Approved Direct-Acting Antivirals for HCV in China (1/2)

- 16 Direct-Acting Antivirals (DAAs) for treating chronic hepatitis C have been approved in China.
- Emitasvir (Yimitasvir) of The Group was approved for marketing in 2020, and it was used in combination with Sofosbuvir to treat adult genotype 1 non-cirrhotic chronic hepatitis C, which is the most common chronic hepatitis C genotype in China. Yimitasvir has entered the national medical insurance catalogue in 2022.
- In addition, The Group has arranged a combination therapy of Netanasvir Phosphate capsules and Encofosbuvir tablets for people with pan-genotype chronic hepatitis C. Netanasvir has been approved recently and Encofosbuvir has been declared for marketing. They are expected to replace imported products with high treatment costs such as products from Gilead.

Approved DAAs for HCV in China

Drug Name	Formulation	Target	Company	Indication	Approval Date	NRDL Included
Netanasvir Phosphate (磷酸萘坦司韦)	Capsule	NS5A	The Group	Combination with Encofosbuvir for the treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	2025-02-08	No
Alfosbuvir (奥磷布韦)	Tablet	NS5B	Sanhome (圣和药业)	Combination with Daclatasvir Hydrochloride for the treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	2023-05-12	Category B
Emitasvir (依米他韦)	Capsule	NS5A	The Group	Combined Sofosbuvir for the treatment of genotype 1 non-cirrhotic chronic hepatitis C in adults	2020-12-21	Category B
Ravidasvir (拉维达韦)	Tablet	NS5A	Ascletis (歌礼生物)	Combination of Ritonavir-boosted Danoprevir and Ribavirin for the treatment of primed genotype 1b chronic HCV infection with non-cirrhotic liver disease in adults	2020-07-29	Category B
Coblopasvir (可洛派韦)	Capsule	NS5A	Beijing Kawin (凯因格领)	Combined Sofosbuvir for the Treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	2020-02-11	Category B

Note: As of Mar 13, 2025

Source: NMPA, Frost & Sullivan Analysis

Approved Direct-Acting Antivirals for HCV in China (2/2)

Approved DAAs for HCV in China

Drug Name	Formulation	Target	Company	Indication	Approval Date	NRDL Included
Sofosbuvir +Velpatasvir +Voxilaprevir (索磷布韦+维帕他韦 +伏西瑞韦)	Tablet	NS5B, NS5A, NS3/4A	Gilead	Chronic HCV infection in adults	2019-12-18	Category B
Glecaprevir +Pibrentasvir (格卡瑞韦+哌仑他韦)	Tablet	NS3/4A, NS5A	AbbVie	Genotype 1, 2, 3, 4, 5, or 6 chronic HCV infection in adults without cirrhosis or with compensated cirrhosis; patients with HCV genotype 1 who have received a prior regimen containing either an NS5A inhibitor or an NS3/4A protease inhibitor (but not a regimen involving both)	2019-05-15	No
Ledipasvir +Sofosbuvir (来迪派韦+索磷布韦)	Tablet	NS5B, NS5A	Gilead	Chronic HCV infection in adults and teens aged 12 to 18 years	2018-11-21	Category B
Danoprevir (达诺瑞韦)	Tablet	NS3/4A	Ascletis (歌礼生物)	Combination with ritonavir, PEG-IFNα and ribavirin to treat genotype 1b chronic hepatitis C in adults	2018-06-08	Category B
Sofosbuvir +Velpatasvir (索磷布韦+维帕他韦)	Tablet	NS5B, NS5A	Gilead	Chronic HCV infection in adults	2018-05-23	Category B
Elbasvir +Grazoprevir (艾尔巴韦+格拉瑞韦)	Tablet	NS3/4A, NS5A	MSD	Genotype 1 or 4 chronic hepatitis C (CHC) infection in adults	2018-04-28	No
Dasabuvir (达塞布韦)	Tablet	NS5B	AbbVie	Combination with other drugs to treat genotype 1 chronic hepatitis C in adults	2017-09-20	No
Ombitasvir +Paritaprevir +Ritonavir (奥比他韦+帕利瑞韦 +利托那韦)	Tablet	NS5A, NS3/4A, CYP3A4	AbbVie	Combination with other drugs to treat genotype 1 or 4 chronic hepatitis C in adults	2017-09-20	No
Sofosbuvir (索磷布韦)	Tablet	NS5B	Gilead	Combination with other drugs to treat chronic HCV infection	2017-09-20	No
Daclatasvir (达卡拉韦)	Tablet	NS5A	BMS	Combination with other drugs to treat chronic HCV infection	2017-04-24	No
Asunaprevir (阿舒瑞韦)	Capsule/Tablet	NS3/4A	BMS	Combination with daclatasvir to treat genotype 1b chronic hepatitis C in adults	2017-04-24	No

Note: As of Mar 13, 2025. Elbasvir+Grazoprevir (MSD) was included in NRDL(2022) and has been removed from NRDL(2023).

Source: NMPA, Frost & Sullivan Analysis

Growth Drivers of China Anti-HCV Drugs Market

Policy Support and Treatment Demand

There are about 9.0 million cases of hepatitis C virus infection in China in 2022. To implement the "Healthy China 2030" plan and the Healthy China Initiative (2019–2030), and to contribute to the global target of eliminating viral hepatitis as a public health threat by 2030, the National Health Commission of China and eight other government departments jointly issued the National Action Plan for Eliminating Hepatitis C as a Public Health Threat (2021–2030). From 2026 to 2030, the key tasks focus on reducing the prevalence of hepatitis C by further implementing the strategies of "testing all in need" and "treating all eligible" among all people living with chronic HCV infection. As a result, there is still a need for new hepatitis C drugs on the market, and studies have shown that if left untreated, hepatitis C can progress to cirrhosis and even liver cancer.

Improvement In Detection Rates and Education

Many patients are poorly aware of how hepatitis C is transmitted, its symptoms and how it can be treated. China is strengthening publicity and education, popularizing HCV knowledge and improving public awareness of HCV control and prevention. In the future, the diagnosis and treatment rates will be further improved.

The Demand of Cost-Effective Medications

Although the price of hepatitis C drugs has decreased, the cost of treatment remains a significant burden for many patients and the healthcare system. In some areas, the original drug for hepatitis C treatment has been included in the local medical insurance drug list, but the outpatient treatment is not fully guaranteed. There are also some cities that only have one basic medical insurance system (employee medical insurance or resident medical insurance) that includes hepatitis C antiviral drugs in the scope of outpatient drug reimbursement. So there is still a need for cost-effective hepatitis C antiviral drugs.

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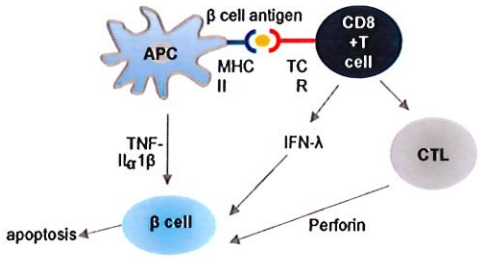
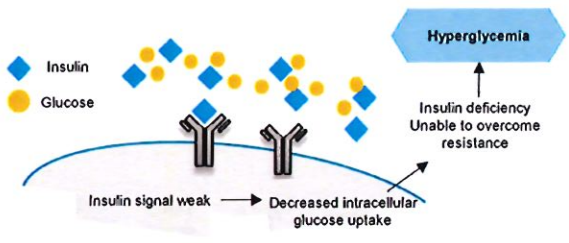
Introduction of Diabetes

- Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Diabetes can be classified into following general categories:

Type 1 diabetes	Due to β-cell destruction, usually leading to absolute insulin deficiency
Type 2 diabetes	Due to a progressive insulin secretory defect on the background of insulin resistance

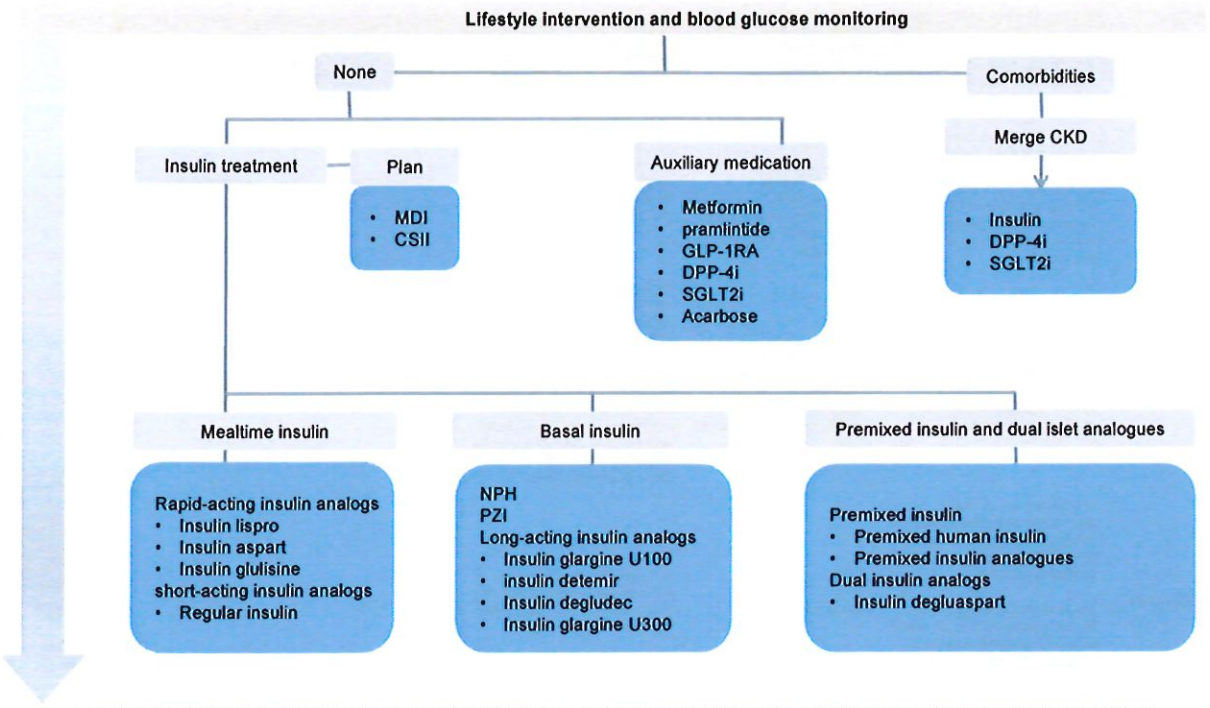




Gestational diabetes mellitus (GDM)	Diabetes diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes
Other types	Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young [MODY]), diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced diabetes (such as in the treatment of HIV/AIDS or after organ transplantation)

Source: IDF, ADA, Frost & Sullivan Analysis

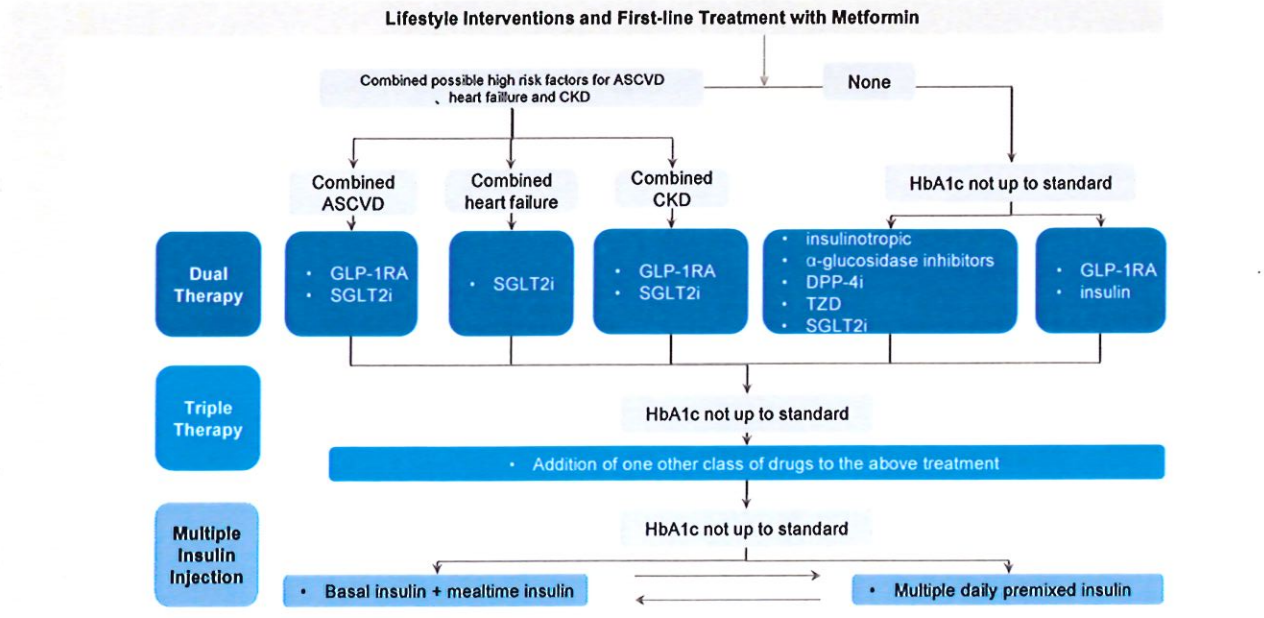
Treatment Paradigm for Type 1 Diabetes in China



1. *DPP-4i : a dipeptidyl peptidase IV inhibitor; SGLT2i : sodium-dependent glucose transporters 2 inhibitor; TZD : thiazolidinedione; GLP-1RA Glucagon-like peptide -1 receptor agonist; NPH: neutral protamine zinc insulin; PZI: protamine zinc insulin; MDI: multiple daily insulin injections; CSII: continuous subcutaneous insulin infusion*

Source: China Guidelines for the Diagnosis and Treatment of Type 1 Diabetes, Frost & Sullivan analysis

Treatment Paradigm for Type 2 Diabetes in China



1. *DPP-4i : a dipeptidyl peptidase IV inhibitor; SGLT2i : sodium-dependent glucose transporters 2 inhibitor; TZD: thiazolidinedione; GLP-1RA Glucagon-like peptide -1 receptor agonist*
2. *If glycemic control is not achieved (HbA1c ≥ 7.0%), proceed to the next step of treatment*

Source: Literature research, Frost & Sullivan Analysis

Comparative Analysis of Drugs for the Treatment of Diabetes (3/3)

Drug type	Mechanism	Representative drugs	Population	HbA1c Reduction	hypoglycemic Risk	Other Adverse Reactions	Combined Benefit Outcome
TZDs	• Insulin sensitizer increases the sensitivity of adipocytes, liver cells and skeletal muscle cells to insulin by stimulating peroxisome-proliferator-activated receptor gamma (PPARγ). • Promote the uptake, transport and oxidative utilization of blood glucose by insulin target cells	• Rosiglitazone • Pioglitazone	• Suitable for patients with heart failure, active liver disease or aminotransferase elevations exceeding 2.5 times the upper limit of normal, severe osteoporosis and a history of fractures	0.7%~1.0%	x	• Edema	• Linked to increased risk of fractures and heart failure
DPP-4 Inhibitor	• Inhibits the inactivation of glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) and increases endogenous GLP-1 and GIP levels • Promote insulin release from pancreatic beta cells • Inhibits glucagon secretion from pancreatic alpha cells	• Sitagliptin • Saxagliptin • vildagliptin • Linagliptin • Alogliptin	• When using sitagliptin, saxagliptin, alogliptin and vildagliptin in patients with renal insufficiency, care should be taken to reduce the drug dosage according to the drug instructions, while linagliptin does not require	0.4%~0.9%	x	• neurogenic inflammation • High blood pressure • Promote immune response	• Does not increase the risk of cardiovascular disease
SGLT-2 Inhibitor	• Inhibits SGLT-2 in the kidney tubules responsible for reabsorbing glucose from urine • Lower renal glucose threshold and promote urinary glucose excretion • Reduces glucose levels in the blood circulation	• Canagliflozin • Dapagliflozin • Empagliflozin	• Suitable for adults with type 2 diabetes • Not recommended for patients with severe hepatic impairment	0.5%~1.2%	x	• Urinary and reproductive system infections • Adverse reactions related to hypovolemia	• Significantly reduces the risk of developing the composite endpoint of major adverse cardiovascular events, heart failure hospitalizations, and renal events

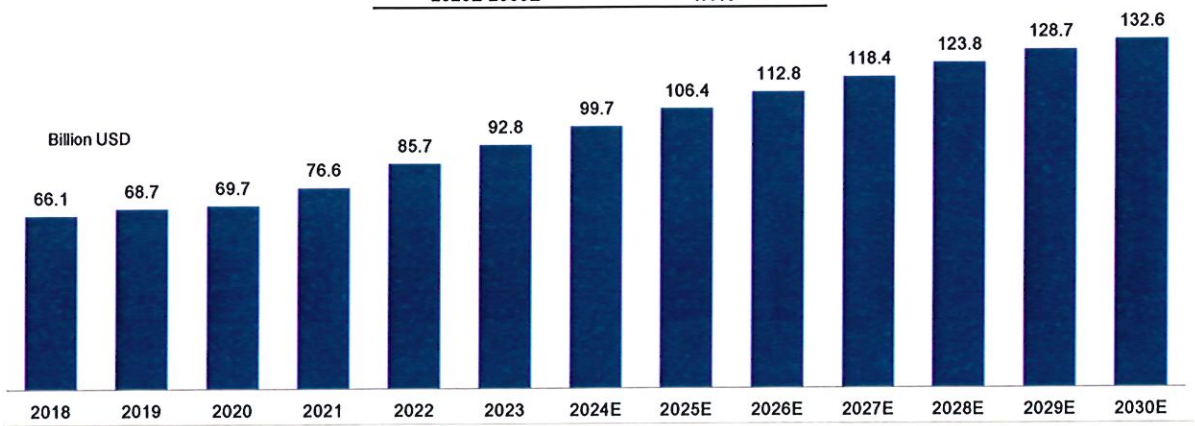
Source: Literature research, Frost & Sullivan Analysis

Global Diabetes Drug Market, 2018-2030E

- In 2023, the global market for diabetes drugs will reach 92.8 billion USD. It is estimated that the global diabetes drug market will grow to 132.6 billion USD in 2030.

Global Diabetes Market, 2018-2030E

Period	CAGR
2018-2023	7.0%
2023-2026E	6.7%
2026E-2030E	4.1%



Source: Annual Report, Frost & Sullivan Analysis

Growth Drivers of Diabetes Market in China

The number of patients is increasing

China has the largest number of patients in the world, and the number continues to grow rapidly. Population ageing is also an issue that cannot be ignored, and the number of patients with chronic diseases such as diabetes is expected to continue to increase as the global population aging trend intensifies. Patients with diabetes have the need to take drugs for a long time, with a huge demand for diabetes drug supply.

Government and health insurance policy support

At present, most of the diabetes treatment drugs in China have been included in the medical insurance catalog with the continuous improvement of medical insurance policies. Since the launch of centralized procurement of drugs, domestic companies have more opportunities to seize the market share.

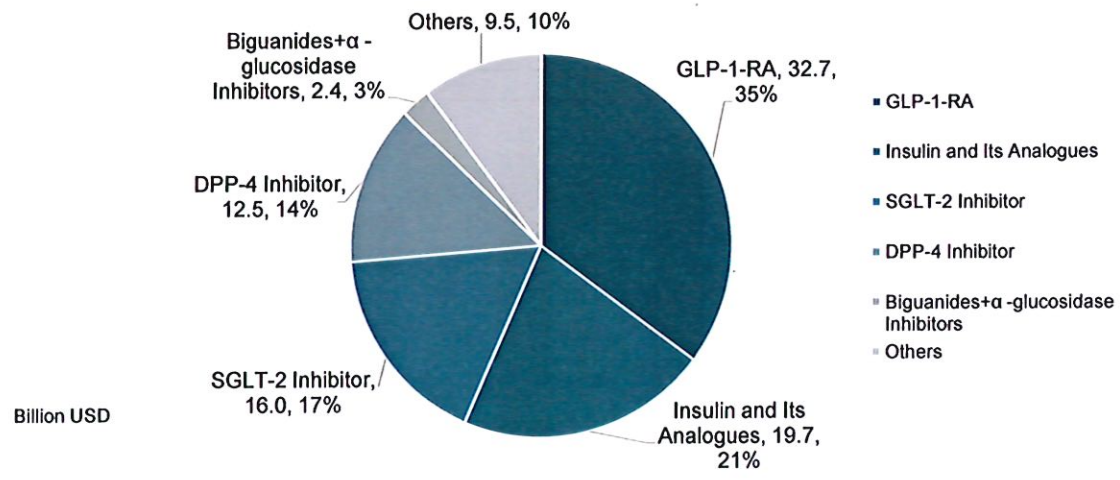
The market potential for drugs with new mechanisms is large

The Chinese market is dominated by traditional drugs such as biguanides, sulfonylureas and α-glycosidase inhibitors that have been on the market for decades. Due to the late entry of new drugs GLP-1 receptor agonists, DPP-4 inhibitors and SGLT-2 inhibitors into the Chinese market, the proportion of sales revenue brought by them is far less than that of other developed countries in the world. The market potential for drugs with new mechanisms is large.

Global Diabetes Drug Market, 2023

- In 2023, the global diabetes drug market has reached 92.8 billion USD, among which GLP-1 drugs, insulin and its analogues and SGLT-2 inhibitors account for the top three.

Global Diabetes Market, 2023



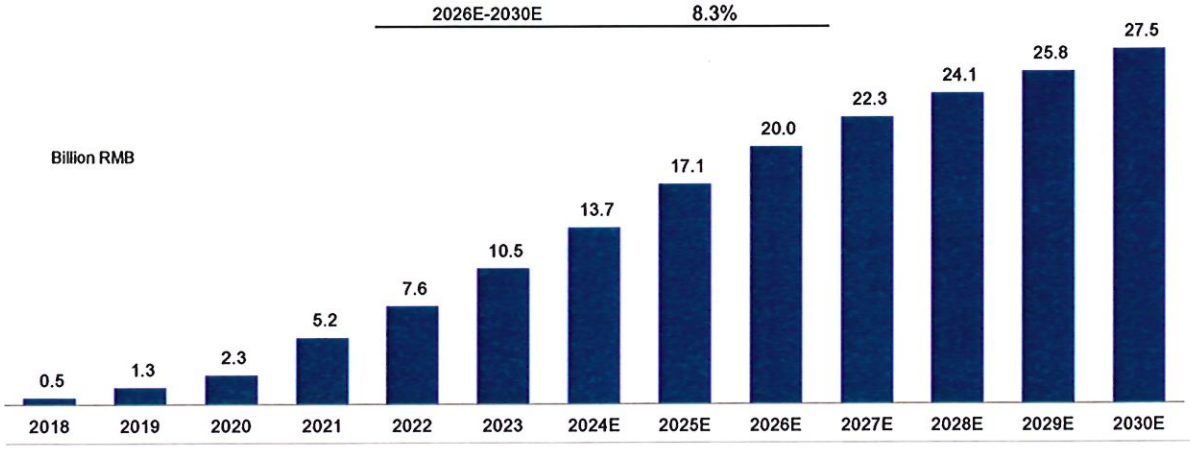
Source: Annual Report, Frost & Sullivan Analysis

China SGLT-2 Inhibitor Drug Market, 2018-2030E

- From 2018 to 2023, the market size of SGLT-2 inhibitor in China increased from 0.5 billion RMB to 10.5 billion RMB, with a CAGR of 83.5%. In the future, the market size of SGLT-2 inhibitor in China will continue to grow rapidly, and it is expected to reach 27.5 billion RMB in 2030 with a CAGR of 8.3% from 2026 to 2030.

China SGLT-2 Inhibitor Drug Market, 2018-2030E

Period	CAGR
2018-2023	83.5%
2023-2026E	23.8%
2026E-2030E	8.3%



Source: Annual Report, Frost & Sullivan Analysis

SGLT-2 Inhibitor Approved and in NDA Stage in China

SGLT-2 Inhibitor Approved in China

Company	Drug Name	Indication Approved	NRDL Included	Approval Date	Approved Generic Drugs
Astrazeneca (阿斯利康)	Dapagliflozin	Type 2 diabetes; Heart failure; Chronic kidney disease	Category B	2017-03-20	Yes
Boehringer-ingelheim (勃林格殷格翰)	Empagliflozin	Type 2 diabetes; Heart failure; Chronic kidney disease	Category B	2017-09-20	Yes
J&J (强生)	Canagliflozin	Type 2 diabetes	Category B	2017-09-29	Yes
MSD / Pfizer(默沙东/辉瑞)	Ertugliflozin	Type 2 diabetes	Category B	2020-07-29	No
Hengrui (恒瑞)	Henagliflozin	Type 2 diabetes	Category B	2021-12-31	No
Sihuan Pharma (四环制药)	Janagliflozin	Type 2 diabetes	NA	2024-01-19	No

Innovative SGLT-2 Inhibitor in NDA Stage in China

Company	Drug Name	Indication	Status	First Posted Date
Theracos/恒翼生物	Bexagliflozin	Type 2 diabetes	NDA	2024-01-04
The Group	Rongliflozin	Type 2 diabetes	NDA	2024-01-11

Note: As of Dec 3, 2024

Source: NMPA, Frost & Sullivan Analysis

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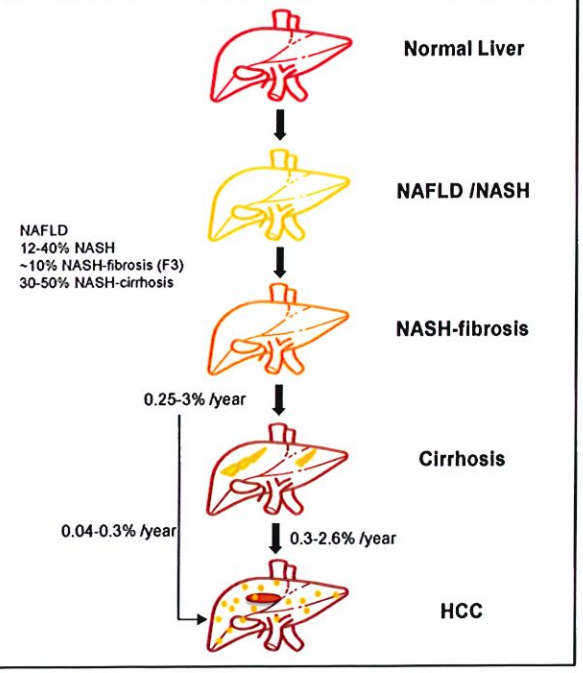
Overview of Non-Alcoholic Steatohepatitis (NASH)

Progression of NAFLD/ NASH



Overview

1 Brief Introduction

- Non-Alcoholic SteatoHepatitis (NASH) is the most severe form of non-alcoholic fatty liver disease (NAFLD). As NASH evolves, it can result in fibrosis, liver cirrhosis or liver cancer. In 2023, the terms NASH and NAFLD have been replaced by metabolic dysfunction-associated steatohepatitis (MASH) and metabolic dysfunction-associated steatotic liver disease (MASLD).

2 Symptom

- No symptoms in the early stages of NASH.
- As NASH progresses, symptoms of fatigue, weight loss for no clear reason, general weakness, an ache in the upper right part of the belly may show up.

3 Diagnosis

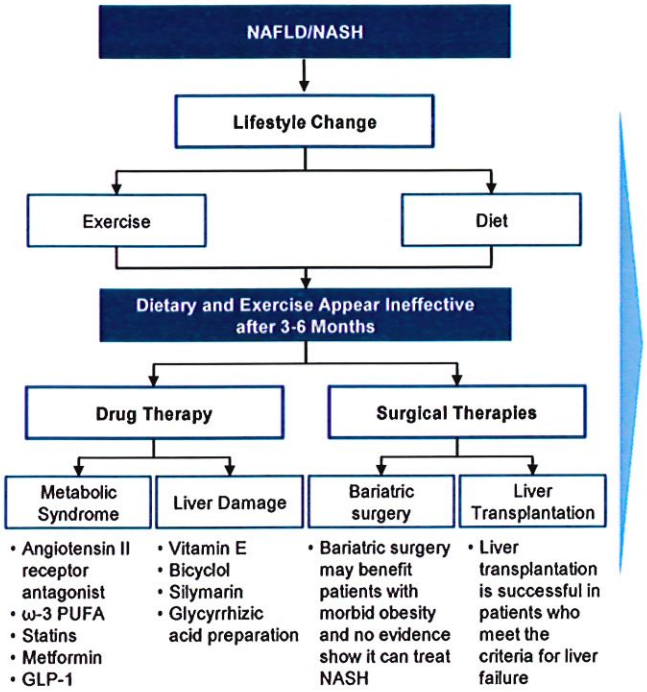
- Liver biopsy is the current gold standard to formally diagnose suspected NASH
- Alternative diagnostic tests for NASH and fibrosis include ultrasound, MRI, transient elastography, ultrasound elastography, MRE

4 Risk Factors

- Overweight and Obesity
- Type-2 diabetes
- Metabolic syndrome
- Insulin resistance

Source: Literature review, Frost & Sullivan analysis

Treatment Paradigm of NAFLD or NASH



Key Implication

1. **Lifestyle change is critical in any attempt to reverse the course of NAFLD**
   - Diet and exercise should be instituted for all patients to combat obesity
   - Lifestyle changes are the single most effective weapon in treating NAFLD
2. **At the present time, there is no evidence-based approved drug therapy for NAFLD**
   - At present, all the drugs applicated are used to treat the complication of NAFLD, lower the risk of further progression or prevent the risk of liver damage, such as statins, angiotensin II receptor antagonist, vitamin E etc. However, no evidence verifies their effects on treat of NAFLD
3. **There is no sufficient evidence to support the surgical therapies for NAFLD or NASH**
   - Bariatric surgery can relieve histological changes in the liver and lower the risk of cardiovascular disease, but no evidence shows it could treat NAFLD or Nash
   - Liver transplantation is difficult due to the lack of liver source, and NAFLD may recur or develop in the transplanted liver

Source: Literature review, Frost & Sullivan analysis

Unmet Need for NASH Treatment

Huge Patient Pool

- With a prevalence of 24% worldwide, nonalcoholic fatty liver disease (NAFLD) is now the most common liver disorder and is characterized by the buildup of excess fat in the livers of people who drink little to no alcohol. Nonalcoholic steatohepatitis (NASH) is the most severe form of NAFLD.
- The increasing prevalence of NASH is related to the growing obesity epidemic and the disease is diagnosed in patients who have diabetes, high cholesterol or high triglycerides.

Limited Treatment Options

- Despite such a high prevalence worldwide, there is no pharmacologic treatment approved specifically for NASH. A broad array of potential new drugs is currently under development, many of which are designed to decrease liver fat, inflammation, insulin resistance, and/or mitochondrial dysfunction.

Difficulties in Developing Drugs for NASH Treatment

- Numerous obstacles make drug development for NASH treatment a challenge. The complexity of the pathogenesis of the disease, which involves multiple pathways, requires targeting of more than one pathway or a combination-based therapy. The complex interactions among numerous metabolic pathways, the immune system, and the gut prevent the development of a "one drug-based therapy" that can provide a "cure" for NASH.

Low Awareness of Disease Progression

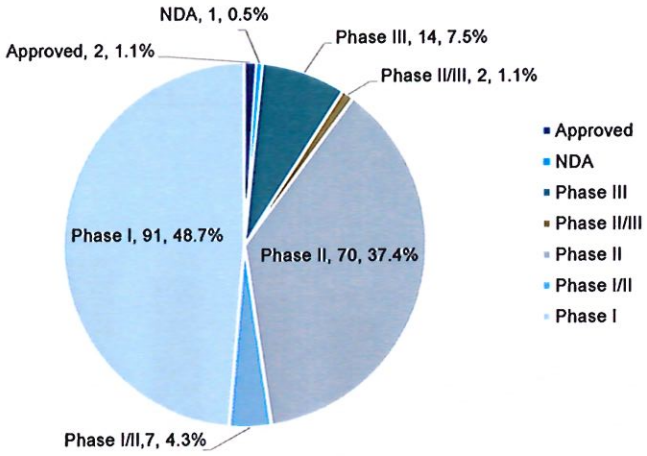
- NASH is now considered to be the leading, and a rapidly increasing, cause of hepatocellular carcinoma, or primary liver cancer, of which up to 40% of cases in NASH patients develop prior to developing cirrhosis. More than 20% of patients with NASH progress to cirrhosis within a decade of diagnosis and, compared to the general population, have a ten-fold greater risk of liver-related mortality.

Source: Literature review, Frost & Sullivan analysis

Global NASH/NAFLD Treatment Pipelines

- On March 14, 2024, resmetirom (Rezdiffra, Madrigal Pharmaceuticals) was approved by FDA, representing the first FDA approved medication for NASH. Rezdiffra is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). The other drug listed in the world is Saroglitazar Magnesium, which was developed by the Indian company Zydus Cadila and approved by the Indian Drug Management Center (DCGI) on March 6, 2020. As of Dec 3, 2024, no drugs for NAFLD/NASH treatment have been approved in China and Europe.
- There are 187 active pipelines in clinical trials for treating NASH/NAFLD in the world. Among them, 1 was in NDA state and 14 were in clinical phase III, most of them were in clinical phase II and clinical phase I.

Global NASH/NAFLD Treatment Pipelines



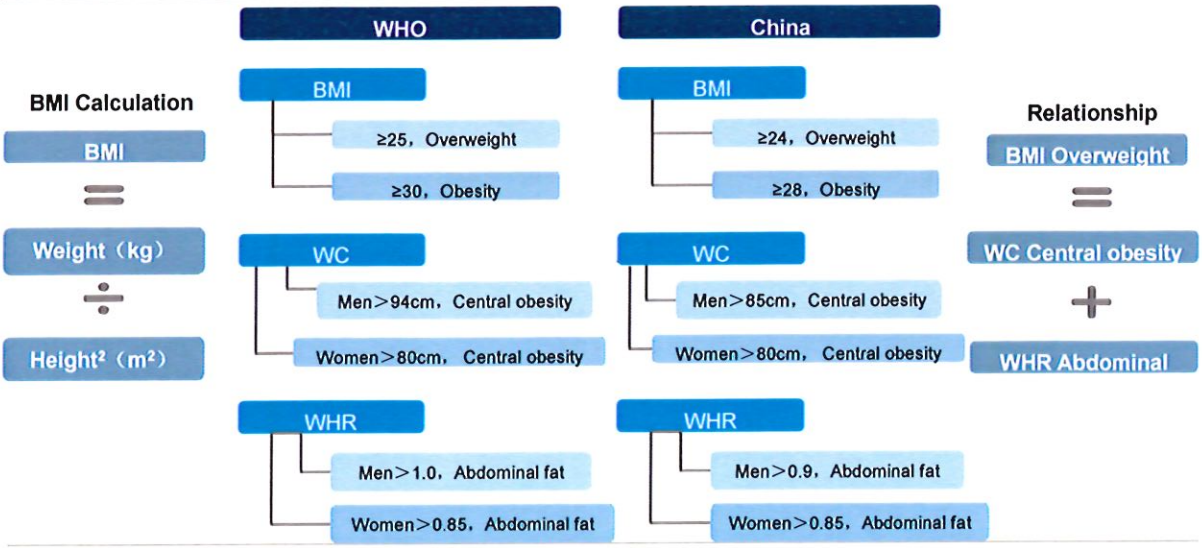
Note: As of Dec 3, 2024

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Overview of Obesity/Overweight

- Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health.
- At present, the commonly used body mass index (BMI) is an internationally recognized grading method for evaluating the degree of obesity/overweight. The specific calculation method is BMI= weight/height 2(kg/m2).
- According to the classification of WHO and National Institutes of Health (NIH), BMI≥25kg/m² is defined as overweight, and BMI≥30kg/m² is defined as obesity. In the Guidelines for Prevention and Control of Overweight and Obesity among Adults in China issued by the Department of Disease Control and Prevention of the Ministry of Health of China, the BMI cut-off value for obesity diagnosis in China was put forward, in which 24kg/m² ≤ BMI < 28kg/m² was overweight and BMI≥28kg/m² was obesity.

Comparison of obesity standards between WHO and China



Source: Frost & Sullivan Analysis

Overview of Idiopathic Pulmonary Fibrosis(IPF)

- Respiratory diseases are a type of diseases that affect the lungs and other parts of the respiratory system. Respiratory diseases may be caused by infection, smoking, or breathing in secondhand tobacco smoke, radon, asbestos, or other forms of air pollution. Common respiratory diseases include chronic obstructive pulmonary disease (COPD), asthma, bronchitis, pneumonia, pulmonary fibrosis, etc. In China, the market size of respiratory disease drugs in China reached about 82.1 billion RMB in 2023, with a CAGR of -2.5% during 2018 to 2023 due to the impacts of COVID-19 pandemic. It is estimated that this market size will grow in the future, reaching about 103.7 billion RMB in 2026 and 123.9 billion RMB in 2030.
- Idiopathic pulmonary fibrosis (IPF), the most common type of pulmonary fibrosis, is a type of lung disease which causes scarring (fibrosis) of the lungs. The word "idiopathic" means it has no known cause. Scarring causes stiffness in the lungs and makes it difficult to breathe.
- Lung damage from IPF is irreversible and progressive, meaning it gets worse over time. In some cases, it can be slowed by certain medications. Occasionally, people with IPF will be recommended for lung transplant.

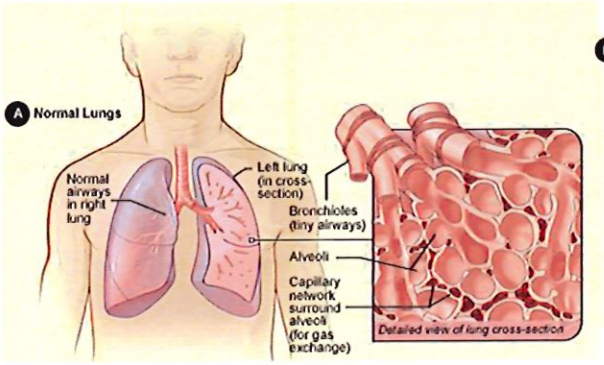


Figure A shows the location of the lungs and airways in the body. The inset image shows a detailed view of the lung's airways and air sacs in cross-section.

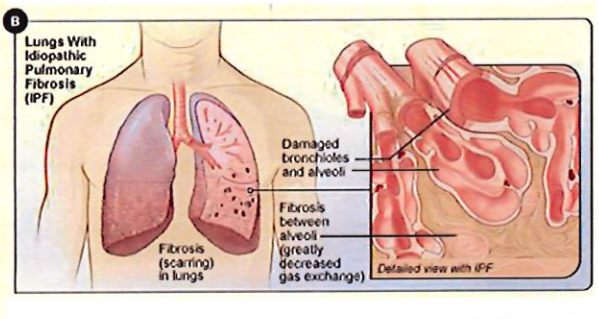


Figure B shows fibrosis (scarring) in the lungs. The inset image shows a detailed view of the fibrosis and how it damages the airways and air sacs.

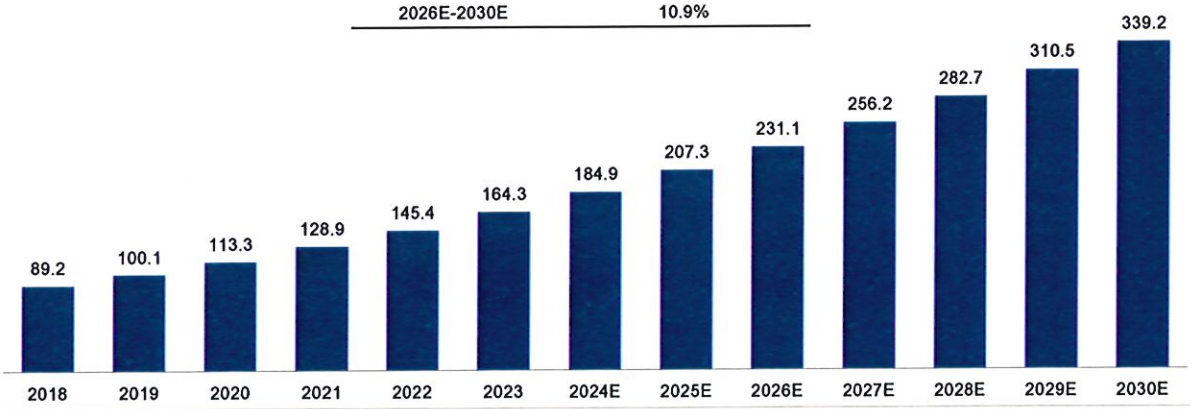
Source: Frost & Sullivan analysis

Prevalence of IPF in China, 2018-2030E

- The aging population, tobacco use and environmental air pollution all promote the rapid growth of IPF incidence. At the same time, the popularization and promotion of medical intervention measures and the education of patients and doctors will prolong the survival time of patients, reduce the mortality rate and increase the base of IPF patients. In 2023, the number of IPF patients reached 164.3 thousand, and the CAGR from 2018 to 2023 was 13.0%. It is estimated that by 2030, the number of patients will reach 339.2 thousand, and the CAGR from 2023 to 2030 will be 10.9%.

Prevalence of IPF in China, 2018-2030E

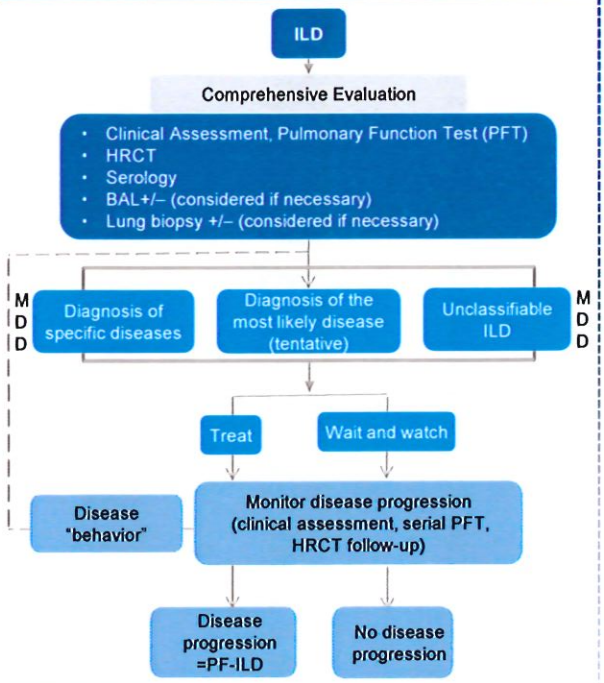
Period	CAGR
2018-2022	13.0%
2026E-2030E	10.9%



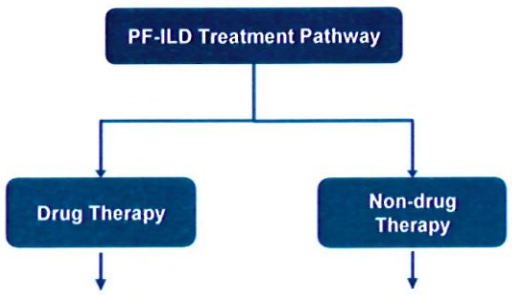
Source: WHO, Frost & Sullivan Analysis

PF-ILD Diagnosis and Treatment Process

PF-ILD Diagnosis Process



PF-ILD Treatment Pathway



- **Anti-fibrosis Therapy:** Nintedanib and Pirfenidone
- **Immunosuppressants:** Cyclophosphamide、Mycophenolate Mofetil、Methotrexate...
- **Glucocorticoid drugs:** Hormones exert their anti-inflammatory and immunosuppressive effects by affecting the functions of endothelial cells, fibroblasts and leukocytes.
- **Biological agents:** Rituximab, tocilizumab and other biological drugs need further experiments to verify the efficacy.

- **Lung Rehabilitation**
- **Oxygen Therapy**
- **Lung Transplantation**

Source: Literature Review, Frost & Sullivan Analysis

China Approved Drugs and Innovative Drug Pipelines in Pulmonary Fibrosis Treatment (1/2)

China Marketed Drugs in Pulmonary Fibrosis Treatment

Brand Name	Drug Name	Company	Indication	Approval Date	NRDL
Ofev	Nintedanib	Boehringer Ingelheim	IPF, SSc-ILD, chronic fibrotic interstitial lung disease with a progressive phenotype	2017/9/20	Category B
艾思瑞®	Pirfenidone	Continent (康蒂尼)	Mild and moderate IPF	2013/12/25	Category B

China Innovative Drug Pipelines for Pulmonary Fibrosis Treatment

Drug Name	Company	Target	Indication	Status	First Posted Date
BMS-986278 Tablets	BMS	LPAR1	IPF	Phase III	2023/12/28
			Progressive pulmonary fibrosis	Phase III	2023/12/15
Nerandomilast/ BI 1015550 Tablets	Boehringer Ingelheim	PDE4B	IPF	Phase III	2022/12/29
			PF-ILD	Phase III	2022/12/23
SC1011 Tablets	Biocity (无锡智康弘仁)	/	IPF	Phase II/III	2023/2/23
Bexotegrast	Pliant Therapeutics	Integrin αvβ1 Integrin αvβ6	IPF	Phase II/III	2024/10/18
BI 1839100	Boehringer Ingelheim	ion channel	Progressive pulmonary fibrosis	Phase II	2024/10/22
			IPF		
BI 1819479	Boehringer Ingelheim	/	IPF	Phase II	2024/08/26
TDI01 Oral Suspension	Tide Pharmaceutical (泰德制药)	ROCK2	IPF	Phase II	2023/8/21

Note: As of Dec 3, 2024.

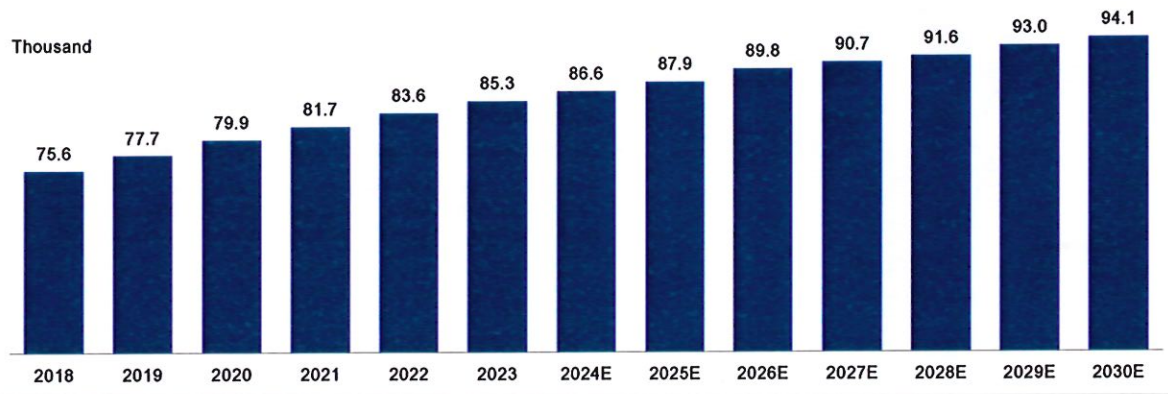
Source: CDE, Frost & Sullivan Analysis

Prevalence of Pulmonary Arterial Hypertension (PAH) in China, 2018-2030E

- Diagnosis of PAH is typically confirmed through right heart catheterization, which is usually performed in Grade III hospitals.
- Many diseases such as congenital heart disease, connective tissue disease, portal hypertension, hemolytic anemia and schistosomiasis may lead to PAH, which represents a large patient pool in China and will further drive the prevalence of PAH.
- The prevalence of PAH in China reached 85.3 thousand in 2023, with a CAGR of 2.4% from 75.6 thousand in 2018. It is predicted that such number will reach 94.1 thousand in 2030, with a CAGR of 1.4% from 2023 to 2030.

Prevalence of PAH in China, 2018-2030E

Period	CAGR
2018-2023	2.4%
2023-2030E	1.4%



Source: Literature review, Frost & Sullivan analysis

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Overview of Depression Treatment

- Depression is a common disease with substantial morbidity and mortality. The direct and indirect costs associated with major depressive disorder are significant, including direct patient care, time lost from work and potential income loss due to suicide. The main treatments of depression are medical therapies, psychotherapy and electroconvulsive therapy.

Major Therapies in Depression Treatment

Therapy	Main Drugs
Chemistry Medicine Therapy	• **Noradrenergic and specific serotonergic antidepressants (NaSSAs)** act by antagonizing the α_2-adrenergic receptor and certain serotonin receptors such as 5-HT_{2A} and 5-HT_{2C}, but also 5-HT_3, 5-HT_6, and/or 5-HT_7 in some cases: e.g., mirtazapine • **Selective serotonin reuptake inhibitors (SSRIs)** work by altering the amount of a chemical in the brain called serotonin: e.g., fluoxetine, paroxetine • **Serotonin and norepinephrine reuptake inhibitors (SNRIs)** treat depression by increasing availability of the brain chemicals serotonin and norepinephrine: e.g., venlafaxine • **5-HT1A receptor partial agonist and SERT inhibitor (SPARI)** is a kind of multi-target drug that can simultaneously target both 5-HT1A and serotonin transporter, proposing a nove lstrategy with enhanced efficacy. • **Melatonin receptor agonists (MRAs)** Melatonin receptor agonists are analogues of melatonin that bind to and activate the melatonin receptor. Agonists of the melatonin receptor have a number of therapeutic applications including treatment of sleep disorders and depression. There is no MRAs listed in USA. • **A norepinephrine–dopamine reuptake inhibitors (NDRIs)** is a drug that acts as a reuptake inhibitor for the neurotransmitters norepinephrine and dopamine by blocking the action of the norepinephrine transporter (NET) and the dopamine transporter (DAT), respectively.
Electroconvu-lsive Therapy	With ECT, electrodes are placed on the patient's scalp and a finely controlled electric current is applied while the patient is under general anesthesia. ECT is one of the fastest ways to relieve symptoms in severely depressed or suicidal patients.

Source: Literature research, Primary interview, CMA, Frost & Sullivan analysis

Innovative Drugs for Depression Treatment Pipelines in China (1/2)

Innovative Drugs for Depression Tretment Pipelines in China

Drug Name	Classification	Target	Company	Indication	Status	First Posted Date
Brexpiprazole Tablet	5.1	DRD2 HTR2A HTR1A	Otsuka (大冢制药)	Depression	NDA	2022/12/24
Mitizodone	1	SERT HTR1A HTR1B	The Group	Depression	Phase II/III	2021/7/12
HS-10353	1	/	Hansoh (豪森药业)	Postpartum Depression	Phase II	2023/7/3
				Depression	Phase II	2023/7/5
Ammoxetine Hydrochloride Tablet	1	SLC6A4 SLC6A2	CSPC (石药集团)/ Academy of Military Medical Sciences(军事医学科学院)	Depression	Phase II	2023/2/13
Liafensine	1	SLC6A4 SLC6A3 SLC6A2	Denovo (索元生物)	Treatment-resistant Depression	Phase II	2022/7/29
GW117	1	MTNR1A MTNR1B HTR2C	Greatway (广为医药)	Depression	Phase II	2022/5/27
JJH201501	1	SLC6A4	Jebel (吉贝尔药业)	Major Depressive Disorder	Phase II	2019/10/29
Hypidone Hydrochloride	1	SLC6A4 HTR1A	Huahai (华海药业)/ Academy of Military Medical Sciences(军事医学科学院)	Major Depressive Disorder	Phase II	2018/2/3
SAL0114	1	/	Salubris (信立泰)	Depression	Phase I/II	2024/01/15

Source: CDE, Frost & Sullivan Analysis

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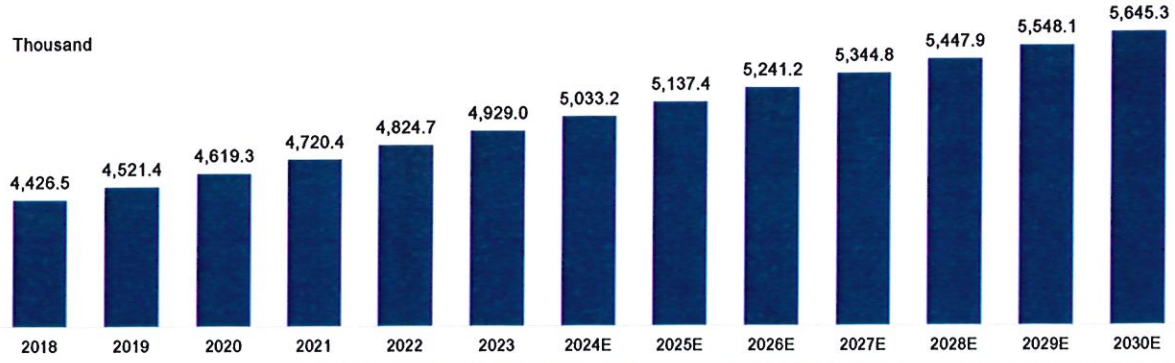
Incidence of Total Cancer in China, 2018-2030E

- Cancer has been the second largest disease in China, the new cases is growing to 4.9 million in 2023 from 4.4 million in 2018 with the CAGR of 2.2%. Due to the awareness and diagnosis for cancer, the number of new cases will increase to 5.6 million in 2030 with the CAGR of 2.0% from 2023 to 2030.

Total Cancer Incidence in China, 2018-2030E

Period	CAGR
2018-2023	2.2%
2023-2030E	2.0%



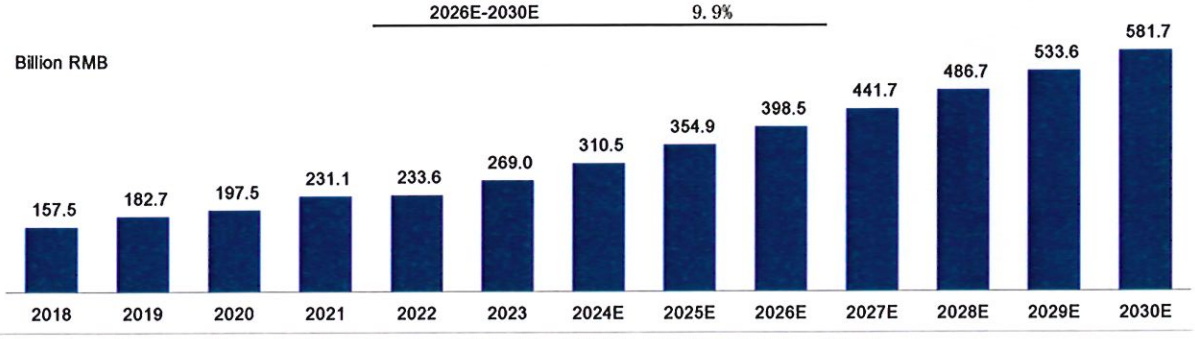
Source: Frost & Sullivan Analysis

China Oncology Drug Market, 2018-2030E

- In Chinese drug market, sales of oncology products has risen steadily in the recent years. China oncology market, generating RMB 269.0 billion in 2023, experienced a CAGR of 11.3% over the past 5 years.
- The ever-changing of successful innovative oncology treatments have promised a high return of pharmaceutical manufacturers. China oncology market is expected to uptrend in the following years. Forecasted data shows that China oncology market would be RMB 581.7 billion in 2030, representing a CAGR of 9.9% from 2026 to 2030.
- While competition in China's oncology drug market is fierce, companies with in-house capabilities throughout the entire value chain of oncology drug development, including drug discovery, process development, clinical development, quality control and assurance and commercialization, are better positioned to capture the growth potential of this market.

China Oncology Drug Market, 2018-2030E

Period	CAGR
2018-2023	11.3%
2023-2026E	14.0%
2026E-2030E	9.9%

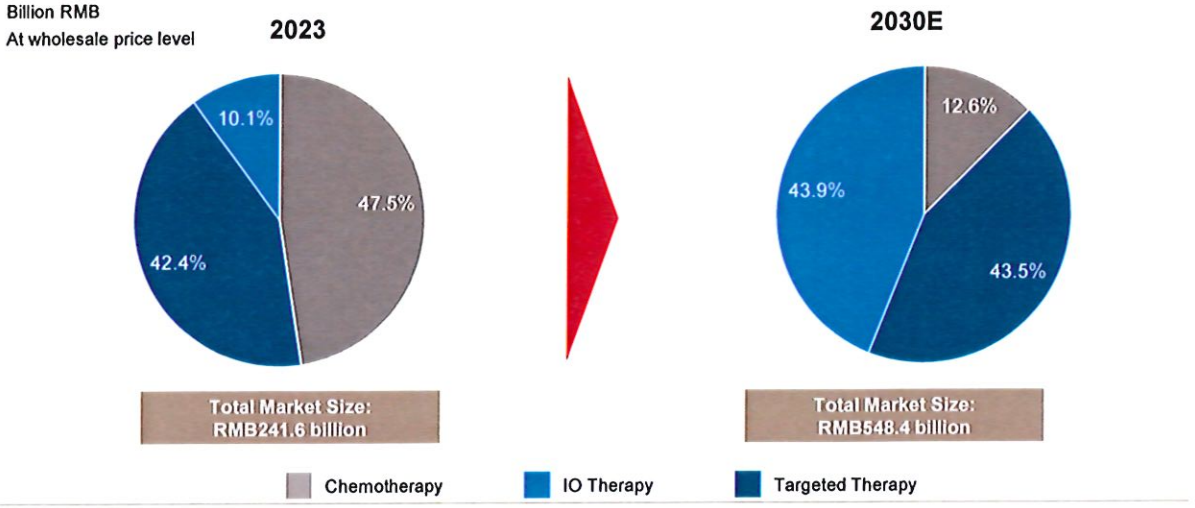


Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Breakdown of China Oncology Market by Therapy, 2023 and 2030E

- Currently, China oncology market is dominant by chemotherapy drugs which takes up to 47.5% of total. Targeted drugs including small-molecularly targeted drugs, biologics, are taking a proportion of 42.4%, leaving 10.1% for IO therapy in 2023.
- With reimbursement policies, new drug development and patients' increasing affordability, the targeted therapy and IO therapy would occupy most of the market by 2030. It is expected that the share of IO therapy approaches 43.9% while targeted drugs share would reach 43.5%.

Breakdown of China Oncology Market by Therapy, 2023 and 2030E



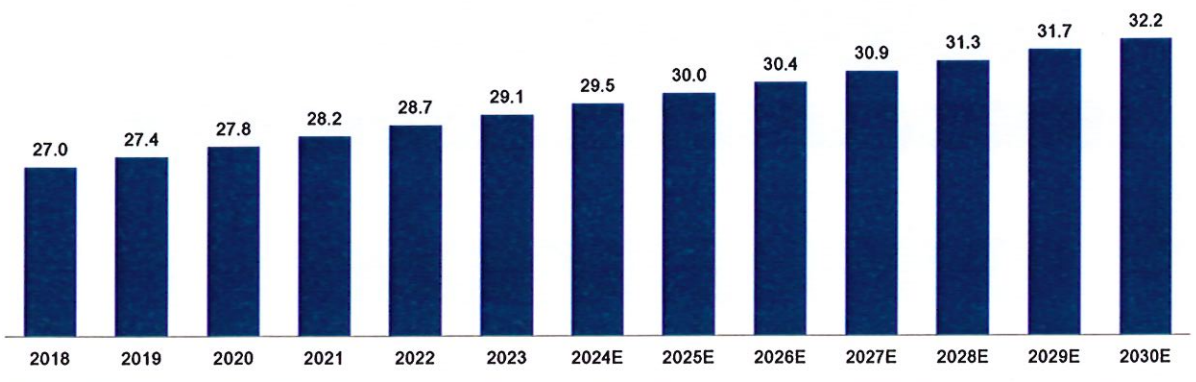
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Incidence of AML in China, 2018-2030E

- In 2023, there were about 29.1 thousand new cases of acute myeloid leukemia (AML) in China, with a CAGR of 1.5% from 2018 to 2023. It is estimated that there will be about 30.4 thousand new cases in 2026 and about 32.2 thousand new cases in 2030.

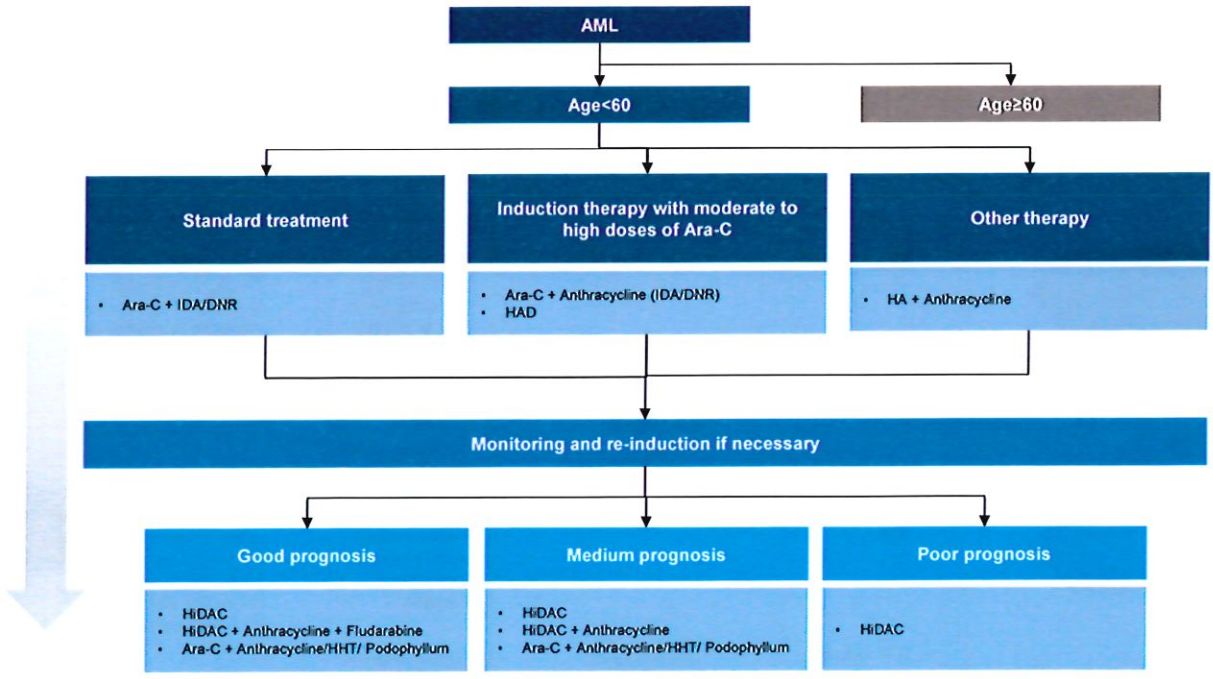
Incidence of AML in China, 2018-2030E

Period	CAGR
2018-2023	1.5%
2023-2030E	1.4%



Source: NCCR, Frost & Sullivan Analysis

Treatment Paradigm of Acute Myeloid Leukemia (AML) in China - 1



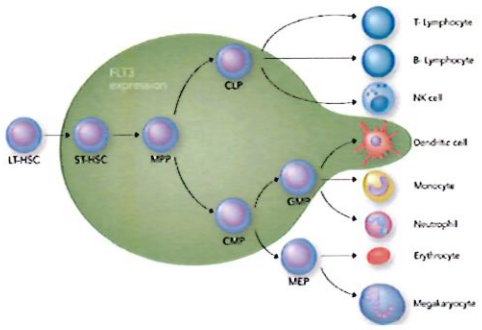
HAD: HHT+Ara-C+DNR; HA: HHT+Ara-C; HiDAC: High dose Ara-C

Source: Chinese Society of Hematology, Frost & Sullivan Analysis

FLT3 Mutation in AML

- FLT3 is a transmembrane ligand-activated receptor tyrosine kinase that is normally expressed by hematopoietic stem or progenitor cells and plays an important role in the early stages of both myeloid and lymphoid lineage development.
- Mutations of FLT3 are found in approximately 30% of newly diagnosed AML cases and occur as either ITDs (20%~ 25%) or point mutations in the TKD (5%~10%).
- FLT3-ITD mutation is a driver mutation that presents with a high leukemic burden, confers a poor prognosis, and has a significant negative impact on the management of patients with AML. About 75% of patients with FLT3ITD–mutated AML at diagnosis continue to have the ITD mutation at relapse.

FLT3 Expression in AML



Source: Frost & Sullivan Analysis

China FLT3 Inhibitor for AML Treatment Pipelines (1/2)

- Only 1 FLT3 inhibitor was approved for the treatment of AML in China.
- 11 FLT3 inhibitors for AML are in clinical trials. 5 FLT3 inhibitors in clinical phase III, and Clifutinib of The Group entered clinical phase III in October 2022.

Marketed FLT3 Inhibitor for AML Treatment in China

Brand Name	Drug Name	Company	Indication	Approval Date	NRDL
Xospata	Gilteritinib	Astellas	Recurrent or refractory AML with FLT3 mutation in adults	2020/3/5	Not included

China FLT3 Inhibitor for AML Treatment Pipelines

Pipeline	Company	Target	Indication	Status	First Posted Date
XY0206	Yiling Pharmaceutical (以岭药业)	FLT3, KIT, PDGFRB, RET, VEGFR2	Relapsed/refractory AML with FLT3-ITD mutation	Phase III	2023-04-6
Clifutinib	The Group	FLT3	Relapsed/refractory AML with FLT3-ITD mutation	Phase III	2022-10-19
			AML in newly diagnosed adult	Phase I/II	2021-10-22
SKLB1028	CSPC（石药集团）	FLT3, EGFR, LYN, ABL	Relapsed/refractory AML with FLT3 mutation	Phase III	2020-12-28
			Newly diagnosed AML	Phase I/II	2021-06-07
Crenolanib	Arog Pharmaceuticals（济莱安生物科技）/Patheon	FLT3, KIT, PDGFR	Relapsed/refractory AML with FLT3 mutation	Phase III	2020-04-15
Qizartinib	Daiichi Sankyo/ Patheon France/ Covance (科文斯)	FLT3	Newly diagnosed AML with FLT3-ITD mutation	Phase III	2017-06-28

Note: 1. Jilaian (Shanghai) Biotechnology is a wholly-owned subsidiary of Arog Pharmaceuticals, Inc, headquartered in Dallas, Texas, USA.
2. As of Dec 3, 2024

Source: NMPA, CDE, Frost & Sullivan Analysis

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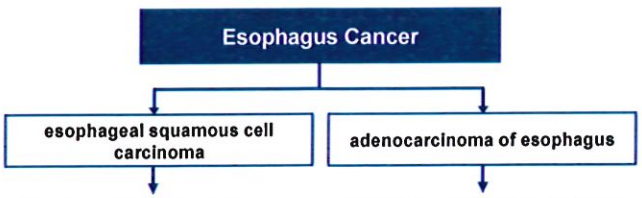
Overview of Esophagus Cancer

- Esophagus cancer, one of the most common cancer around the world, arises from the lining cells of esophagus .
- Esophagus cancer cells that derived from different layers of esophagus wall behave differently. There are two main types of esophagus cancer, based on the type of cell it starts in. The esophageal squamous-cell carcinoma(ESCC) is more common in the developing world while the esophageal adenocarcinoma(EAC) is more common in developed countries.



- Esophageal squamous cell carcinoma (ESCC) mainly occurs in the eastern and developing countries especially in China. Esophageal squamous cell carcinoma is usually diagnosed in the middle and late stage, so the overall prognosis is poor and the 5-year survival rate is only between 10% and 20%.

- Adenocarcinoma of the esophagus is a malignant tumor from the gland of the cardia or submucosa of the esophagus. In western countries such as the United States, it has been the highest incidence rate of esophageal malignancy. The incidence rate of male is generally higher than that of female.

Risk Factors

Tobacco and alcohol

The use of tobacco products, including cigarettes, cigars, pipes, and chewing tobacco, is a major risk factor for esophageal cancer.

Age

Gender

Men are more likely than women to get esophageal cancer.

Diet

Frequently drinking very hot may increase the risk for the squamous cell type of esophageal cancer.

Source: ACS, NCCN Guideline, ESMO Clinical Practice Guidelines, Frost & Sullivan Analysis

China Esophageal Cancer Treatment Small Molecule Targeted Therapeutic Drugs Pipelines

Marketed Esophageal Cancer Treatment Small Molecule Targeted Therapeutic Drugs in China

None

China Esophageal Cancer Treatment Small Molecule Targeted Therapeutic Drugs Pipelines

Pipeline	Target	Company	Indication	Status	First Posted Date
KC1036	VEGFR2, AXL	Beijing Konruns (康辰药业)	Esophageal Squamous Cell Carcinoma	Phase III	2023/12/26
Larotinib	EGFR	The Group	Esophageal Squamous Cell Carcinoma	Phase III	2020-05-27
Simmitinib	CSF1R FGFR VEGFR2	CSPC/Shanghai Runshi (上海润石)	Esophageal Squamous Cell Carcinoma	Phase II	2024/2/18
JAB-3068	SHP2	Jacobio (加科思药业)	Esophageal Squamous Cell Carcinoma	Phase I/II	2021-01-22
Donafenib	FLT3, BRAF, KIT, RAF1, BRAF V600E, VEGFR2, VEGFR3, PDGFRB	Zelgen (泽璟制药)	Digestive Cancer (include esophageal cancer)	Phase I/II	2020-11-3
AN0025/ Palupiprant	PTGER4	Adlai Nortye (杭州阿诺)	Esophageal Cancer	Phase I	2021-11-26

Note: As of April 3, 2024

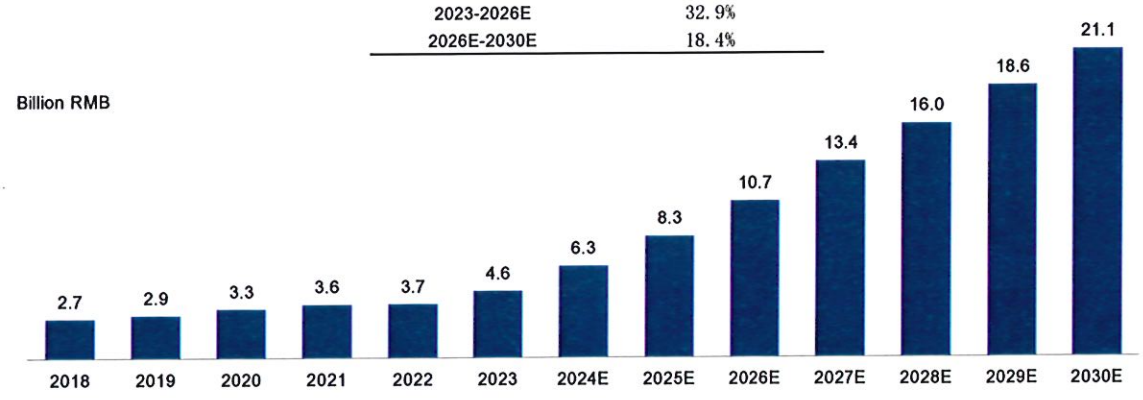
Source: Clinicaltrials.gov, CDE, Frost & Sullivan Analysis

Esophagus Cancer Drug Market in China, 2018-2030E

- China's esophagus cancer drug market size will reach RMB4.6 billion in 2023, with a CAGR of 11.1% from 2018 to 2023. Due to the large number of patients in China and the continuous expansion of medical insurance coverage, and the future approval of targeted drugs, the market size will climb to RMB10.7 billion and RMB21.1 billion in 2026 and 2030 respectively.

Esophagus Cancer Drug Market in China, 2018-2030E

Period	CAGR
2018-2023	11.1%
2023-2026E	32.9%
2026E-2030E	18.4%



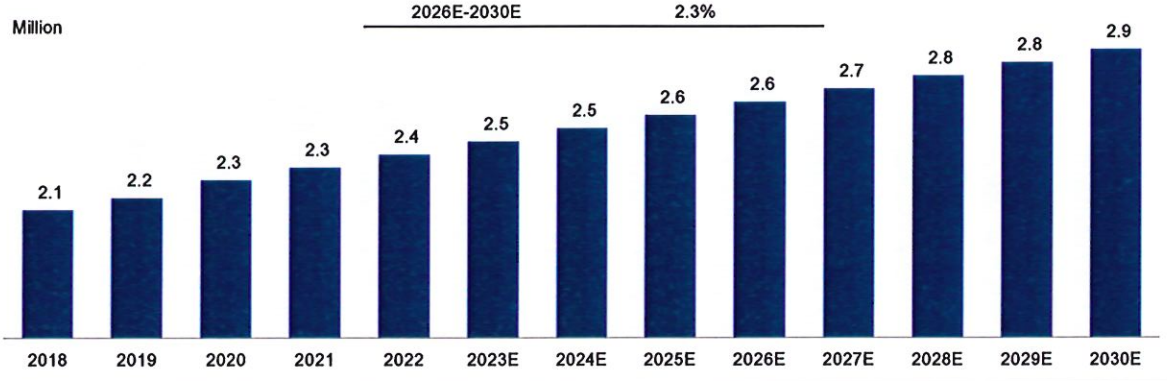
Source: Frost & Sullivan Analysis

Incidence of Cancer and Chemotherapy-Related Anemia in China, 2018-2030E

- With the increasing incidence of cancer in China and the increasing penetration rate of chemotherapy drugs, including new small molecule targeted drugs, it is expected that the incidence of CRA will continue to increase.
- In 2022, there were about 2.4 million new cases of CRA in China, with a CAGR of 3.0% from 2018 to 2022. It is estimated that there will be about 2.6 million new cases in 2026 and about 2.9 million new cases in 2030.

Incidence of Cancer and Chemotherapy-Related Anemia in China, 2018-2030E

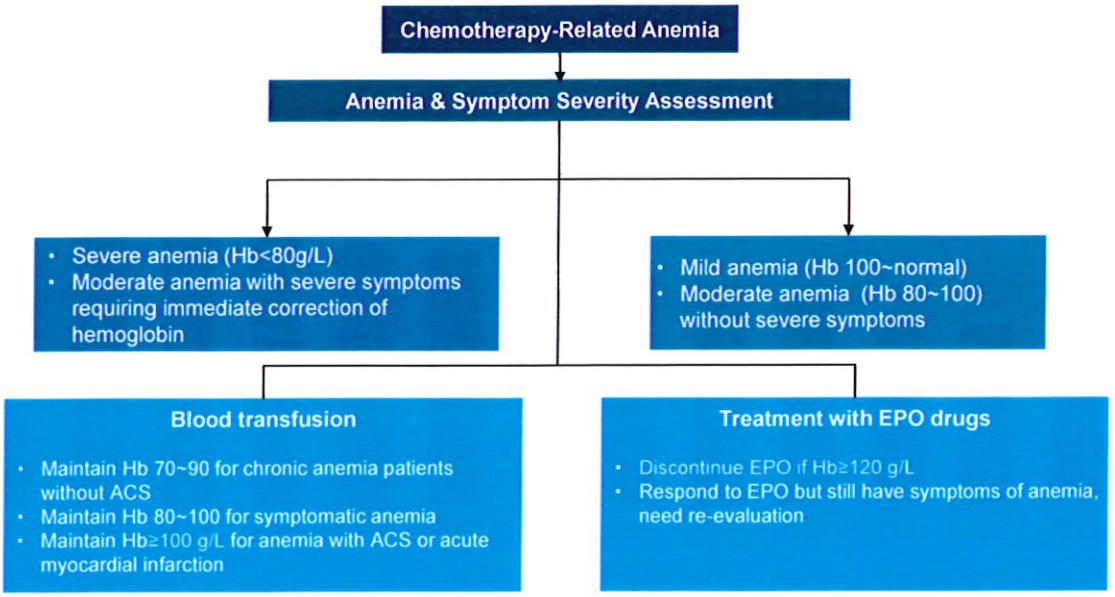
Period	CAGR
2018-2022	3.0%
2022-2026E	2.6%
2026E-2030E	2.3%



Source: Frost & Sullivan analysis

Treatment Paradigm of CRA in China

- Myelosuppression is a common adverse effect of chemotherapy and radiotherapy for tumors. Chemotherapeutic agents promote apoptosis of red lineage cells and can also cause renal damage and anemia by damaging renal tubular cells leading to a decrease in endogenous EPO.



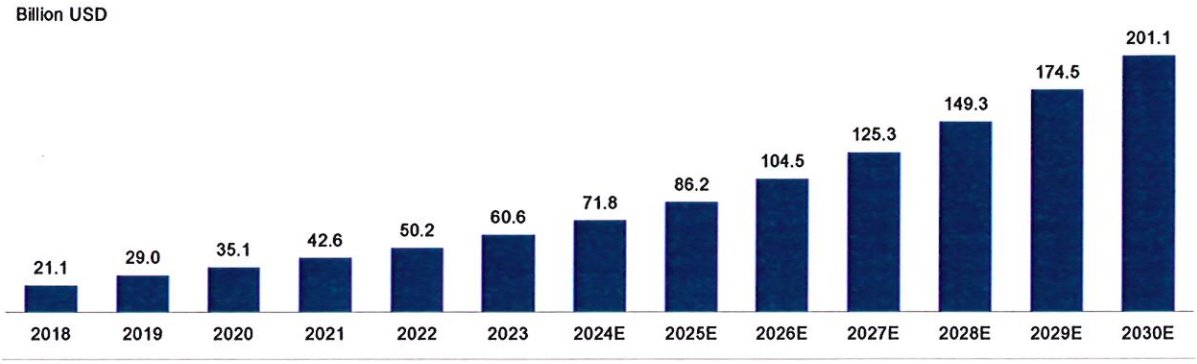
Source: Clinical guidelines on tumor associated anemia (CSCO 2022), Frost & Sullivan analysis

Global Immuno-Oncology Drug Market, 2018-2030E

- Immuno-Oncology therapies are emerging cancer therapies in global market, including the therapies of cytokines, therapeutic cancer vaccine, checkpoint antibodies and adoptive cell transfer therapies. In 2023, global Immuno-Oncology therapies market has reached US$ 60.6 billion, growing from US$ 21.1 billion in 2018. It is expected to reach US$104.5 billion in 2026 and US$201.1 billion in 2030 at a CAGR of 19.9% from 2023 to 2026 and 17.8% from 2026 to 2030.

Global Immuno-Oncology Drug Market, 2018-2030E

Period	CAGR
2018-2023	23.5%
2023-2026E	19.9%
2026E-2030E	17.8%



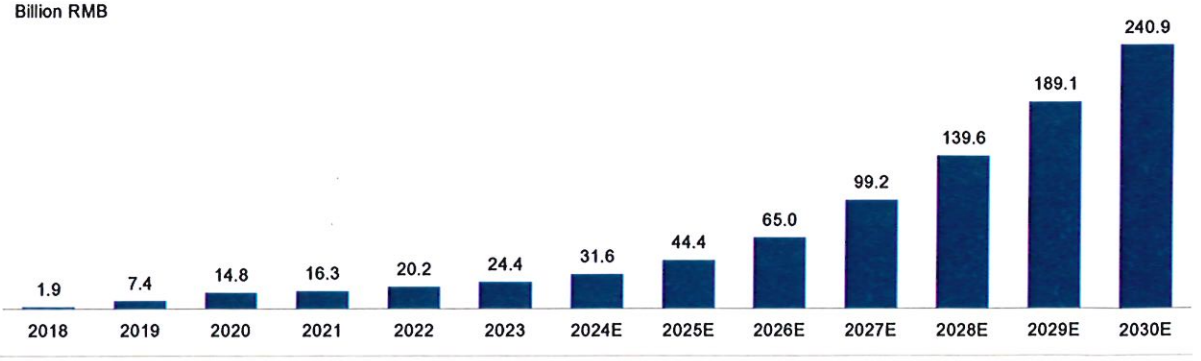
Source: Frost & Sullivan Analysis

China Immuno-Oncology Drug Market, 2018-2030E

- Immuno-Oncology therapies are emerging cancer therapies in global market, including the therapies of cytokines, therapeutic cancer vaccine, checkpoint antibodies and adoptive cell transfer therapies. In 2023, China Immuno-Oncology therapies market has reached RMB24.4 billion, growing from RMB1.9 billion in 2018. It is expected to reach RMB65.0 billion in 2026 and RMB240.9 billion in 2030 at a CAGR of 38.6% from 2023 to 2026 and 38.7% from 2026 to 2030.

China Immuno-Oncology Drug Market, 2018-2030E

Period	CAGR
2018-2023	66.4%
2023-2026E	38.6%
2026E-2030E	38.7%



Source: Frost & Sullivan Analysis