenue by 27%

**The emission reduction target is based on the emission in 2017*

**Five Zeros and One Low- zero cases of death, serious injuries, multiple injuries, occupational disease and poisoning incident as well as low incident rate of minor injuries*


WeChat of CSPC IR Team：

# Thanks!