

# 2024 China Stem Cell Industry Market Research Report



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◆ Overview of the Development of the China Stem Cell Industry



1.1 Development Background and Profile of the China Stem Cell Industry



1.2 Market Demand and Application Potential of the China Stem Cell Industry



1.3 Regional Competitive Landscape of the China Stem Cell Industry



1.4 Competitive Landscape of Enterprises in the China Stem Cell Industry

# 1.1.1 Development History of China's Cell Industry

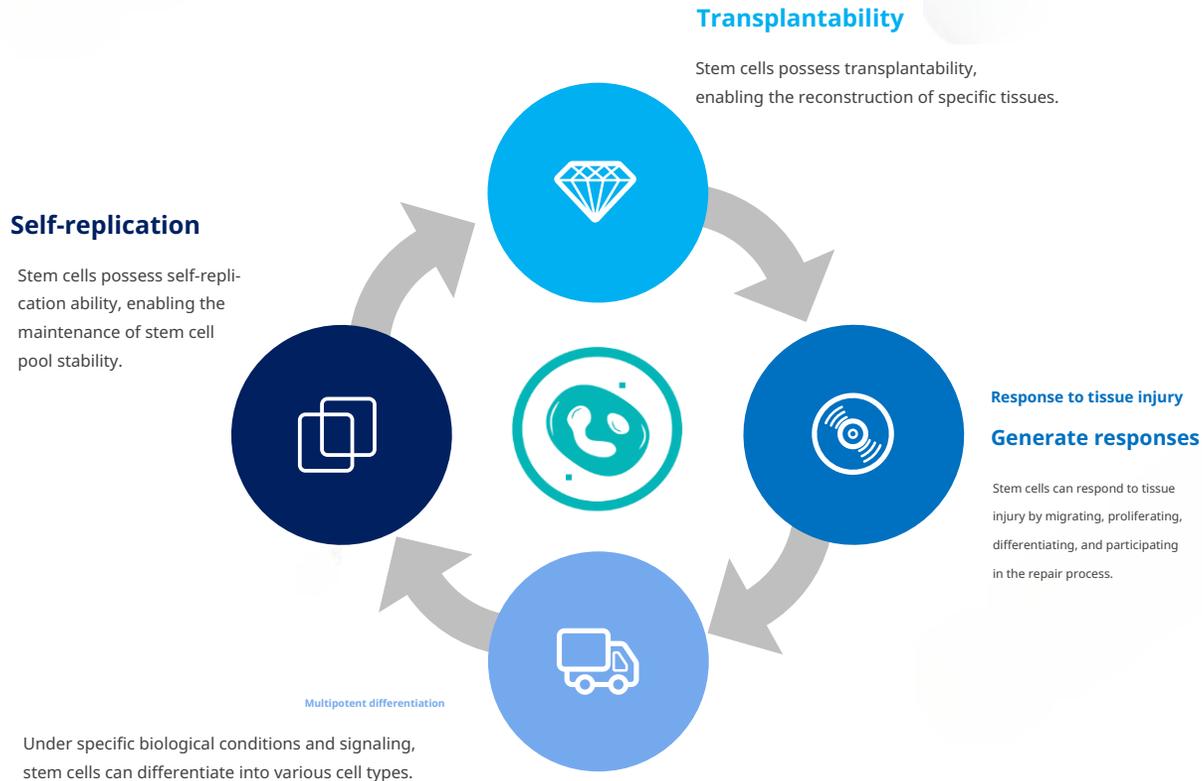
From umbilical cord blood storage to diversified tissue-derived cell banks, the cell ecology industry is gradually emerging.



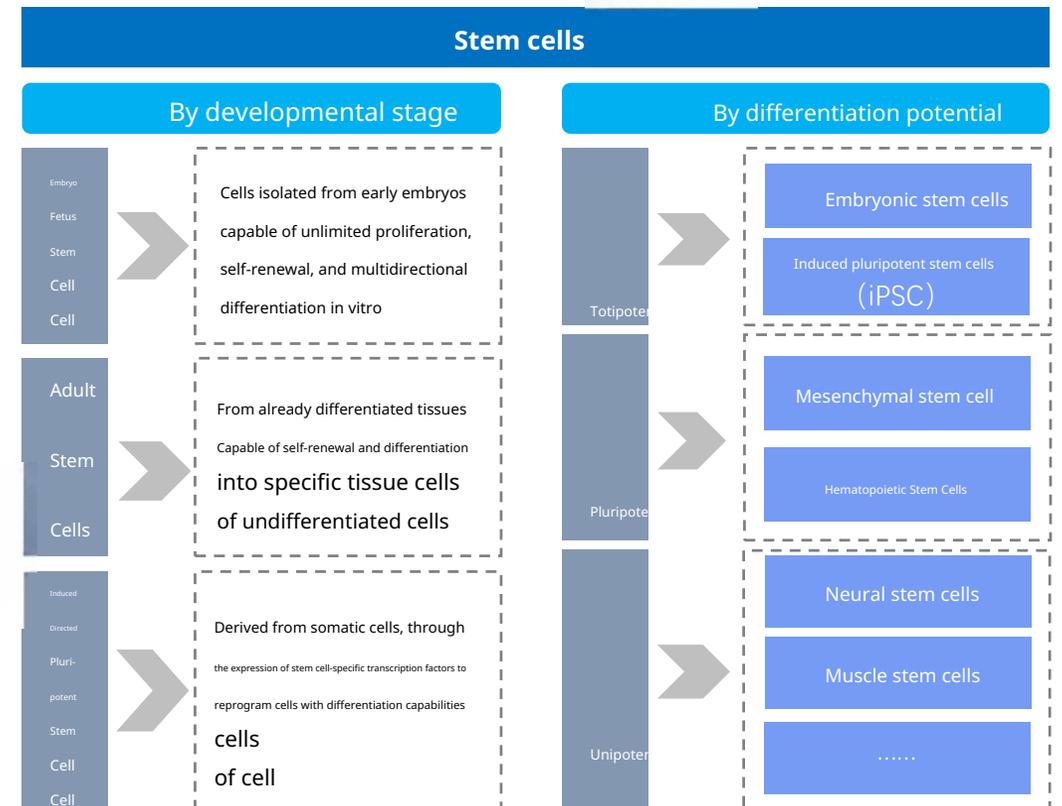
# 1.1.2 Characteristics and Classification of Stem Cells

Stem cells are multipotent cells with self-renewal capability that, under specific conditions, can differentiate into various functional cell types. Stem cell therapy involves transplanting healthy stem cells into a patient's body to repair and replace damaged or dead cells, thereby restoring normal physiological functions. It has potential applications in treating multiple major diseases in the future.

## Characteristics of Stem Cells

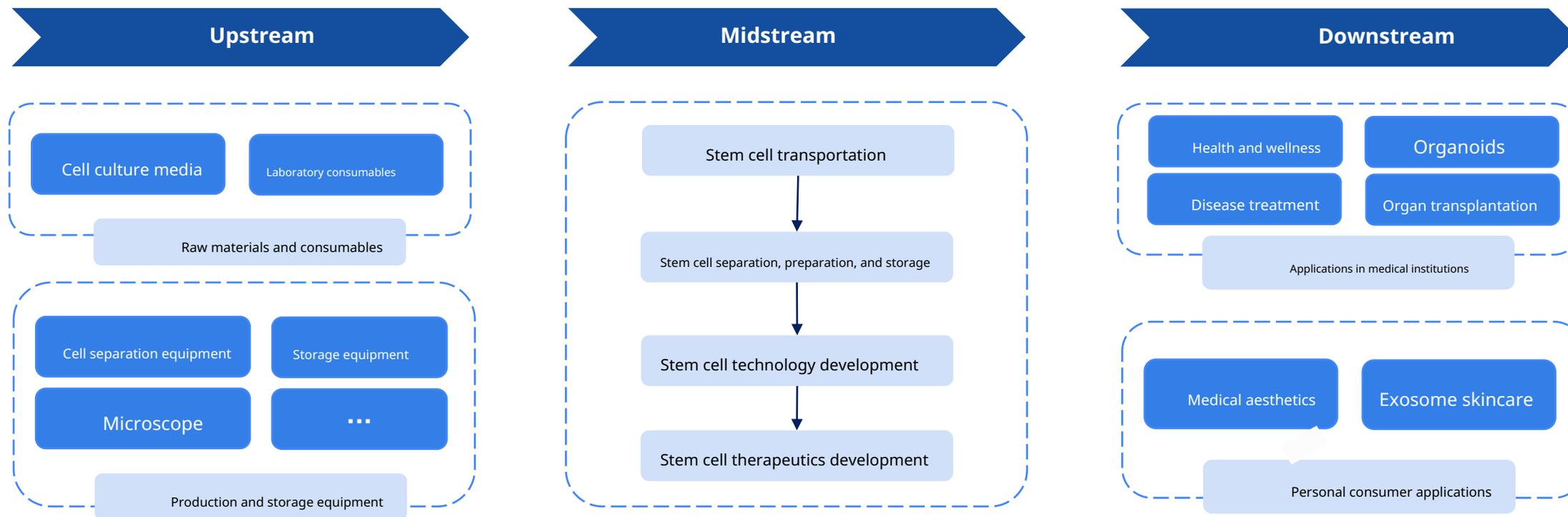


## Classification of Stem Cells



# 1.1.3 Structure of the China stem cell industry chain

The stem cell industry is divided into upstream (reagents and consumables, biomedical materials, and instruments and equipment), midstream (transportation, collection and storage, technology development, and drug development), and downstream (clinical treatment and consumer applications). Stem cell collection and storage in the midstream segment of China are relatively mature; multiple umbilical cord blood hematopoietic stem cell banks have been established at the national level, and most provinces and cities across the country have set up adult stem cell banks. Additionally, a number of enterprise stem cell banks with substantial storage capacity have also emerged; The state is strongly supporting the clinical translation of stem cells in the development of stem cell technology and the preparation of stem cell products.

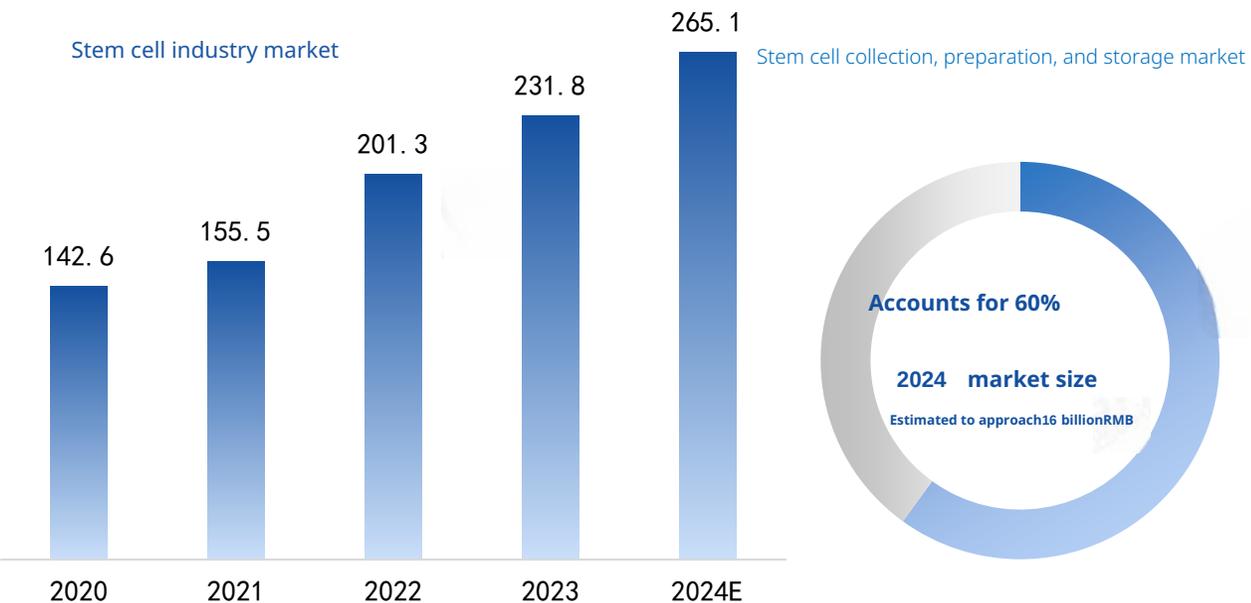


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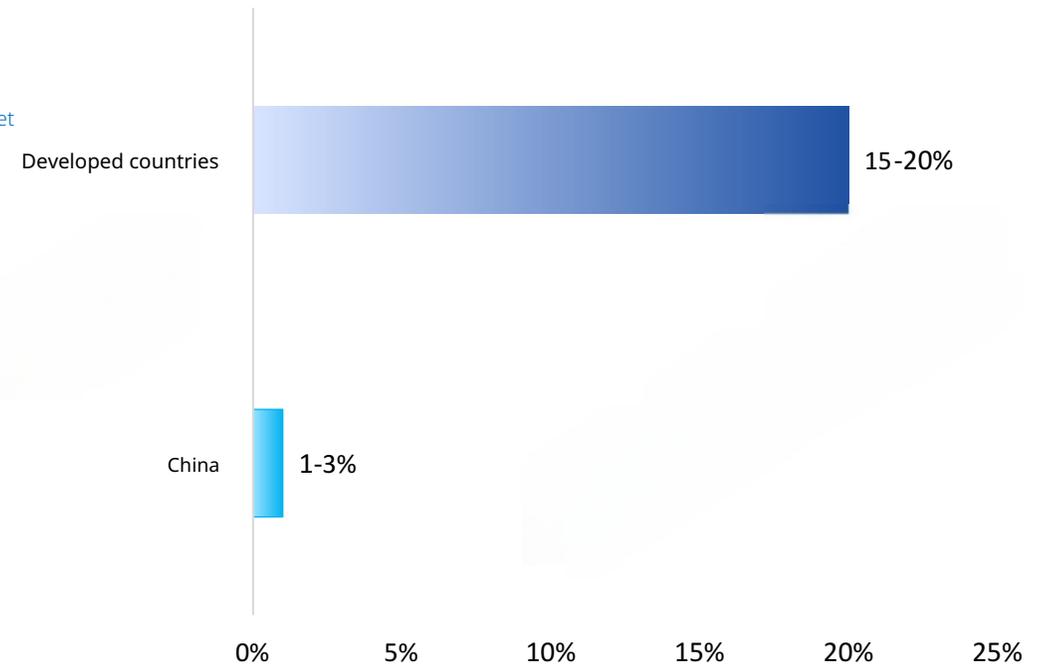
## 1.2.1 Market demand in the China stem cell industry

In 2024, the market size of stem cells in China is expected to reach approximately 26.5 billion RMB. Among these, stem cell collection, preparation, and storage represent the most mature industrialized projects in China's stem cell industry. The market size of stem cell collection, preparation, and storage is close to 16 billion RMB. However, the overall stem cell storage rate in China remains below 3%, presenting a significant gap compared to the 15%–20% storage rate observed in developed countries. Given China's annual birth cohort of over 10 million newborns and with reference to developed countries, there is substantial market potential for stem cell storage

2020 – 2024 China stem cell industry and collection, preparation, and storage market size (100 million yuan)



Comparison of domestic and international stem cell storage rates (%)



Note: The market size of the China stem cell industry is estimated based on the global market size and historical proportions. The market size of stem cell banks (including stem cell collection, preparation, and storage businesses) accounts for approximately 60% of the total stem cell industry market.

Source: Precedence Research, Zhengda Stem Cell Bank, et al.; compiled by Qianzhan Industry Research Institute

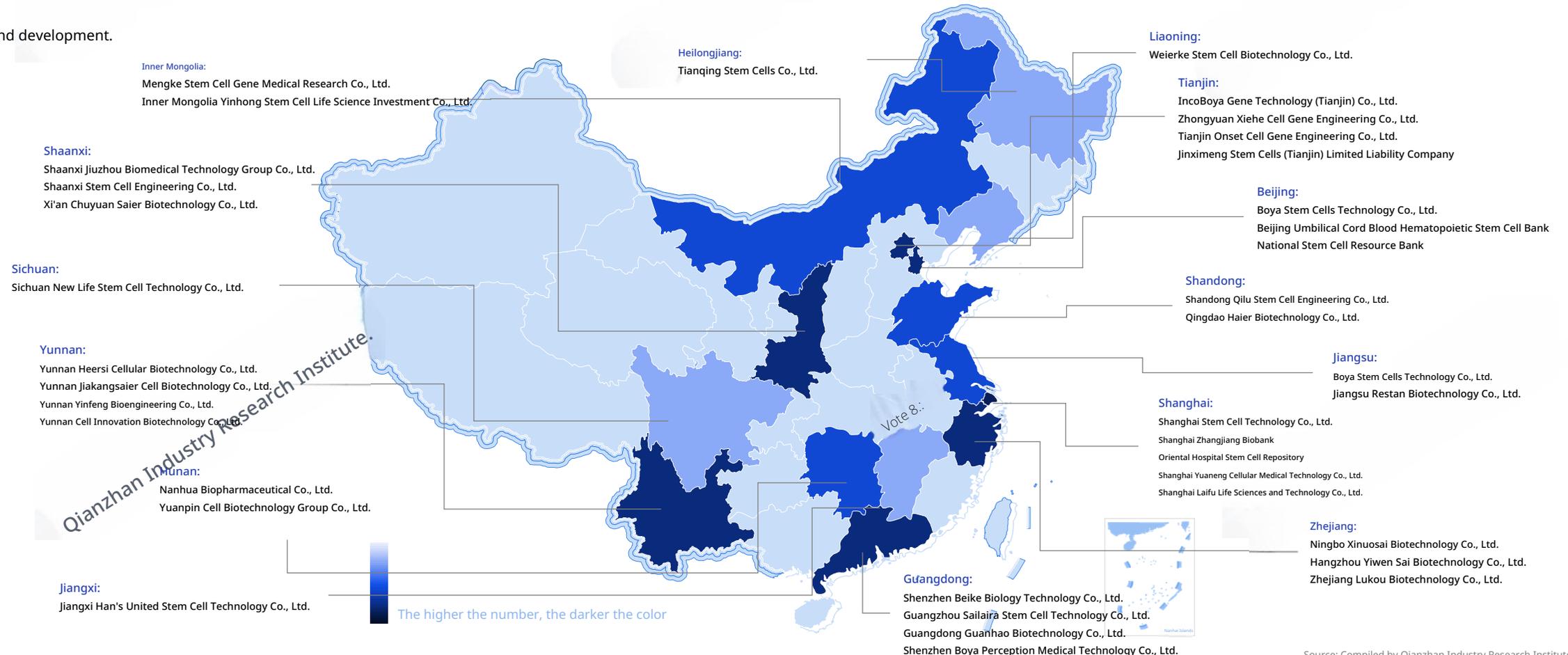
## 1.2.2 Application potential of the China stem cell industry

Stem cells possess strong regenerative and reparative capabilities, with potential applications in the treatment of numerous diseases. Currently, stem cell therapy has been applied in clinical research for more than one hundred diseases, involving the prevention, treatment, and rehabilitation of major illnesses. With the continuous advancement of science and technology, stem cells will play an increasingly important role in the future of medical care.



# 1.3.1 Regional Competitive Landscape of the China Stem Cell Industry

Based on the distribution of representative stem cell enterprises in various provinces and cities of China, the Beijing-Tianjin-Hebei, Yangtze River Delta, and Guangdong-Hong Kong-Macao Greater Bay Area show high enterprise concentration and intense competition; The three northeastern provinces, central region, and southwest region tend to be dominated by a single leading enterprise; At the same time, previously blank market regions such as Inner Mongolia and Shaanxi-Gansu-Ningxia have been penetrated by numerous small stem cell application or storage agencies, leveraging medical institution resources or high-net-worth client channels for regional operation and development.

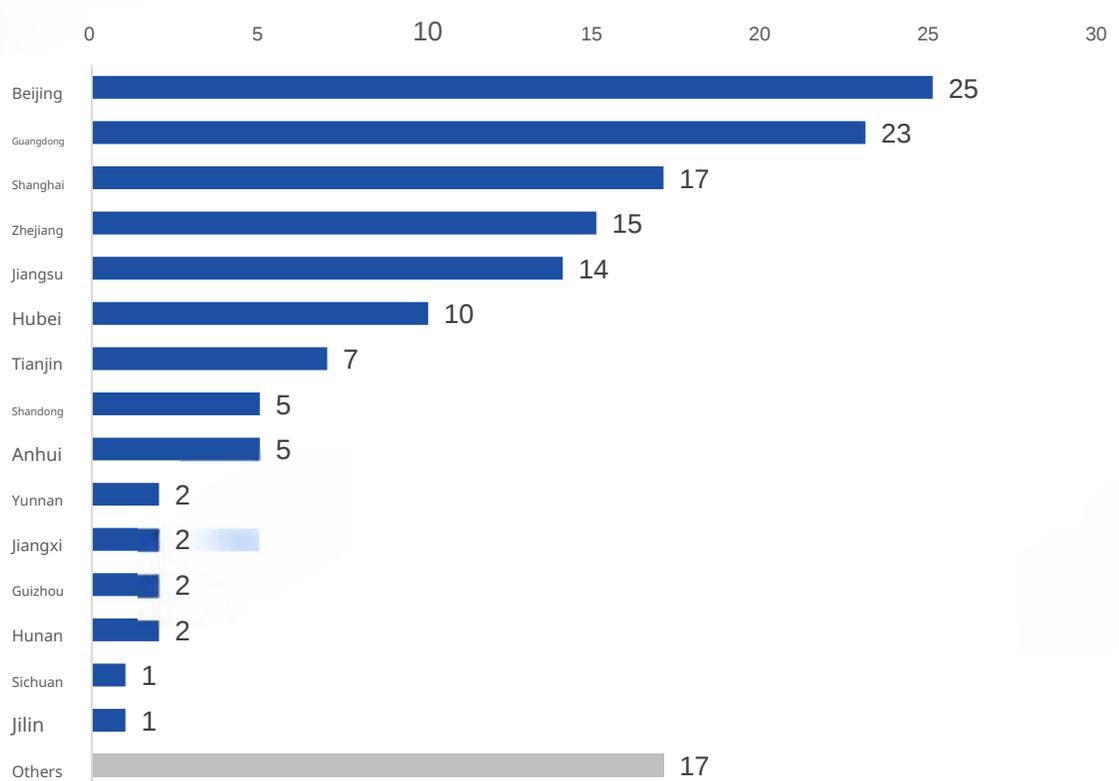


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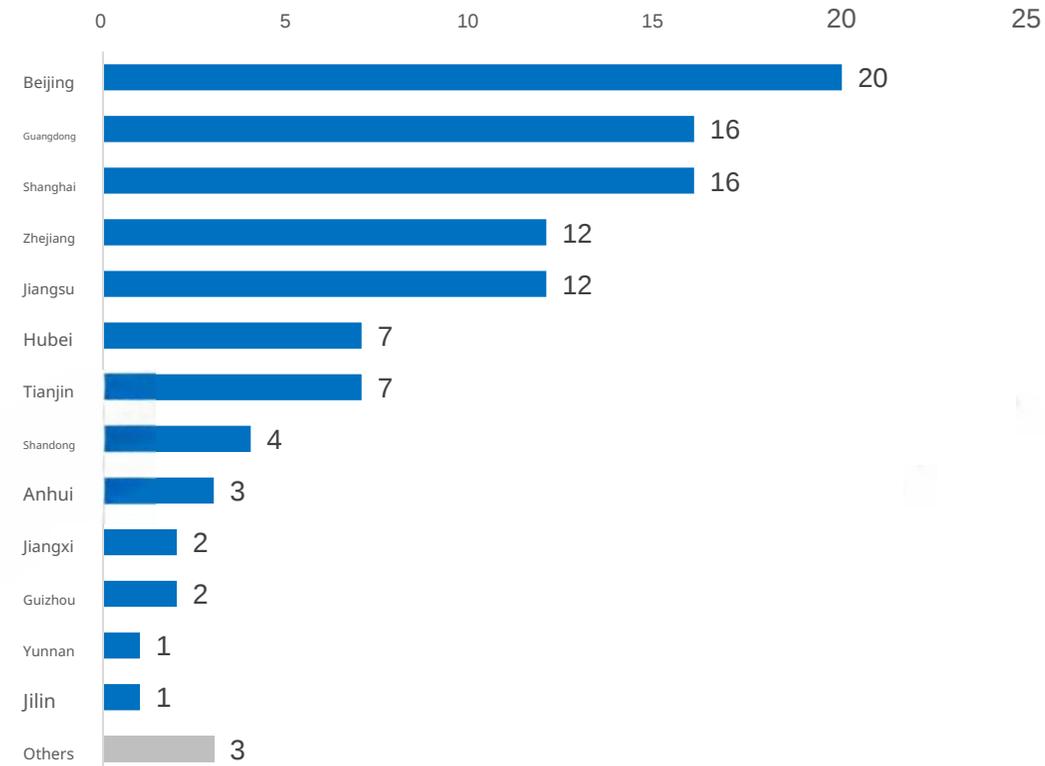
## 1.3.2 Regional competitive landscape of China stem cell industry

Based on the filings and implicit approval projects for stem cell therapeutics across provinces and cities, the Yangtze River Delta region, Beijing, and Guangdong are the principal regions for stem cell therapeutics R&D in China. Beijing ranks first in both the number of accepted filings and implicit approval projects, making it the most active region for stem cell therapeutics R&D.

Number of stem cell therapeutics project filings accepted by provinces and cities in China as of 2024(year) (units)



Number of implicit approval projects for stem cell therapeutics in provinces and cities in China as of 2024(year) (units)



Note: Statistical cutoff date is the end of October 2024.

Source: National Medical Products Administration Center for Drug Evaluation, compiled by Qianzhan Industry Research Institute

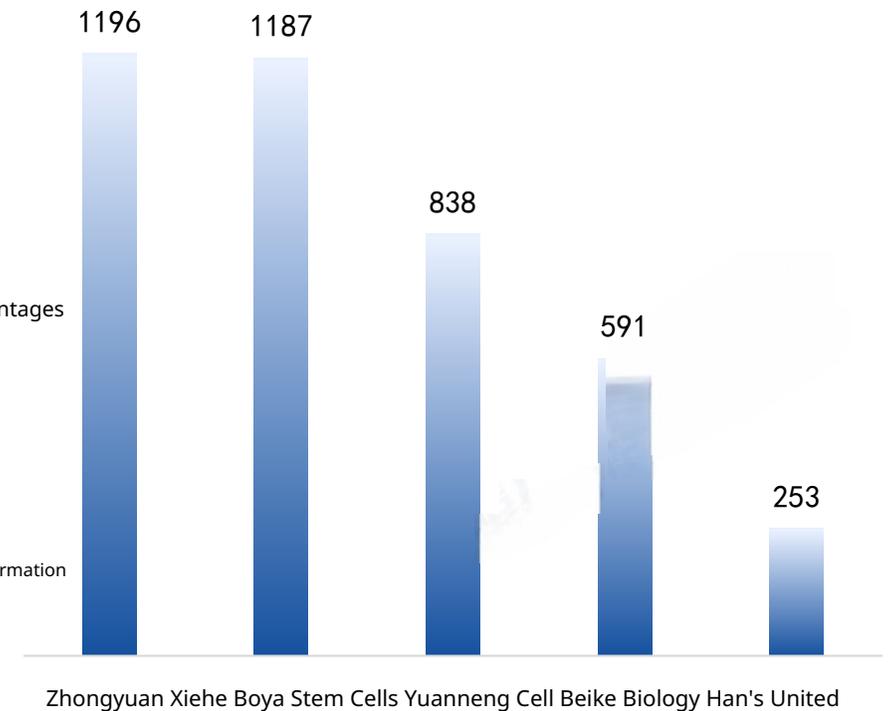
# 1.4.1 Competitive landscape of enterprises in the China stem cell industry

In terms of stem cell brand influence, Zhongyuan Xiehe and Boya Stem Cells lead in both business coverage and brand media exposure; Leading first-tier brands such as Zhongyuan Xiehe, Boya Stem Cells, Beike Biology, and Han's United, established cell storage institutions with accumulated brand equity, hold significant first-mover advantages and possess stronger influence in the stem cell market.

Competitive Tiers of China Stem Cell Storage Companies



2023 China Stem Cell Storage Brand Media Volume (reports/month)



Source: Baidu Public Opinion Monitoring Platform, compiled by Qianzhan Industry Research Institute

# 1.4.2 Competitive Landscape of Enterprises in China's Stem Cell Industry

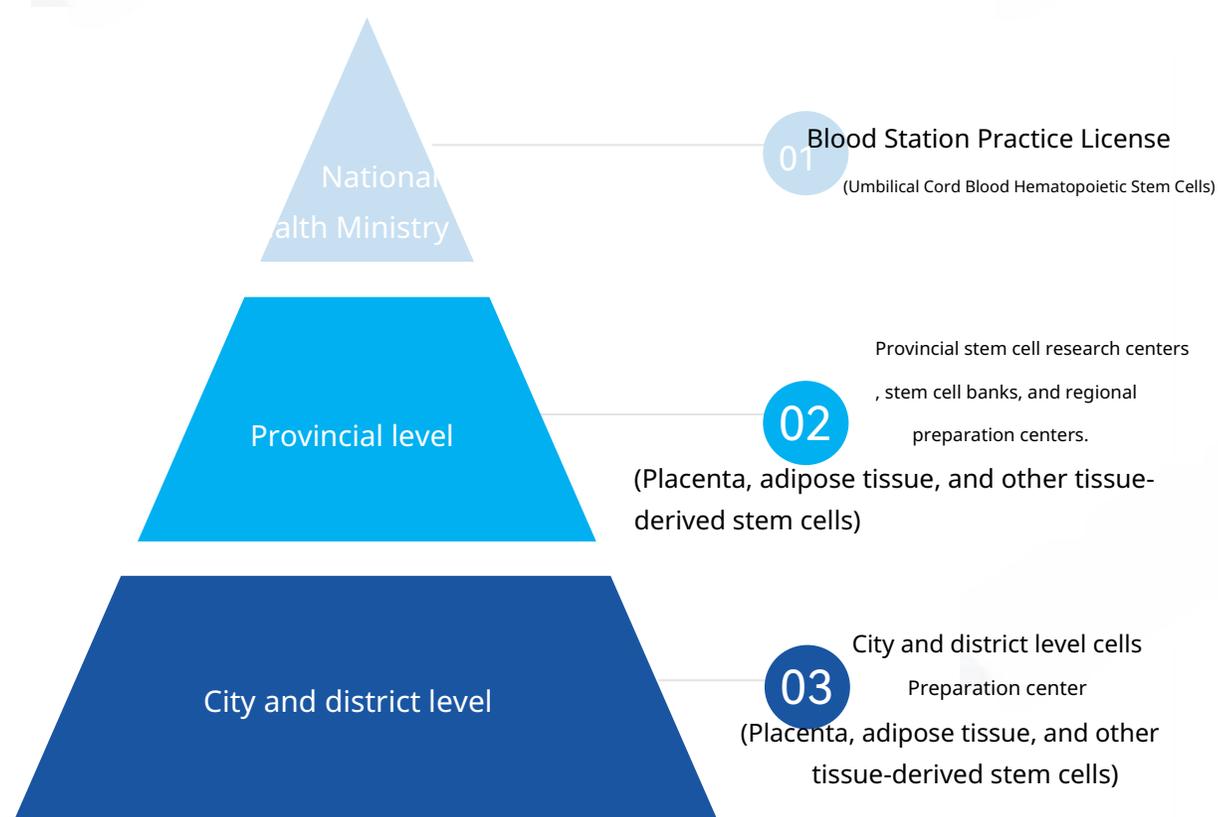
Qualifications are a key indicator of the authority of stem cell institutions, and government endorsement also serves as strong support and validation of the institution's technical strength and compliance

. Regarding the qualifications of stem cell preparation and storage institutions in China, the seven public welfare banks approved and licensed by the National Health Commission with 'umbilical cord

blood licenses' serve as designated storage licenses for hematopoietic stem cells; Institutions such as Han's United, Boya Stem Cells, and Beike Biology have obtained government endorsement as '

Provincial Stem Cell Research Centers' or 'Regional Cell Preparation Centers.'Xinuosai, Chengdu Kangjing, and others serve as city-level and district-level 'tissue-derived stem cell storage centers.'

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**Representative Institutions**

7 cord blood banks  
(Beijing, Tianjin, Shanghai, Hainan, Guangdong, Shandong, Sichuan, Zhejiang)

Han's United, Nanhua Biology, Beike Biology, Boya Stem Cells, etc.

Xinuosai, Chengdu Kangjing, etc.

# 1.4.3 Competitive Landscape of Enterprises in the China Stem Cell Industry

At present, the stem cell industry has formed a relatively clear brand landscape, with leading enterprises largely long-established companies whose experience accumulation has created significant technical barriers. For example, Zhongyuan Xiehe is a domestic A-share listed stem cell company; Beike Biology has been engaged in cell therapy and wellness services relatively early, with an extensive network of partnered and acquired peripheral enterprises. Boya Stem Cells leads in quality management systems and holds a strong position in the neonatal perinatal stem cell storage market. Additionally, emerging companies such as YuanNeng Cells and BGI Cells are noteworthy.

Stem cells TOP10 Brands	Founding Date	Standard Business Model	Special Business Layout/Additional Tracks/Strength Enhancements
<b>Zhongyuan Xiehe</b>	1995 Year June	Focusing on cord blood license+genetic testing+cell storage;	<b>Umbilical cord hematopoietic stem cell business ('license'), stem cell storage business primarily promotes the license; Genetic Testing: 2022 Ranked 7th among genetic testing companies</b>
<b>Beike Biology</b>	2005 Year July	Focusing on cell storage and therapy/wellness	The 2nd Shenzhen Top 100 Brands List; Extensive clinical pipeline; Regional policy advantages
<b>Boya Stem Cells</b>	2009 Year July	Comprehensive industry chain layout covering cell medical devices, cell storage, and cell application; primarily focused on perinatal stem cell storage, with expansion into adult immune cell business	<b>The only clinical-grade cell bank with triple international certification from AABB, NRL, and CAP; the sole stem cell company operating in the animal sector</b>
<b>Han's United</b>	January 2007	Primarily focused on cell tourism and wellness + cell store agency + cell medical aesthetics + clinical pipeline	Recipient of national or provincial/municipal science and technology awards; included in Artery Network's Future Medical100 Leading Enterprises List
<b>Sichuan New Life</b>	July 1999	Primarily focused on Cord Blood Bank licensing+Sichuan/Yunnan cell application	Approved as Adult Stem Cell Development and Application National (Local) Joint Engineering Laboratory, and Sichuan Stem Cell Engineering Technology Research Center; Maintains close collaboration with West China Hospital, facilitating a streamlined cell application pathway
<b>Yuan Neng Cell</b>	2014 Year July	Comprehensive industry chain layout encompassing automated processing equipment, cell storage, and cell application	Establish a nationwide 1+N standardized, intelligent, and industrialized cell bank network, creating the country's first 'automated cell bank.' <b>Acknowledged by U.S. government legislators for possessing leading automation technology.</b>
<b>BGI Cell</b>	2017 Year September	Based on BGI Genomics&the National Gene Bank, primarily engaged in cell storage business.	Supported by the National Gene Bank, demonstrating significant brand influence and advantages. The industry influence of BGI's founder and CEO is significant, gaining widespread consumer trust through media and public welfare activities.
<b>Yuanpin Bio</b>	June 2015	Using cell storage+SourceGene Hospital as the primary model	With few competitors in the central region, investing in the construction of the SourceGene Stem Cell Industrial Park, closely collaborating with Hunan Normal University and Xiangya Hospital, <b>independently developing digital cell transport boxes, pioneering digital management; advisory experts include academicians Pei Gang and Wei Yuquan</b>
<b>Nanhua Bio</b>	October 1991	Based on stem cells and regenerative medicine, driven by clinical translational research and applications of cells, deploying across cell storage, health management, and anti-aging beauty sectors	<b>The only domestically state-owned controlled listed company in the stem cell industry</b>
<b>China Stem Cell Group</b>	March 2011	Possessing a cord blood bank license, with a focus on stem cell storage+clinical applications	Established and operates the only domestic stem cell hospital — China Stem Cell Group Hainan Boao Affiliated Stem Cell Hospital; Referred to within the industry as the 'national team' of the biopharmaceutical sector, holding the Blood Station Practice License of the People's Republic of China issued by the National Health Commission <b>Certificate and medical institution practice license for the stem cell hospital</b>

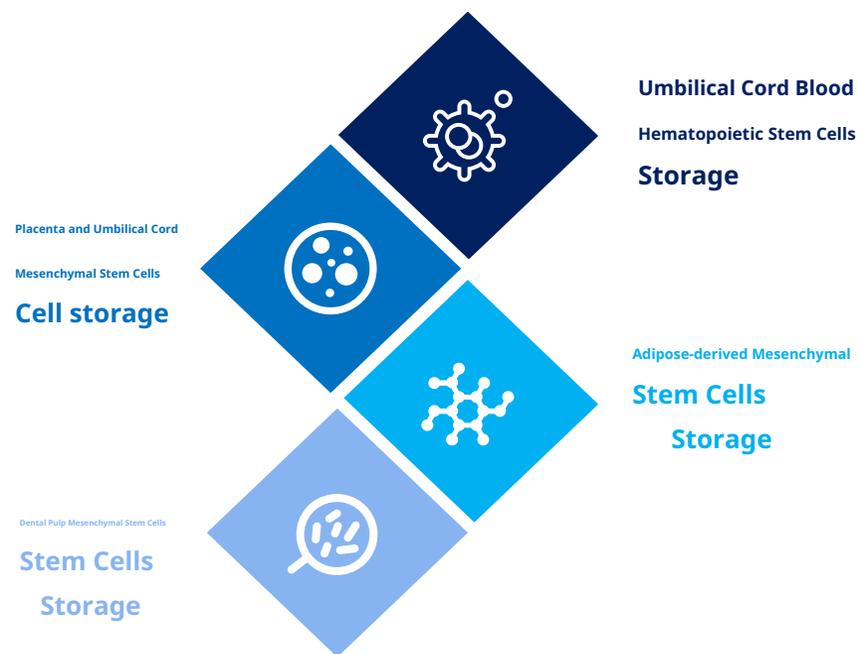
Note: Selection is based on a comprehensive assessment of brand awareness, brand recognition, brand operation duration, market share, and other multidimensional factors. Rankings are presented in no particular order.

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# 1.4.4 Competitive Landscape of Enterprises in the China Stem Cell Industry

In the segmented market of stem cell storage, the umbilical cord blood hematopoietic stem cell market is strictly regulated by the state and dominated by seven licensed 'national team' cord blood bank operators; regulations also explicitly prohibit cord blood banks from operating for profit or collecting samples across regions. The neonatal mesenchymal stem cell market, primarily derived from placenta and umbilical cord sources, is essentially divided among established neonatal banks such as Zhongyuan Xiehe, Nanhua Biology, Sichuan New Life, and Boya Stem Cells, with Boya Stem Cells' placenta mesenchymal stem cell storage accounting for approximately 30% of the market share.

## Primary Types of Stem Cell Storage



## Ownership of Umbilical Cord Blood Hematopoietic Stem Cell Bank 'Licenses' and Operated For-Profit Enterprises/Institutions

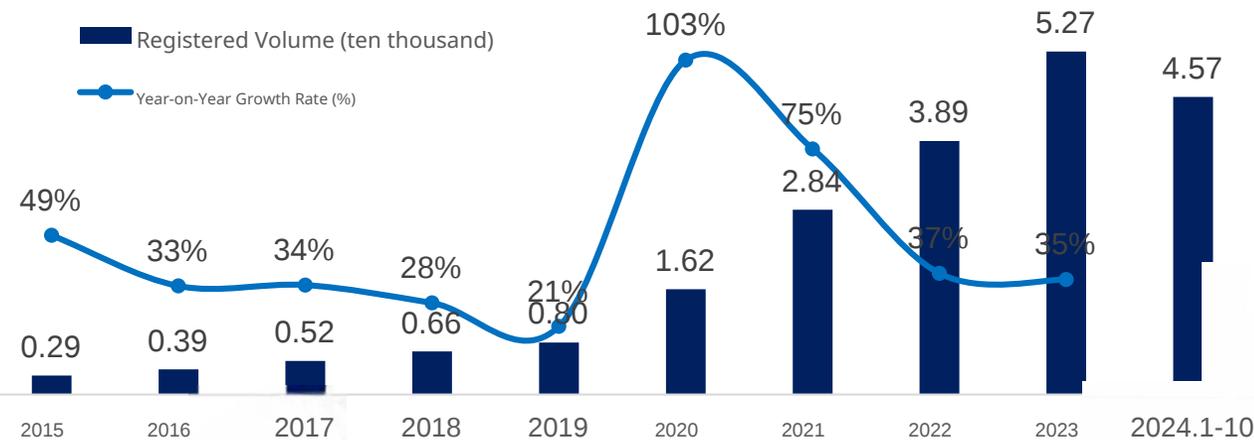
Cord Blood Bank	Operating Profit Entities	Partners	License Ownership
Shanghai Cord Blood Bank	Shanghai Stem Cell Technology Co., Ltd.	Shanghai Red Cross Society Shanghai Blood Center	Jukang Biotech
Tianjin Cord Blood Bank	Xiehe Stem Cell Genetic Engineering Co., Ltd.	Chinese Academy of Medical Sciences Peking Union Medical College Institute of Hematology and Blood Hospital	Zhongyuan Xiehe
Sichuan Cord Blood Bank	Sichuan New Life Stem Cell Technology Co., Ltd.	Institute of Blood Transfusion, Chinese Academy of Medical Sciences	Chengdu Zhuxin Group
Shandong Province Cord Blood Bank	Shandong Qilu Stem Cell Engineering Co., Ltd.	Qilu Hospital of Shandong University	Nanjing Xinbai
Zhejiang Province Cord Blood Bank	Zhejiang Lvkou Biotechnology Co., Ltd.	Zhejiang Province Blood Center	
Beijing Cord Blood Bank	Beijing Jiachenhong Biotechnology Co., Ltd.	Peking University People's Hospital	
Guangdong Province Cord Blood Bank	Guangzhou Tianhe Noah Bioengineering Co., Ltd.	Guangdong Province Women and Children's Hospital	

Note: Currently, the only globally recognized stem cell therapy is hematopoietic stem cell transplantation; The 2020 document titled 'Notice from the General Office of the National Health Commission on Matters Related to the Approval of Umbilical Cord Blood Hematopoietic Stem Cell Bank Establishments' states that 'applications for the establishment approval of umbilical cord blood banks will not be accepted in 2021,' and no new approvals have been issued since. Source: Official websites of various Cord Blood Banks, Deloitte, and Qianzhan Industry Research Institute

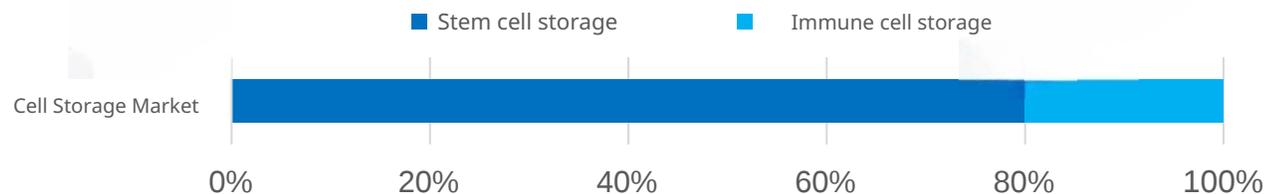
# 1.4.5 Competitive Landscape of Enterprises in the China Stem Cell Industry

From the perspective of existing enterprises and substitute threat competition, numerous companies have entered the cell industry over the past decade, with an increasing number of competitors and business diversification from stem cells to immune cells. However, stem cell storage accounts for approximately 80% of the cell storage market and remains the most mainstream type of cell storage currently. The immune cell market penetration rate is low, and the profitability of companies operating in this sector is relatively weak. Therefore, stem cell enterprises face a relatively low risk of substitute competition, especially those with established advantages in the neonatal stem cell storage market, demonstrating deeper accumulation and comparatively stronger sustainable operational capabilities.

2014 – 2024 Annual Registered Volume and Growth Rate of Cell Therapy-Related Enterprises in China (ten thousand, %)



Market Share of China's Cell Storage Industry Segments (%)



Substitutive Competitive Analysis of Immune Cells versus Stem Cells

### Comparative advantages of immune cell storage enterprises:

- Market awareness advantage: The immune cell therapy market is developing more rapidly. Currently, there are 6 CAR-T immune cell therapies approved domestically. In terms of market education and public awareness, immune cells hold an advantage compared to stem cells.

### Comparative disadvantages of immune cell storage enterprises:

- Application Demand Disadvantage: The application scope of immune cell therapy is relatively narrow, currently mainly focused on cancer, autoimmune diseases, anti-aging, and other areas, whereas stem cells, particularly mesenchymal stem cells, are clinically applied to hundreds of diseases across eight major human systems.
- Storage efficiency disadvantage: Immune cells, unlike stem cells, cannot be passaged and can only be amplified a limited number of times, typically only 2-6 times. Therefore, immune cell storage faces limitations in both quantity and quality.



**Immune cells pose a relatively limited substitution threat to stem cells**

Note: The enterprise count statistics are as of October 31, 2024.

Source: Qichamao and others; compiled by Qianzhan Industry Research Institute

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# 02

## ◆ Perspective on representative enterprises in China's stem cell industry



2.1 Zhongyuan Xiehe: A-share listed company in the stem cell industry



2.2 Boya Stem Cells: Domestic leader in quality standards system



2.3 Han's United: Actively promoting tourism and wellness and commercial applications

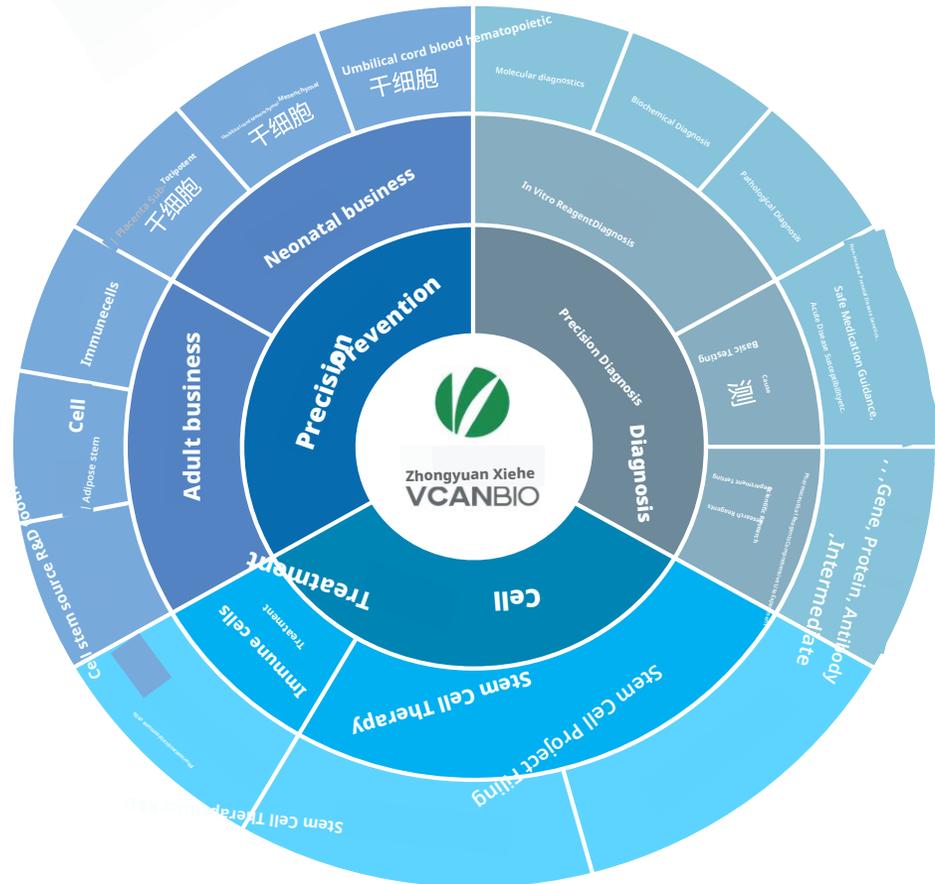


2.4 Beike Biology: Established cell institution in the core competitive region of Guangdong-Hong Kong-Macao

# 2.1 Zhongyuan Xiehe: Stem Cell Industry A-Share Listed Company

Zhongyuan Xiehe has strategically developed its business around three core sectors: 'precision prevention,' 'precision diagnosis,' and 'cell therapy.' It is publicly listed with its main business focused on stem cells, holds advanced cell technology, and operates a nationwide cell resource storage network. The company has established 20 comprehensive cell banks, with cell storage exceeding 300,000 units.

As of the end of 2023, the company's Tianjin Umbilical Cord Blood Hematopoietic Stem Cell Bank has provided 3,613 transplant donors for clinical application.

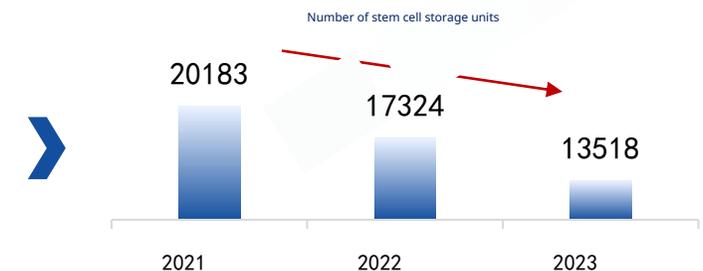


### Advantages:

- Brand seniority: It is a senior brand with over 20 years of operation, recognized as one of the leading brands in the stem cell industry, holding a cord blood bank license and extensive operational experience, with a leading presence in brand media coverage.
- Technical support: Leveraging the company's national stem cell engineering product industrialization base, national stem cell engineering technology research center, and regional cell preparation center, it possesses key technologies including directed differentiation of stem cells and efficient stem cell amplification.
- Business advantages: Capable of testing, preparation, and storage for Umbilical Cord Blood Hematopoietic Stem Cells, Umbilical Cord Mesenchymal Stem Cells, Placenta Subtotal Potent Stem Cells, Immune Cells, Adipose Stem Cells, and Dental-Derived Stem Cells, with broad business coverage.

### Challenges:

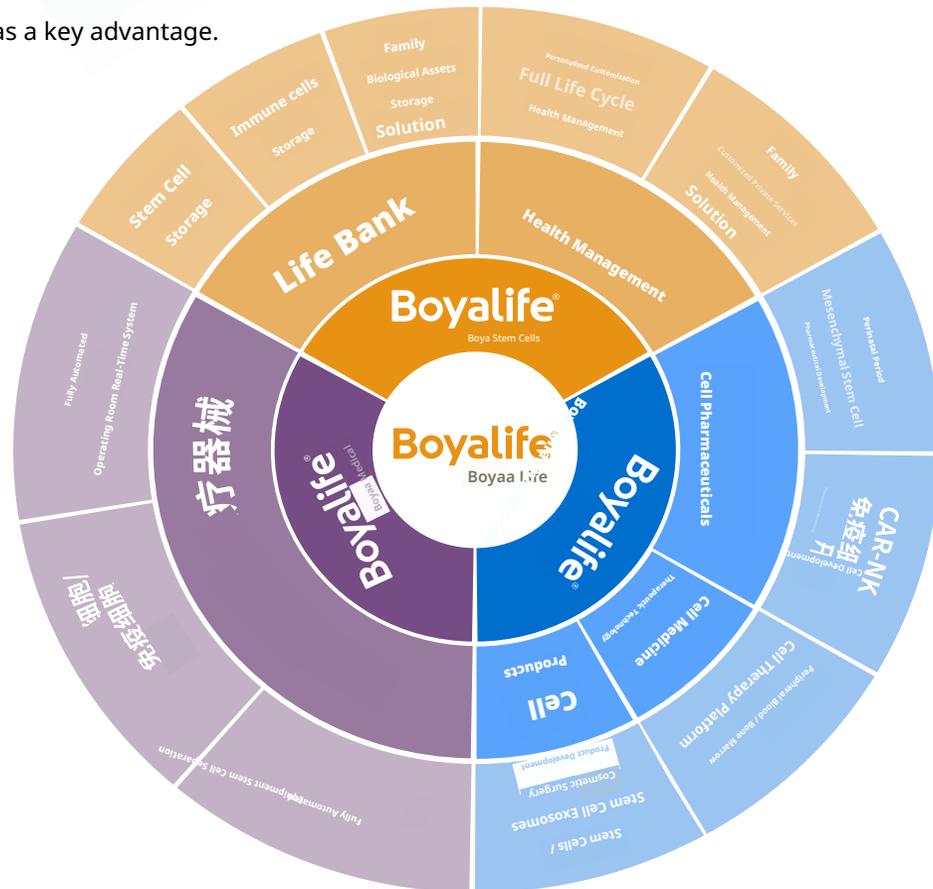
- In recent years, Zhongyuan Xiehe's stem cell storage business has shown weak growth, with a significant decline in stored units, gradually losing its first-mover advantage.



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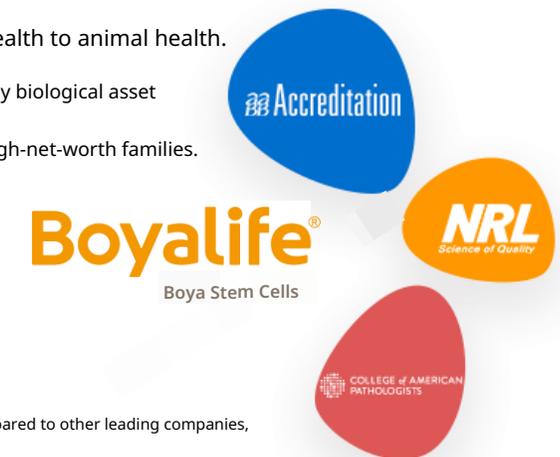
## 2.2 Boya Stem Cells: Domestic leader in quality standards system

Boya Stem Cells, founded in 2009, is one of the earliest established cell banks in China and ranks among the first-tier cell bank brands. It holds over 32% market share in the placental mesenchymal stem cell storage market and cooperates with more than 40 Class III Grade A hospitals on multiple cell clinical programs. The company implements a 'digital customer center + transparent laboratory' depositor service model to ensure clear and traceable 'self-storage and self-retrieval' of cells, supported by a rigorous cell quality management system aligned with international standards as a key advantage.



### Advantages:

- Industry Chain Integration: Boya Stem Cells is affiliated with Boya Life, covering the entire cell therapy industry chain, including upstream cell automation equipment and medical devices, midstream cell storage and health management, and downstream cell pharmaceuticals and technology development.
- Pharmaceutical R&D: Possesses more than 20 proprietary cell clinical pipelines, over 100 patents, in 2023, a stem cell therapy drug for osteoarthritis obtained IND approval, demonstrating strong R&D capabilities in stem cell-related pharmaceuticals.
- Sector Innovation: Capitalizing on emerging trends by entering pet regenerative medicine, it is the first domestic enterprise to extend cell technology from human health to animal health.
- Product Innovation: In 2024, introducing the new concept of a family biological asset package — consistent with health management trends among high-net-worth families.
- Quality Leadership: The only domestic clinical-grade cell institution simultaneously accredited by AABB, NRL, and CAP, three international certifications.



### Challenges:

- The number of new stem cell drug IND approvals accepted is relatively lower compared to other leading companies, and the competitive advantage in the therapeutic drug R&D field remains inconspicuous.

## 2.3 Han's United: Vigorously Promoting Tourism and Wellness and Commercial Applications

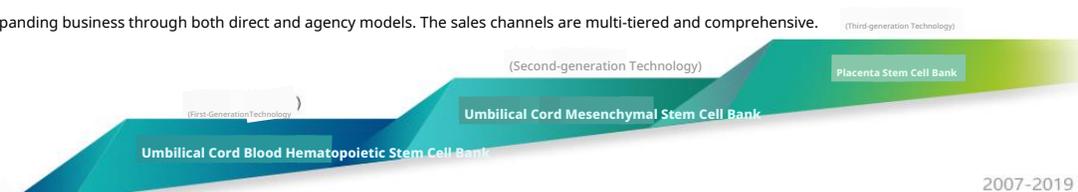
Han's United, founded in 2007, is a pioneering enterprise and established brand in the stem cell industry, boasting a cutting-edge R&D team led by Academician Han Zhongchao.

Known as the 'Whampoa Military Academy of the Stem Cell Field,' it has become a benchmark for perinatal stem cell technology research both domestically and globally.



### Advantages:

- **R&D Capability:** Centered on stem cell regenerative medicine technology, supported by a strong scientific research team, with multiple stem cell Class 1 new drug clinical trial applications approved to conduct clinical trials, maintaining a leading position in the domestic cell new drug R&D sector.
- **Industry Chain Ecosystem:** Engaging in cell storage and preparation, CDMO technical services, product R&D, cell clinical research, health tourism, international cell valley, medical industry, precision testing, new drug development, health management, biocosmetics, and other business areas, establishing a comprehensive closed-loop industrial chain for regenerative medicine.
- **Application channels:** The company has strong market operation capabilities. Its subsidiaries are located in more than ten provinces and cities nationwide, expanding business through both direct and agency models. The sales channels are multi-tiered and comprehensive.



### Disadvantages:

- **Business risk points:** Due to constraints in the development of the storage business, the operational focus has shifted from cell storage to cell application and cell-based beauty and skincare exploration; Emerging application channels such as tourism and wellness and medical services, developed through an agency model, may face substantial compliance and reputational risks.

## 2.4 Beike Biology: Established Cellular Institution in the Core Region of the Guangdong-Hong Kong-Macao Greater Bay Area

Beike Biology, founded in Shenzhen in 2005, has developed over 19 years in biotechnology clinical translation, stem cell basic research, and clinical translation. It is one of the earliest established stem cell bank brands in China, with significant industry influence.



### Advantages:

- Brand advantages: Awarded the 2021 "Shenzhen Well-known Brand", "Leading Enterprise in the Cell Field in China", and the 2022 Guangdong-Hong Kong-Macao Greater Bay Area Brand Influence Series—Most Influential Brand of the Year, with high brand recognition.
- Technical advantages: Possess seven major R&D platforms, including the pluripotent stem cell research platform (transdifferentiation) and the empowered mesenchymal stem cell research platform; have applied for 207 patents in the cell field, of which 162 have been granted.
- Channel Advantage: Infrastructure for the industrialization of cell therapy has been established in South China, East China, Southwest China, Northwest China, North China, and Northeast China — "Comprehensive Cell Bank + Regional Cell Preparation Center".



### Challenges:

- Competitive environment: Within the intense competitive landscape of the Guangdong-Hong Kong-Macao region, may face severe challenges to the pricing system.
- Agency Risk: The numerous agency branches and unclear boundaries in the storage business pose a significant risk of negative disputes.

## ◆ Development Challenges in the China Stem Cell Industry

The most mature segments of the China stem cell industry remain collection, preparation, and storage; the further advancement of stem cells toward translational research and applications still faces numerous challenges, mainly in the following three aspects. At present, all industry stakeholders are actively exploring and committed to expanding the development pathways for stem cell industrialization.

### 3. 1 Industry Development Challenge One: Absence of a Standard System

### 3. 2 Industry Development Challenge Two: Ambiguity in Industry Regulatory Regulations

### 3. 3 Industry Development Challenge Three: Difficulties in Product Assurance

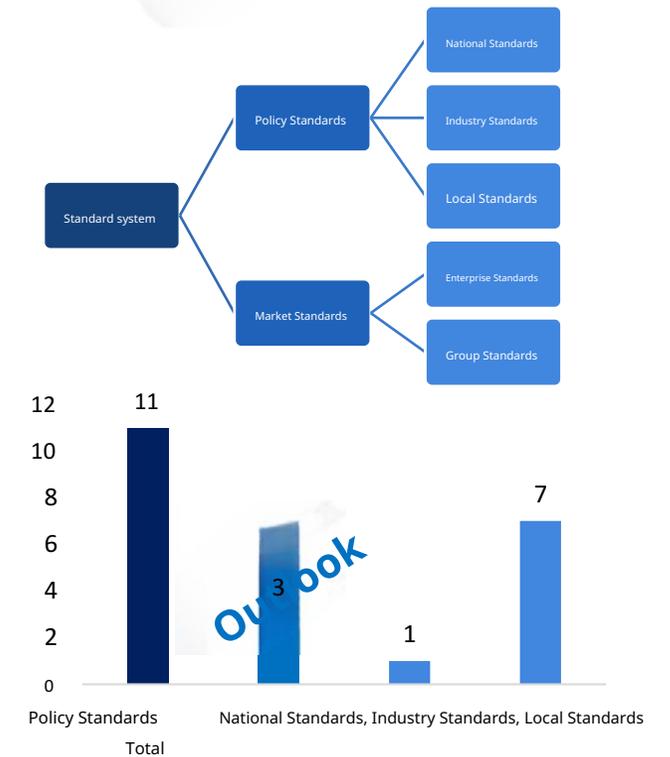
### 3.1 Development Challenges in the China Stem Cell Industry: Lack of a Standard System

China's stem cell field lacks technical standards and operational specifications in areas such as cell quality control, production processes, and clinical trial design. As of October 2024, China has only three national standards related to stem cells, with only Shaanxi, Jilin, Zhejiang, and Jiangsu having established local standards for Mesenchymal stem cell storage and quality management.

Summary of Current Standards in the China Stem Cell Industry as of 2024

Standard Number	Standard Name	Release Date	Implementation Date
<b>DB13/T 5863-2023</b>	Guidelines for Infection Prevention and Control in Hematopoietic Stem Cell Transplantation Wards	2023-10-25	2023-11-25
<b>DB22/T 3574-2023</b>	Specification for Mesenchymal Stem Cell Storage Services	2023-09-28	2023-11-16
<b>GB/T 42466-2023</b>	Technical Specification for Pluripotent Stem Cell Management in Biobanks	2023-09-07	2023-09-07
<b>DB61/T 1497-2021</b>	Specification for the Construction and Management of Human Mesenchymal Stem Cell Banks	2021-12-17	2022-01-17
<b>DB22/T 3203-2020</b>	Stem Cell Quality Management Specification	2020-11-23	2020-12-30
<b>GB/T 38788-2020</b>	Technical Specification for Porcine Pluripotent Stem Cell Line Establishment	2020-04-28	2020-11-01
<b>DB32/T 3544-2019</b>	Quality Control Management Specification for Clinical-Grade Human Tissue-Derived Mesenchymal Stem Cells	2019-02-28	2019-03-30
<b>GB/T 35520-2017</b>	Chemical Embryotoxicity Embryonic Stem Cell Test	2017-12-29	2018-07-01
<b>DB33/T 2030-2017</b>	Specification for the Construction and Management of Human Mesenchymal Stem Cell Banks	2017-05-10	2017-06-10
<b>DB22/T 2394-2015</b>	Preparation and Identification of Porcine Induced Pluripotent Stem Cells (iPSCs)	2015-12-15	2016-01-25
<b>SN/T 2330-2009</b>	Cosmetic Embryotoxicity and Developmental Toxicity Mouse Embryonic Stem Cell Test	2009-07-07	2010-01-16

China Stem Cell Industry Standard System



Source: National Standard Information Public Service Platform, compiled by Qianzhan Industry Research Institute

## 3.2 Development Challenges of the China Stem Cell Industry: Unclear Industry Regulatory Regulations

Currently, China's stem cell industry faces multiple challenges in the development of regulatory regulations, including ethical, legislative, and supervisory aspects. In the context of rapid development in stem cell technology and increasing application demands, China's current regulatory system and framework are lagging in certain areas and fail to adequately adapt to new conditions. Compared to countries such as the United States and Japan, the industrialization pathway of China's stem cell industry remains relatively singular. The lack of synchronization between regulatory and industrialization processes has caused significant challenges for the translational research and applications of stem cells.

### ① Ethical issues in stem cells

A sound ethics committee for stem cell clinical research is a necessary prerequisite for the smooth conduct of clinical studies; however, the organizational development of such ethics committees in China is severely lagging. This is mainly reflected in two aspects: 1) **there is no specialized stem cell ethics committee to review stem cell clinical research**; 2) To restrict unethical research and treatment related to stem cells, internationally, the Declaration of Helsinki and the Belmont Report are regarded as the fundamental ethical principles for stem cell research. Currently, **few research institutions in China strictly comply with these**.

### ② Legislative issues in stem cells

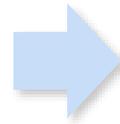
At present, there is no unified legislation on stem cells in China. Government-issued documents concerning stem cells are mostly departmental regulations, policies, or guidelines, without specific legal provisions governing the development and application of stem cells. The management measures and guiding principles issued in 2015 and 2017 constitute the current normative documents guiding the development of the stem cell field in China. While they regulate stem cell clinical research activities and promote healthy development, their restrictive authority is limited, and penalties for illegal activities are relatively constrained.

## 3.2 Development Challenges of the China Stem Cell Industry: Unclear Industry Regulatory Regulations

In the context of regulatory challenges, in recent years, multiple regions including Hainan, Shenzhen, Yunnan, Beijing, and Tianjin have carried out pilot initiatives and relaxed entry classification for stem cell medical technologies. Local governments and industry experts have been actively promoting the construction of a scientific regulatory system for stem cell medical treatment. Notably, the Tianjin Free Trade Zone has explored the management approach of 'risk classification and entry classification' for cell therapy, providing a regulatory pathway model for the industry.

### ③ Stem Cell Regulatory Issues

In early 2019, the National Health Commission issued the 'Regulations on the Clinical Application Management of Biomedical New Technologies (Draft for Comments),' categorizing stem cell products as high-risk biomedical new technologies. Although these products are developed by enterprises with advanced R&D capabilities, the standards of institutions conducting stem cell clinical research are uneven. To date, cell-based products are classified as Category I biopharmaceuticals. There are still no corresponding quality evaluation standards in the Chinese Pharmacopoeia, and strict regulation and approval of stem cell therapy projects and products remain challenges for the Chinese government.



Active exploration  
Management methods

- In recent years, the entry for stem cell medical technologies in Hainan, Shenzhen, Yunnan, Beijing, Tianjin, and other regions has successively been opened as 'pilot zones for pioneering trials.'
- The '14th Five-Year Plan' special plan for the development of the biomedical industry in Tianjin proposes taking the lead in implementing the national biopharmaceutical industry policy pilot, relaxing entry restrictions for advanced medical technologies such as stem cells, and exploring 'risk classification and entry classification' management of cell therapy within the Tianjin Free Trade Zone, allowing relevant policies to be implemented in the China-Japan (Tianjin) Health Industry Development Cooperation Demonstration Zone.
- In September 2024, the Cell Application Branch of the Anti-Aging Promotion Association of China issued the 'Expert Recommendations on the Management of Autologous Stem Cells as a Third-Class Medical Technology,' with 54 experts jointly supporting the implementation of autologous stem cells as a third-class medical technology.

### 3.3 Development Challenges of the China Stem Cell Industry: Difficulties in Product Assurance



> Prospective Industry Research Institute

#### Efficacy issues

- **Complex Mechanism of Action:** The mechanism of action of stem cells is highly complex, encompassing aspects such as cell differentiation and paracrine effects. These mechanisms remain not fully elucidated, posing challenges to the efficacy evaluation of stem cell products.
- **Insufficient Clinical Data:** At present, many clinical trials of stem cell products remain at early stages and lack long-term follow-up data, complicating the assessment of their long-term efficacy.

#### Quality control issues

- **Complex production process:** Stem cell extraction, culture, and amplification require high technical expertise and are operationally challenging, with a high risk of contamination, imposing stringent demands on the production environment and equipment.
- **Storage and transportation conditions:** Stem cells are sensitive to storage parameters and must be preserved at specific temperatures; additionally, maintaining cell viability during transportation imposes strict requirements on the logistics system.
- **Challenges in standardization:** Due to the diverse sources of stem cells (including bone marrow, adipose tissue, cord blood, umbilical cord, and placenta tissue), the properties of stem cells differ significantly, presenting substantial challenges in establishing unified quality standards.

#### Safety issues

- **Contamination Risk:** Due to the inability to perform terminal sterilization or viral clearance on stem cell products, there is an elevated risk of contamination by exogenous factors.
- **Tumor risk:** Certain stem cells (such as embryonic stem cells and induced pluripotent stem cells) may pose safety risks related to biological safety, genetic stability, and tumorigenicity/carcinogenicity.
- **Immune rejection response:** Some categories of non-autologous stem cells (particularly hematopoietic stem cells) may induce a host immune rejection response, causing Graft-versus-Host Disease (GVHD), which can lead to treatment failure and may threaten patient survival.
- **Source reliability:** The presence of hereditary diseases, risk genes, or other factors in stem cell donors is a critical safety issue to be thoroughly evaluated before stem cell transplantation.

## ◆ Analysis of the Main Operational Strategies of Stem Cell Institutions in China

Currently, leading enterprises in the stem cell field are actively pursuing diversified strategic directions, with each company displaying different approaches when extending their strategies and determining operational development priorities. Overall, it includes the following six strategic directions, each with its respective advantages and disadvantages.



4. 1 Strategy One: Establish a Quality Management System to Obtain Authoritative Certification



4. 2 Strategy Two: Develop a Digitalized and Transparent Cell Traceability System



4. 3 Strategy Three: Actively Promote Research and Development of Stem Cell Therapeutics



4. 4 Strategy Four: Extend Layout to Upstream and Downstream Sectors of the Industry Chain



4. 5 Strategy Five: Leverage Policy Benefits to Operate in Advantageous Regions



4. 6 Strategy Six: Develop Agency Channels to Expand Market Coverage

# 4 .1 Strategy One: Establish a Quality Management System and Obtain Authoritative Certification

Developing a comprehensive quality management system through obtaining international and domestic cell quality certifications and laboratory capability accreditations such as AABB, NRL, CAP, FACT, ISO, CNAS, inter-laboratory quality assessments, and verification by the National Institute of Metrology is a key operational strategy for domestic stem cell companies.



✓ The Association for the Advancement of Blood & Biotherapies (AABB) is the authoritative organization responsible for establishing standards and certifications within the international blood and cell therapy industry. AABB certification is the "gold standard" of international certification, featuring comprehensive and rigorous audit criteria.



✓ The ISO 9001 Quality Management System is among the most influential standards issued by the International Organization for Standardization (ISO), regarded as a 'passport to the international market.'



✓ Designated as a WHO Collaborating Center since 1985, NRL certification demonstrates that the laboratory is capable of virus diagnosis and detection, ensuring that samples stored in cell banks are protected from the risk of bloodborne infectious disease contamination.



✓ The National Institutes for Food and Drug Control (NIFDC) is a public institution directly under the National Medical Products Administration. **Obtaining inspection reports is one of the essential requirements for applying for clinical research of cell products. Recognition as qualified upon re-examination by NIFDC indicates that the enterprise possesses the capability to produce clinical-grade cell products.**



✓ The College of American Pathologists (CAP) is recognized as one of the most authoritative international accreditation bodies for clinical testing laboratories, and serves as the global gold standard for clinical laboratory quality, acknowledged by relevant international organizations.



✓ Inter-laboratory quality assessment is conducted by the National Clinical Laboratory Center under the National Health Commission, accredited by the Ministry of Health, as well as clinical testing centers of provincial health departments. **Stem cell companies obtaining certificates demonstrate adherence to high-quality standards in stem cell-related testing and preparation processes, and the ability to provide accurate and reliable results.**



✓ FACT certification, provided by the Foundation for the Accreditation of Cellular Therapy (FACT), is recognized as one of the authoritative accreditations in the international cell therapy sector.



✓ Accredited by the China National Accreditation Service for Conformity Assessment (CNAS), demonstrating the technical capability to perform testing and calibration services in accordance with the relevant accreditation standards.

China  
Country  
Stem  
Cell  
Cell  
Machine  
Organization  
Operation  
Management  
Strategy  
Plan  
Segment  
Analysis

# 4.1 Strategy One: Establish a Quality Management System and Obtain Authoritative Certification

In the international standard system, AABB certification is recognized as the 'gold standard' for the quality of cellular institutions. Only a few stem cell companies in China have obtained AABB certification. Beike Biology was the earliest company to obtain certification, successfully passing six consecutive reaccreditations; Boya Stem Cells has maintained certification for twelve consecutive years; Sichuan New Life Stem Cells, Shanghai Laifu Life Sciences, and other companies have also repeatedly passed certification.

## AABB Audit System



### "Hardware Configuration"

- Facility
- Scale
- Equipment Configuration
- Staff Allocation
- Infrastructure
- .....



### "Comprehensive Management Capability"

- Safety Management Standards
- Quality Management System
- Customer Service Process
- Promotional Materials
- .....

## 2024 List of Stem Cell Enterprises in China with AABB Certification

Name of Stem Cell Enterprise	Location		
Beijing Cord Blood Bank, Beijing Jiachenhong Bio-Tech Co. LTD <sup>1</sup>	Beijing		CHN
Jiangsu Beike Bio-Technology Co., Ltd <sup>1</sup>	Taizhou, Jiangsu Province		CHN
Boyalife Inc.	Wuxi	JIANGSU PROVINCE	CHN
Chengdu Qingke Biotechnology Co., Ltd. <sup>1</sup>	Chengdu	SICHUAN	CHN
Shenzhen Beike Biotechnology Co., Ltd. <sup>1</sup>	Shenzhen	GUANGDONG PROVINCE	CHN
Sichuan Wuyan Biotechnology Co. Ltd <sup>1</sup>	Chengdu		CHN
Jilin Guojian Life Engineering Science <sup>1</sup>	Changchun, Jilin		CHN
Hainan Yiling Medical Industry Development Co., Ltd. <sup>1</sup>	Qionghai		CHN
Shanghai Life Medical Science and Technology Co., Ltd.	Shanghai	MINHANG DISTRICT	CHN
Sichuan Neo-Life Stem Cell Biotech Inc, Sichuan Stem Cell Bk <sup>1</sup>	Chengdu		CHN
Shenyang Engineering Technology R&D Center of Cell Therapy	Shenyang		CHN
Hangzhou Sanjiang Shangyu Biology Co., LTD <sup>1</sup>	Zhejiang Hangzhou		CHN
Hangzhou Fengzhehuang Biotechnology Co., Ltd <sup>1</sup>	Hangzhou	ZHEJIANG	CHN

Note: The inquiry date is the end of October 2024; Superscript 1 in the table indicates that the applicant organization requested allowance for certain deviations during the AABB certification process and did not fully comply with all AABB standard clauses.

Source: AABB official website Compiled by Qianzhan Industry Research Institute

# 4.1 Strategy One: Establish a Quality Management System and Obtain Authoritative Certification

According to incomplete statistics, as of October 2024, a total of 64 institutions in China have been approved to obtain stem cell quality inspection reports from the National Institute for Food and Drug Control, with private institutions as the main force and only five public institutions; institutions approved in Guangdong and Shanghai account for more than 35%. Leading stem cell institutions such as Zhongyuan Xiehe, Boya Stem Cells, Han's United, and Beike Biology have all passed evaluation by the National Institute for Food and Drug Control.

Serial Number	Province/City	Institution Name	Nature
1	Guangdong Province 15 entities	Guangdong Xiankangda Biotechnology Co., Ltd.	Private
2		Guangdong Xiangxue Stem Cell Regenerative Medicine Technology Co., Ltd.	Private
3		Guangzhou Saicaila Stem Cell Technology Co., Ltd.	Private
4		Shenzhen Yinguan Biotechnology Co., Ltd.	Private
5		Guangdong Fujin Stem Cell Regenerative Medicine Co., Ltd.	Private
6		Dongguan Enlian Stem Cell Biotechnology Research Institute	Private
7		Guangdong Weitai Biotechnology Co., Ltd.	Private
8		The Third Affiliated Hospital of Guangzhou Medical University	Public
9		<b>Shenzhen Beike Biology Technology Co., Ltd.</b>	Private
10		China-US Cell(Guangdong)Stem cells	Private
11		Shenzhen BGI Stem Cell Technology Co., Ltd.	Private
12		Guangdong-Hong Kong-Macao Stem Cell Biotechnology Co., Ltd.	Private
13		Beihai Stem Cell and Regenerative Medicine Research Institute Co., Ltd.	Private
14		The Third Affiliated Hospital of Sun Yat-sen University	Public
15		Shenzhen 150 Life Science and Technology Co., Ltd.	Private
16	Shanghai 8 entities	Tongji University Affiliated Oriental Hospital	Public
17		Shanghai Sai'ao Biotechnology Co., Ltd.	Private
18		Yuanneng Cell Technology Group Co., Ltd.	Private
19		Huaxia Source (Shanghai) Cell and Gene Engineering Co., Ltd.	Private
20		Bopin (Shanghai) Biopharmaceutical Technology Co., Ltd.	Private
21		Yingyi Biotechnology (Shanghai) Co., Ltd.	Private
22		Shanghai Quansheng Biotechnology Co., Ltd.	Private
23		Shanghai Laifu Life Sciences and Technology Co., Ltd.	Private

Serial Number	Province/City	Institution Name	Nature
24	Tianjin 5 Entities	Tianjin Onset Cell Gene Engineering Co., Ltd.	Private
25		Huayu Biotechnology(Tianjin)Co., Ltd.	Private
26		Shunhao Cell Biotechnology(Tianjin)Co., Ltd.	Private
27		Tianjin Changhe Biotechnology Co., Ltd.	Private
28		<b>Zhongyuan Xiehe Cell and Gene Engineering Co., Ltd.</b>	Private
29	Zhejiang Province 5 Entities	Zhejiang Lingwei Biotechnology Co., Ltd.	Private
30		Zhejiang Jinshidai Biotechnology Co., Ltd.	Private
31		Zhejiang Shengchuang Precision Medical Technology Co., Ltd.	Private
32		Hangzhou Yiwen Sai Biotechnology Co., Ltd. /Zhejiang Province Mesenchymal Stem Cell Bank	Private
33		Ningbo Xinuosai Biotechnology Co., Ltd.	Private
34	Beijing 4 entities	Beijing Jiyuan Biotechnology Co., Ltd.	Private
35		<b>Beijing Han's United Biotechnology Co., Ltd.</b>	Private
36		Beijing Hengfeng Mingcheng Biotechnology Co., Ltd.	Private
37		Jiuzhitang Meike(Beijing)Cell Technology Co., Ltd.	Private
38	Jiangsu Province 4 entities	<b>Boya Stem Cells Technology Co., Ltd.</b>	Private
39		Leading Stem Cell Regenerative Medicine Engineering Co., Ltd.	Private
40		Suzhou Jimeirui Biomedical Technology Co., Ltd.	Private
41		Nanjing Aierpu Regenerative Medicine Technology Co., Ltd.	Private
42	Yunnan Province 3 entities	Affiliated Yan'an Hospital of Kunming Medical University	Public
43		Yunnan Cancer Hospital	Public
44		Yunnan Shunxi Regenerative Medicine Engineering Co., Ltd.	Private

Serial Number	Province/City	Institution Name	Nature
45	Hunan Province 3 entities	Hunan Yuanpin Cell Biotechnology Co., Ltd.	Private
46		Hunan Guangxiu High-tech Life Science Co., Ltd.	Private
47		Hunan Nanhua Biotechnology Co., Ltd.	Private
48	Sichuan Province 3 entities	Chengdu Kangjing Biotechnology Co., Ltd.	Private
49		Chengdu Shilian Kangjian Biotechnology Co., Ltd.	Private
50		Sichuan Chiding Shengtong Biotechnology Co., Ltd.	Private
51	Jilin Province 2 entities	Jilin Zhongke Bioengineering Co., Ltd.	Private
52		Jilin Xinhai Biotechnology Development Co., Ltd.	Private
53	Hebei Province 2 entities	Hebei Life Origin Biotechnology Co., Ltd.	Private
54		Hebei Betsea Biotechnology Co., Ltd.	Private
55	Henan Province 2 entities	Henan Yinfeng Bioengineering Technology Co., Ltd.	Private
56		Henan Hualong Biotechnology Co., Ltd.	Private
57	Liaoning Province 2 entities	Liaoning Medical Diagnosis and Treatment Technology R&D Center Co., Ltd.	Private
58		Bio-otec(Shenyang)Biomedical Group Co., Ltd.	Private
59	Heilongjiang Province	Tianqing Stem Cells Co., Ltd.	Private
60	Shandong Province	Shandong Qilu Cell Therapy Engineering Co., Ltd.	Private
61	Chongqing Municipality	Chongqing Boerfei Cell Biotechnology Co., Ltd.	Private
62	Hubei Province	Wuhan Hamilton Biotechnology Co., Ltd.	Private
63	Guizhou Province	Guizhou Zhongguan Biotechnology Co., Ltd.	Private
64	Hainan Province	Hainan Jimin Boao International Hospital	Private

## 4.2 Strategy Two: Establish a Digital and Transparent Cell Traceability System

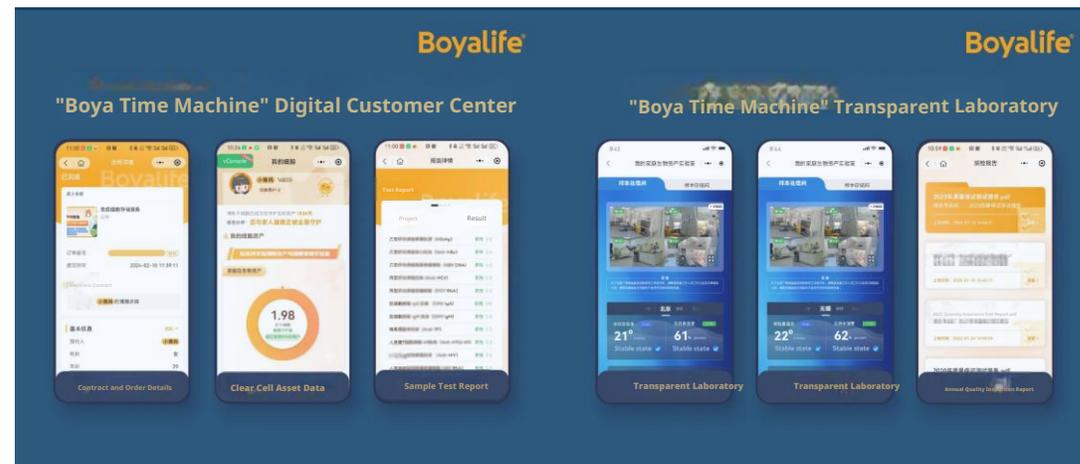
Currently, highly digitalized, productized, and internet-based membership management centers are rare in the cell technology industry. The cell industry's refined customer service still has significant ground to cover to catch up with the mature paradigms of 'intelligent, smart, and digital' consumer goods markets. However, with the continuous development of the Internet and AI technologies, the application of cell technology in the healthcare sector is expanding, the customer base and demands for refined customer service are increasing, making digitalization, transparency, and refinement inevitable trends in the cell technology industry. Zhongyuan Xiehe, Boya Stem Cells, and other leading stem cell enterprises are at the forefront of developing digital cell traceability systems, continuously enhancing quality management to fulfill compliance requirements for cell products and operations.

China **Zhongyuan Xiehe Stem Cell New Drug Digital Traceability System**



- ✓ Zhongyuan Xiehe and Zhihi Technology have developed a leading digital traceability system for stem cell novel drugs. Utilizing digital and artificial intelligence capabilities, it connects the entire bidirectional traceability chain from tissue collection, transportation, formulation preparation, warehouse release, to clinical reinfusion. This guarantees that donor material transport, receipt, product manufacturing, and utilization processes are more standardized, precise, and traceable, meeting regulatory requirements and enabling a fully closed-loop operation.

**"Boyaa Time Machine" Digital Membership Center+Transparent Laboratory**



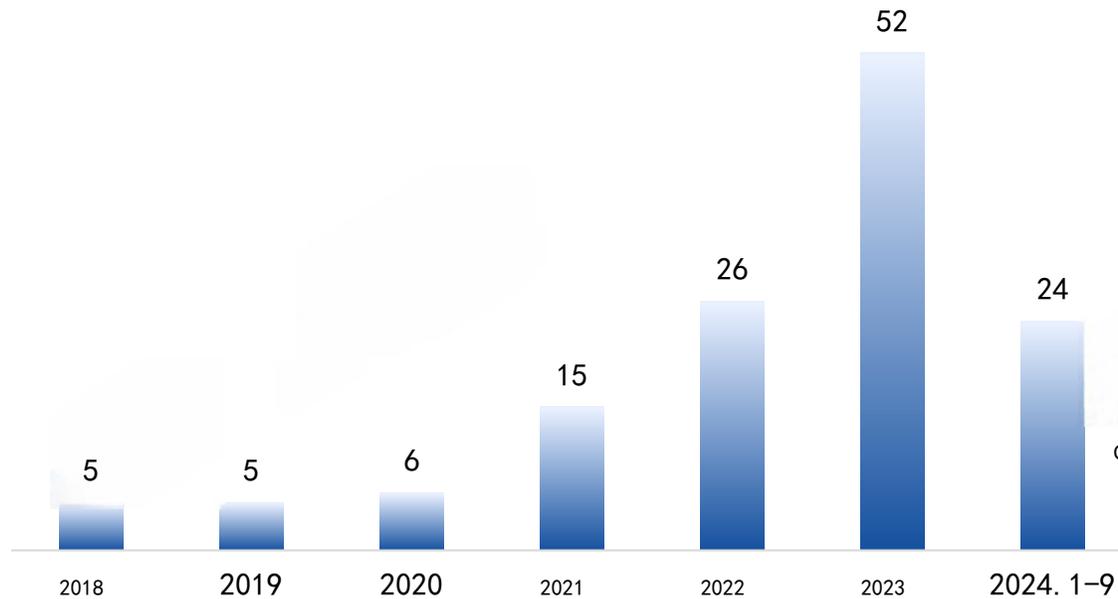
- ✓ Leveraging a comprehensive quality management system, Boyaa has established the "Boyaa Time Machine" Digital Membership Center and Transparent Laboratory, which clearly documents the "storage" and "retrieval" of each cell through a digital system. Additionally, the laboratory's sample processing environments are transparently accessible to customers. Ensure full traceability of cell samples, data security, and quality management.

Note: Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd. is a subsidiary of Zhongyuan Xiehe.

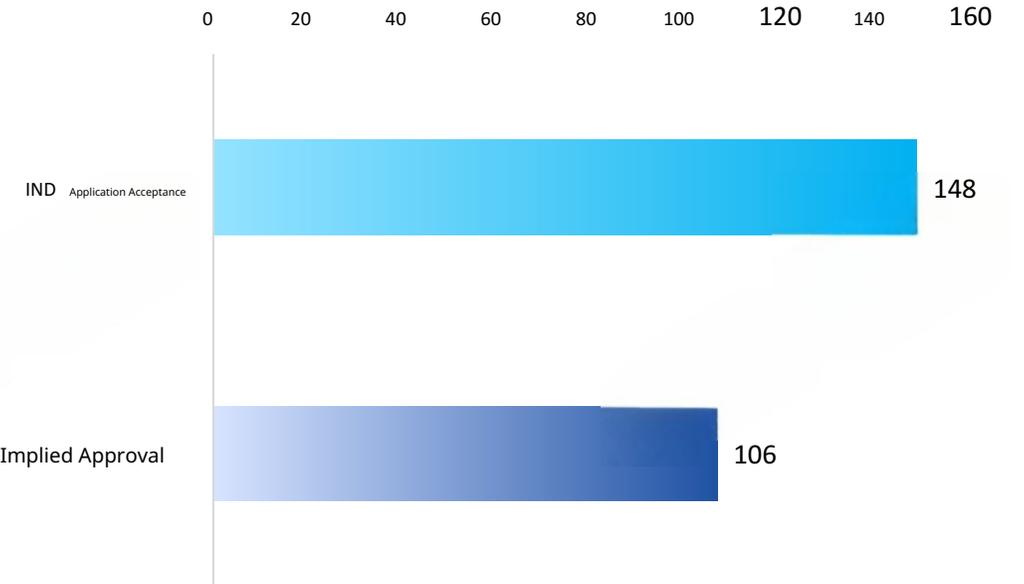
## 4.3 Strategy Three: Actively Promote Stem Cell Therapeutics R&D

Since stem cell preparation, storage, and differentiation therapy are closely interconnected, clients typically consider a company's comprehensive technical capabilities in differentiation therapy and drug development when selecting a stem cell preparation and storage provider. Consequently, domestic stem cell industry companies are actively expanding into drug development. Although no stem cell therapeutics have yet been marketed in China, related drug development projects continue to increase domestically. Companies actively advance their own clinical pipelines and submit IND applications to enhance market competitiveness based on their research and development capabilities. As of October 2024, a total of 148 stem cell therapeutics IND applications have been accepted in China, of which 106 have been approved.

Trends in the number of stem cell therapeutics IND applications accepted in China from 2018 to 2024 (cases)



Total stem cell therapeutics IND applications accepted and approved in China as of October 2024 (cases)



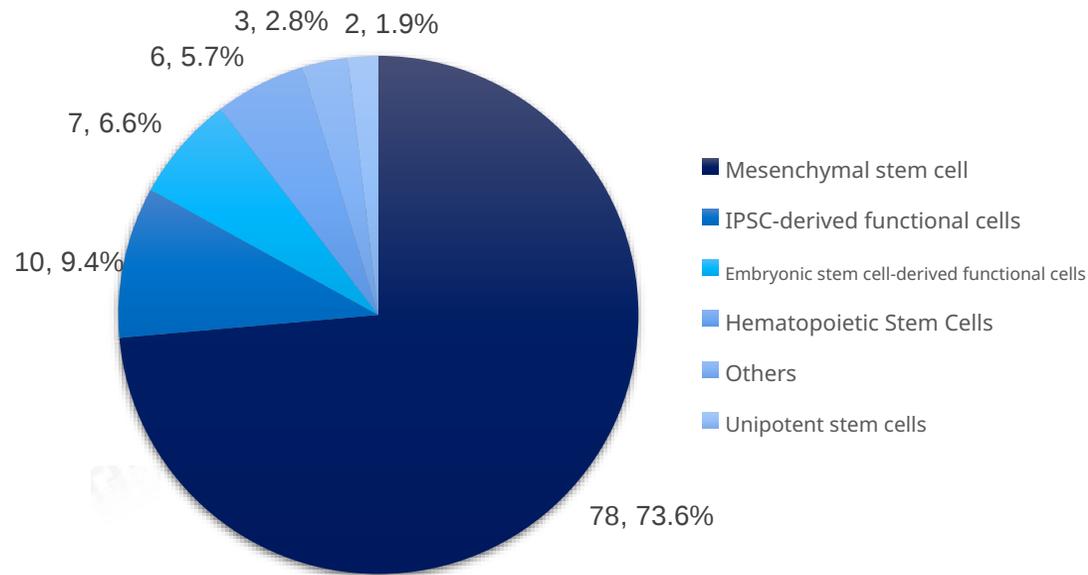
Note On October 26, 2017, the revised Management Measures for Drug Registration stipulated that cell therapy products shall be accepted for filing as new drugs. In December 2017, the CFDA issued the Guiding Principles for the Research and Evaluation of Cell Therapy Products (Trial), which clearly specified that cell products are to be registered and regulated in accordance with pharmaceutical review procedures.

Source: National Medical Products Administration Center for Drug Evaluation, compiled by Qianzhan Industry Research Institute

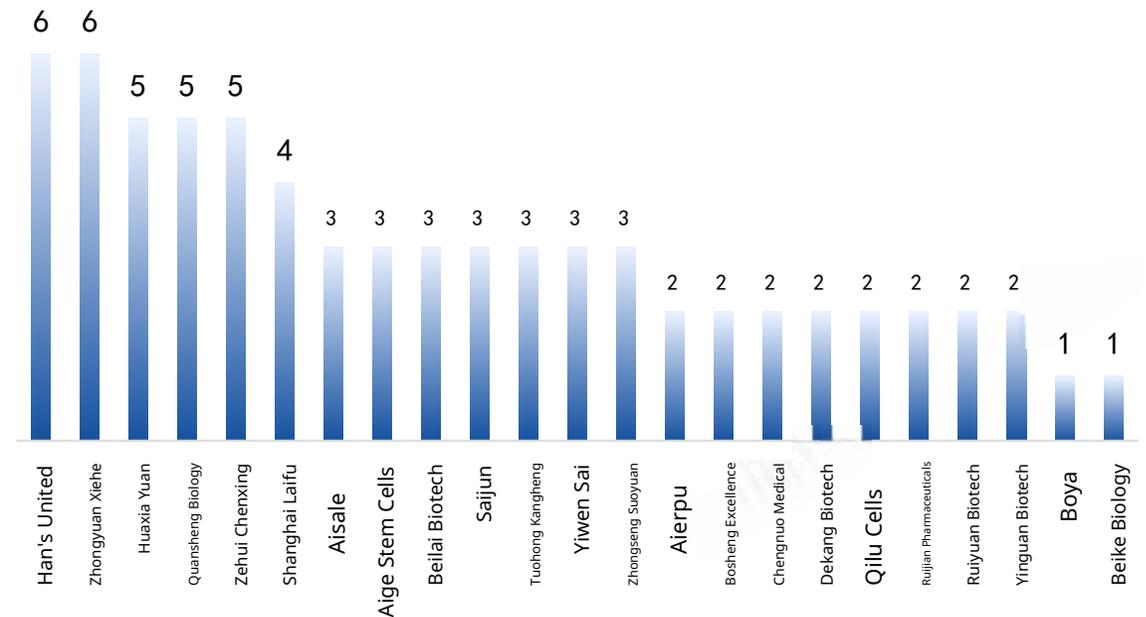
## 4.3 Strategy Three: Actively Promote Stem Cell Therapeutics R&D

As of October 2024, among the approved IND cell types, mesenchymal stem cell therapeutics total 78 cases, accounting for 73.6%, representing the primary cell type in stem cell therapeutic development; there are 10 approved stem cell therapeutics derived from iPSC functional cells. As of October 2024, regarding the approval status of IND stem cell therapeutics by companies, Zhongyuan Xiehe and Han's United, two leading enterprises, each have the highest number of approved stem cell therapeutics, with 6 cases respectively; Beike Biology, Boya Stem Cells, Chen-nuo Medical, Bosin Excellence, and others all possess stem cell therapeutics. At the same time, many R&D companies have established multiple proprietary clinical pipelines.

As of 2024, China has approved INDs for stem cell therapeutics categorized by cell type composition (example, %)



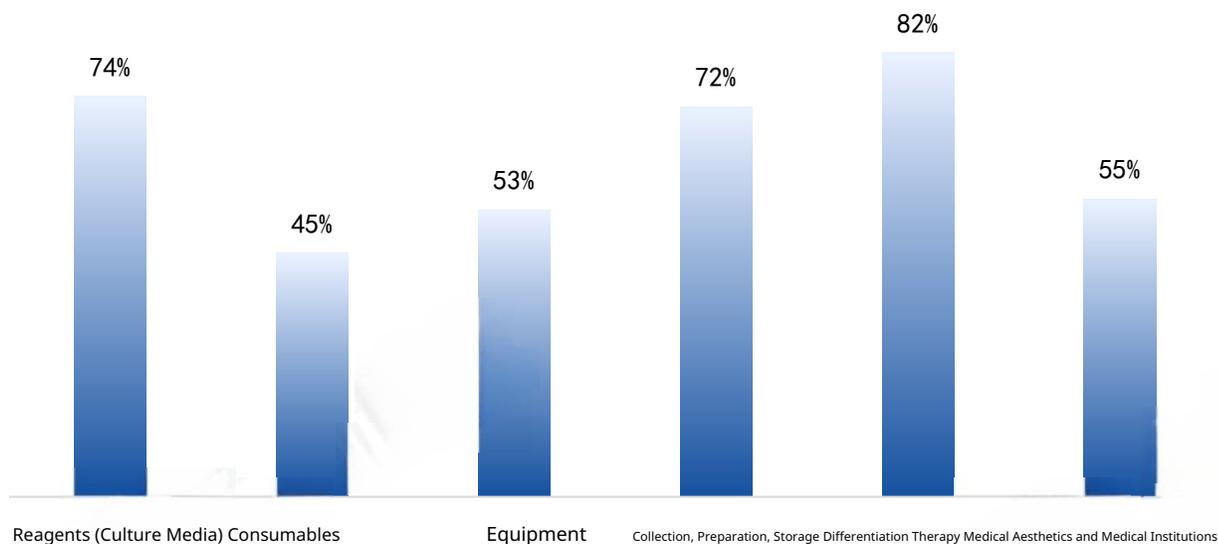
As of 2024, representative Chinese companies have obtained IND approvals for stem cell therapeutics (example)



# 4.4 Strategy Four: Expanding Layout to Upstream and Downstream Segments of the Industry Chain

The storage segment is presently the most mature and competitive part of the stem cell market. Certain companies enhance the autonomy and controllability of the entire industry chain by extending their presence into upstream materials and equipment or downstream application areas. For instance, stem cell companies such as Yuanneng Cell and Boya Stem Cells have expanded into upstream automated separation/storage equipment and medical device sectors.

Comparison of Gross Margin Levels Across Various Segments in China's Cell Industry (%)



Examples of upstream equipment extension layouts by representative domestic stem cell companies

**AXP® Stem Cell Automated Isolation Equipment**  
High-throughput Fully Automated

**Boyalife®**  
Boya Stem Cells

**BioArchive® Fully Automated Zero-contamination Liquid Nitrogen Storage Device**  
Cell Recovery Survival Rate >94%

Due to the level of technological development and the first-mover advantage of overseas manufacturers, the domestic stem cell industry's equipment, consumables, and reagents largely depend on imports, typically sold as bundled equipment and reagent packages; domestic stem cell collection, storage, and preparation companies have relatively weak bargaining power. Some domestic companies have conducted R&D and manufacturing of upstream equipment, but the investment costs are high and the development cycle is long

## 4.4 Strategy Four: Expanding Layout to Upstream and Downstream Segments of the Industry Chain

Expanding applications into downstream consumer sectors such as stem cell-based cosmetics is also among the strategies of some domestic stem cell companies. Taking stem cell applications in cosmetic beauty as an example, with the rapid growth in demand among Chinese consumers for high-quality beauty solutions, the stem cell beauty industry has developed accordingly. In 2023, China accepted three IND filings for stem cell therapeutics related to medical aesthetics, which implicitly granted approval for clinical trials; The market size of stem cell beauty exceeded 2 billion yuan in 2023, with a year-on-year growth approaching 20%. Cytori Stem Cells is a representative stem cell enterprise positioned in the beauty application sector, with beauty-related business revenue accounting for up to 70%.

2023-2024 IND applications and approvals for aesthetic medicine-related indications Stem cell new drugs

- 1



**Wuxi Huatai Innovation Pharmaceutical Research Institute**  
WUXI HUATAI INNOVATION PHARMACEUTICAL RESEARCH INSTITUTE

IND-approved new drug: IHS002 Human umbilical cord mesenchymal stem cell

Indications: Repair of burns, diabetic foot ulcers, and pressure ulcer wounds
- 2



**Beijing Aige Stem Cell Technology Co., Ltd.**

IND-approved new drug: Human adipose-derived mesenchymal stem cell injection

Indications: Treatment of localized scleroderma with skin sclerosis affecting the head, face, and limbs
- 3

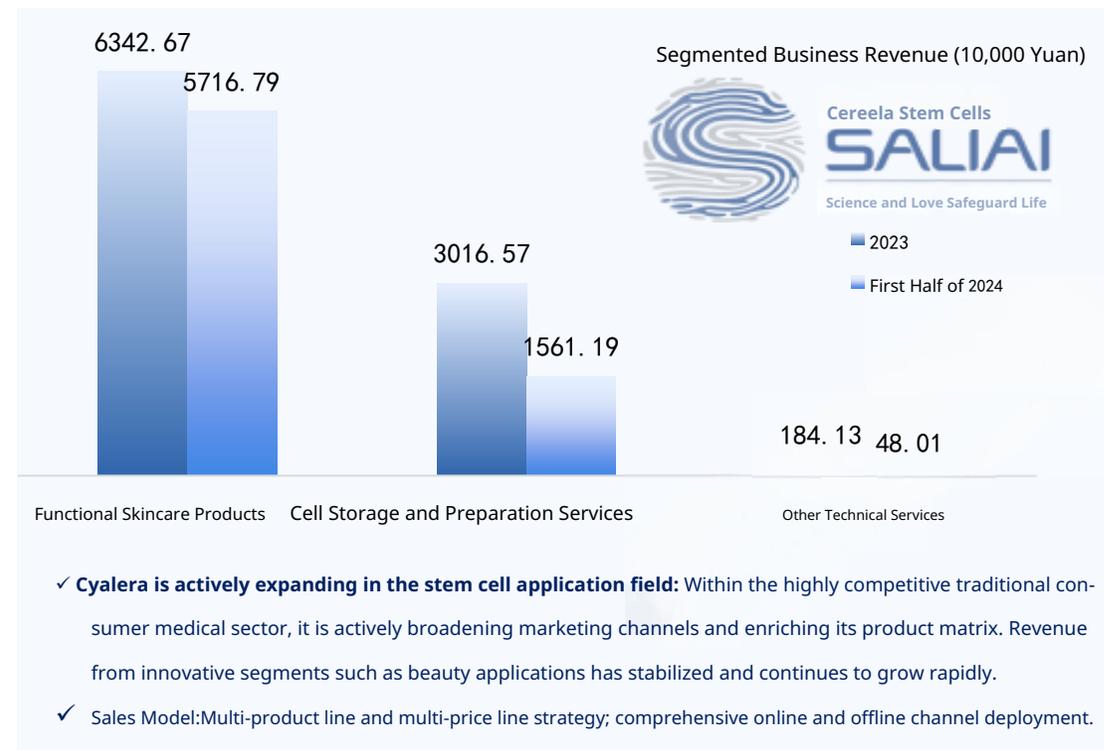


**Hangzhou Yiwen Sai Biotechnology Co., Ltd.**

IND Approved New Drug: Human Umbilical Cord Mesenchymal Stem Cell Injection

Indication: Moderate to Severe Atopic Dermatitis

Case study on the application expansion of Cytori Stem Cells in the field of beauty

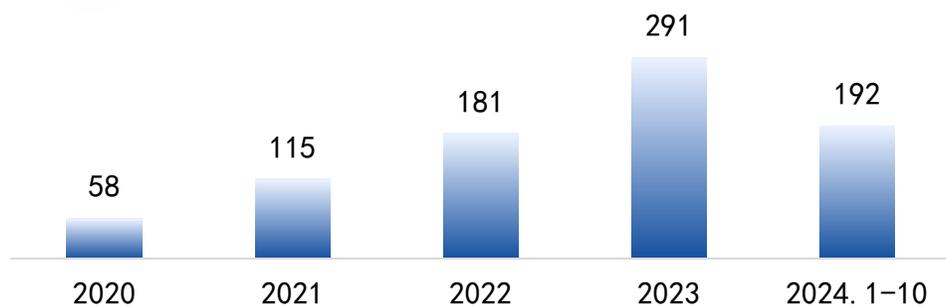


# 4.4 Strategy Four: Expanding Layout to Upstream and Downstream Segments of the Industry Chain

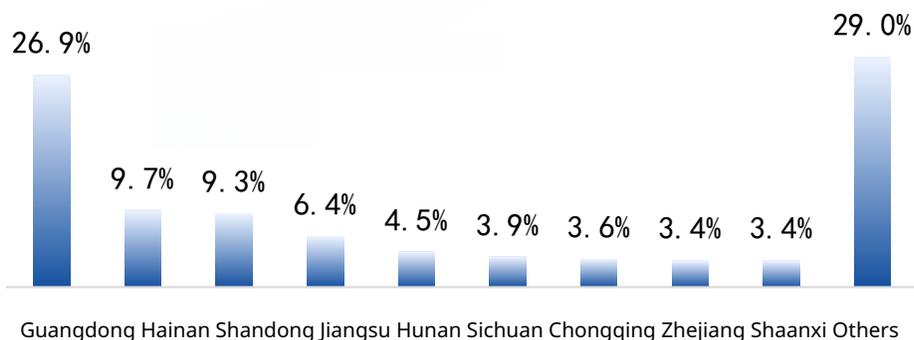
As of October 2024, there are approximately 1,009 stem cell beauty-related enterprises in China, with rapid growth in newly established companies in recent years; nearly 30% are located in Guangdong.

Although the stem cell beauty application sector in China currently shows rapid development trends, the potential risks for stem cell enterprises entering this field should not be overlooked, including market competition risks, policy change risks, and product compliance risks.

Number of enterprises registered in China's stem cell cosmetics field from 2020 to 2024 (units).



Regional distribution of stem cell cosmetic enterprises in China as of 2024 (%).



Potential operational risks faced by enterprises in the stem cell cosmetics sector.

### Policy change risks:

Stem cell-based beauty applications are an emerging field, with relevant laws, regulations, and technical standards still under ongoing development. Authorities such as the National Health Commission and the National Medical Products Administration enforce stringent approval and supervision of stem cell products; policy changes may significantly impact company operations.

### Market competition risks:

As more enterprises enter the stem cell cosmetics market, competition will intensify. Meanwhile, consumer awareness of stem cell cosmetics remains limited, resulting in high market education costs. Some stem cell companies are expanding the beauty application market through private domain marketing and low-price strategies, presenting significant risks of market disorder.

### Compliance risks of stem cell-derived products:

Stem cell exosomes have not yet been included in the 'Catalogue of Approved Cosmetic Ingredients' and thus cannot currently be added as cosmetic ingredients. The number of registered related products in the market is extremely limited, and most products are registered under labels such as 'umbilical cord extract,' which to some extent poses risks in promotional activities.

Note: Data as of the end of October 2024.

Source: Qichamao, compiled by Qianzhan Industry Research Institute

# 4.5 Strategy Five: Leveraging Policy Incentives to Operate in Advantageous Regions

In the context of an underdeveloped stem cell regulatory system in China, some enterprises rely on regional policy support advantages, fostering the development of industrial chain enterprises to establish regional industrial ecosystem clusters. For example, certain stem cell enterprises located in policy-advanced regions such as Yunnan and Hainan not only benefit from policy incentives but also capitalize on the convenience of upstream and downstream industrial chain resource integration, forming regional operational advantages.

## Case Studies of Stem Cell-Related Specialized Industry Clusters in China

### Yunnan - Kunming High-tech Zone Cell Industry Cluster Innovation Park

#### Policy Guidance: 'Kunming Cell Industry Development Plan (2021-2023)'

- Mobilize the Entire City's Efforts to Build a Stem Cell and Regenerative Medicine Cluster to Establish It as a Flagship Highlight of the Public Health Industry.
- Prioritize Support for Autologous, Minimal Manipulation, and Cell Therapy Technologies, Which Currently Have No Effective Treatments but Are Clinically Proven Effective, for Technology Translation.

#### Industry Cluster: Centered on the Yunnan Cell Engineering Center, Aggregating Enterprises in the Cell Application Sector

- Centered on the Yunnan Provincial Cell Quality Testing and Evaluation Center and the Yunnan Provincial Cell Preparation Center, the park provides shared facilities, attracting numerous ecological enterprises and a concentration of cell application companies, engaged in health care and therapeutic services .
- The park hosts a total of 139 cell ecology enterprises, of which 37 explicitly include the stem cell sector within their business scope.



Subordinate entities include the Yunnan Provincial Cell Bank, Yunnan Provincial Cell Preparation Center, Yunnan Provincial Cell Quality Testing and Evaluation Center, and Yunnan Provincial Cell Medical Center.

### Hainan - Lecheng Pilot Zone Stem Cell Specialized Hospital Cluster

#### Policy Leadership: 'Regulations of the Boao Lecheng International Medical Tourism Pilot Zone in Hainan Free Trade Port'

- Medical institutions in the pilot zone may conduct research and translational applications of new technologies including stem cell therapy, immune cell therapy, monoclonal antibody pharmaceuticals, gene therapy, and tissue engineering within the pilot zone.

#### Industry Cluster: Stem Cell Therapy Specialized Hospital Cluster

- Both Haikou and Sanya have formed industry clusters related to cell therapy and health care. Stem cell industry companies, such as China Stem Cell Group, capitalizing on Hainan's open policies, have established specialized stem cell therapy hospitals locally.



China Stem Cell Group Hainan Boao Affiliated Stem Cell Hospital  
China Stem Cell Group Affiliated Stem Cell Hospital, Boao, Hainan  
Shanghai Jiao Tong University School of Medicine Affiliated Tongren Hospital Palliative Care Branch  
St. Luke's Hospital Boao Branch, Shanghai Jiao Tong University School of Medicine

## 4.6 Strategy Six: Develop agency channels to expand market coverage

Expansion through franchise agency models or the 'centralized storage service ecosystem' model represents a mainstream approach for business development and market coverage in the stem cell storage industry. For example, Han's United and Haier Cell have developed franchise agency models, authorizing agents nationwide; Beike Biology has established a 'centralized storage service ecosystem,' deploying cell bank testing platforms in Jiangsu, Shenzhen, Guizhou, Hebei, and other regions. It is noteworthy that, under this operational strategy, enterprises must implement strict control over agents, requiring adherence to stringent management standards, a digital management platform, and a rigorous training system, while still facing substantial risks of management disruption and business loss due to channel team changes

### Han's United 'Offline Popular Science Store' Agency Franchise Model

**Standardized Outsourced Operation Output System**

**Han's Ark Health Ark**

**Brand Image Support**  
Unified Brand Image, Shared Headquarters Promotional Resources

**Member Resources Support**  
Member Customer Resource Sharing

**Training Support**  
Project Design Training, Professional Technical Training, Sales Training, Professional Knowledge Classroom Training

**Renovation and Construction Support**  
Unified V&S Management

**Human Resources Support**  
Training for Store Managers, Consulting Advisors, and Experts  
Regular Support for the Marketing Team

**01** **02** **03** **04** **05**

**No Experience Required, Easy Copy Successful**

✓ The 'Han's Ark Offline Popular Science Stores' are currently operating in Shanghai, Guangzhou, Beijing, Chengdu, Hangzhou, Nanjing, Chongqing, Quanzhou, Yixing, Fengcheng, Taiyuan, Linyi, Haikou, and Fuyang.

### Haier International 'Cell Bank Service Center' Authorized Agency Model

**MERCHANTS JOIN**

**Lingyin Advanced Medical System**  
LEADING INNOVATIVE HEALTHCARE

**INDUSTRY ADVANTAGES**

<b>National Support</b>	<b>Current Domestic Status</b>	<b>Policy Follow-up</b>
<p>The 'Special Plan for Innovation in Health and Medical Technology' explicitly requires strengthening research on key technologies including stem cells and regenerative medicine, immunotherapy, gene therapy, and cell therapy.</p> <p>National Policy Support, Industry Prospects</p>	<p>China has currently approved the establishment of 119 registered institutions for stem cell clinical research. A total of 74 stem cell clinical research projects have been approved and registered. As of March 29, 2019, 529 stem cell clinical research projects conducted in China were registered on the Clinical Trials website.</p>	<p>The nation, particularly in relation to the biotech industry, focuses on stem cell and immune cell therapy. A substantial number of industry problems have been successfully solved to standardize and encourage the rapid development of the biotech industry. Rapid development of the industry.</p>

✓ Currently disclosed authorized agents include 35 "Haier International Cell Bank Service Centers," distributed across Beijing, Tianjin, Shijiazhuang, Qingdao, Shenzhen, Guangzhou, Zhongshan, Wuxi, Nantong, Chongqing, Hangzhou, Fuzhou, Dalian, Chengdu, Yanbian, and other locations.

05

# Appendix: Stem Cell Therapeutics IND Acceptance/Approval List as of 2024 - FORWARD 前瞻

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Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
1	2024/10/15	CXSL2400695	YFQLXB -UC01 Injection	Mesenchymal stem cell	New Drug		Shandong Qilu Cell Therapy Engineering Technology Co., Ltd.;	
2	2024/9/28	CXSL2400674	Human Amniotic Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Sourcecell Biotechnology Group Co., Ltd.;	
3	2024/9/26	CXSL2400667	VUM02 Injection	Mesenchymal stem cell	New Drug		Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	
4	2024/9/18	CXSB2400108	VUM02 Injection	Mesenchymal stem cell	Supplementary Application		Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	
5	2024/9/10	CXSB2400097	NCR100 Injection	IPSC-derived functional cells	Supplementary Application		Anhui Zhongsheng Suyuan Biotechnology Co., Ltd.;	
6	2024/8/29	CXSB2400089	Allogeneic Endothelial Progenitor Cell (EPCs) Injection	IPSC-derived functional cells	Supplementary Application		Chengnuo Regenerative Medicine Technology (Zhuhai Hengqin New Area) Co., Ltd.;	
7	2024/8/24	CXSL2400561	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Beijing Beilai Pharmaceutical Co., Ltd.;	
8	2024/8/15	CXSB2400084	Allogeneic Human Adipose-Derived Mesenchymal Stem Cell Injection	Mesenchymal stem cell	Supplementary Application		Jiangsu Dekang Biotechnology Co., Ltd.;	
9	2024/8/3	CXSL2400516	YFQLXB -UC01 Injection	Mesenchymal stem cell	New Drug	For the treatment of moderate to severe acute respiratory distress syndrome.	Shandong Qilu Cell Therapy Engineering Technology Co., Ltd.;	1
10	2024/8/2	CXSL2400513	IHS002-Enabled Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Wuxi Huatai Innovative Pharmaceutical Technology Research Institute Co., Ltd.;	
11	2024/7/16	CXSL2400453	YT001 Injection	Mesenchymal stem cell	New Drug	Knee Osteoarthritis (KOA)	Shanghai Yuantian Biotechnology Co., Ltd.;	1
12	2024/6/19	CXSL2400401	VUM02 Injection	Mesenchymal stem cell	New Drug	Systemic Sclerosis	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
13	2024/6/13	CXSL2400382	Human GLP-1 and FGF21 Dual-Factor Overexpressing Adipose Stem Cell Injection	Unipotent stem cells	New Drug	Type 2 Diabetes Mellitus	Beijing Jiyuan Biotechnology Co., Ltd.;	1
14	2024/6/13	CXSL2400380	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to Severe Active Inflammatory Bowel Disease	Hangzhou Yiwen Sai Biotechnology Co., Ltd.;	1
15	2024/5/30	CXSL2400353	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Zhejiang Quansheng Biotechnology Co., Ltd.; Hainan Xinshengquan Stem Cells Pharmaceuticals Co., Ltd.;	
16	2024/5/30	CXSB2400054	Allogeneic Endothelial Progenitor Cells (EPCs) Injection	IPSC-derived functional cells	Supplementary Application		Chengnuo Regenerative Medicine Technology (Zhuhai Hengqin New Area) Co., Ltd.;	
17	2024/4/23	CXSL2400258	Human Amniotic Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Sourcecell Biotechnology Group Co., Ltd.;	
18	2024/4/8	CXSL2400212	Injectable human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug	Postmenopausal osteoporosis with very high risk of fracture	Alpro Regenerative Medicine Technology (Shenzhen) Co., Ltd.;	1
19	2024/2/26	CXSL2400156	Uterine blood mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Severe pneumonia caused by viral infection	Zhejiang Shengchuang Precision Medical Technology Co., Ltd.;	1
20	2024/2/26	CXSL2400157	SCM -181 Injection	Mesenchymal stem cell	New Drug	Idiopathic pulmonary fibrosis	Yunnan Shunxi Regenerative Medicine Engineering Co., Ltd.;	1

# Appendix: List of Stem Cell Therapeutics IND Acceptances/Approvals as of 2024

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
21	2024/2/8	CXSL2400111	Allogeneic Human Adipose-Derived Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Complex Anal Fistula	Jiangsu Dekang Biotechnology Co., Ltd.;	1
22	2024/2/3	CXSL2400092	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to Severe Systemic Lupus Erythematosus	Shenzhen Beike Biology Technology Co., Ltd.;	1
23	2024/1/10	CXSL2400023	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	This product is a pharmaceutical for digestive system diseases, indicated for Decompensated Hepatitis B Cirrhosis	Jilin Province Tohwa Biology Technology Co., Ltd.;	1
24	2024/1/10	CXSL2400021	CS-101 Injection	Hematopoietic Stem Cells	New Drug	For the treatment of severe $\beta$ - thalassemia	Zhengxu (Shanghai) Biopharmaceutical Technology Co., Ltd.;	1
25	2023/12/30	CXSL2300909	CG - BM1 Allogeneic Human Bone Marrow Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Ischemic Stroke	Guangzhou Saijun Biotechnology Co., Ltd.;	1
26	2023/12/30	CXSB2300150	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	Supplementary Application	Interstitial Lung Disease	Shanghai Laifu Medical Technology Co., Ltd.;	1
27	2023/12/14	CXSL2300857	Human Adipose Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Diabetic Foot Ulcer	Beijing Aige Stem Cell Technology Co., Ltd.;	1
28	2023/12/13	CXSL2300854	YFQLXB - UC01 Injection	Mesenchymal stem cell	New Drug	Decompensated Cirrhosis	Shandong Qilu Cell Therapy Engineering Technology Co., Ltd.;	1
29	2023/11/30	CXSB2300138	HBG Gene-Modified Autologous CD34+Hematopoietic Stem Cell Injection	Hematopoietic Stem Cells	Supplementary Application	Transfusion-dependent $\beta$ - Thalassemia	Guangzhou Ruifeng Biotechnology Co., Ltd.;	1
30	2023/11/22	CXSL2300795	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Injectable administration for chronic obstructive pulmonary disease	Zhejiang Quansheng Biotechnology Co., Ltd.;	1
31	2023/11/14	CXSL2300776	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Beijing Belai Biotechnology Co., Ltd. ; Beijing Belai Pharmaceuticals Co., Ltd. ;	
32	2023/11/10	CXSL2300770	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Shenzhen Yinguan Biotechnology Co., Ltd.;	
33	2023/11/10	CXSL2300769	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Guangzhou Dabo Biological Products Co., Ltd.;	
34	2023/11/4	CXSL2300760	Injection of mesenchymal stem cells (umbilical cord)	Mesenchymal stem cell	New Drug	Acute ischemic stroke	Tianjin Ansaier Cell Gene Engineering Co., Ltd.;	1
35	2023/11/1	CXSL2300747	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to severe active ulcerative colitis	Shenzhen Yinguan Biotechnology Co., Ltd.;	1
36	2023/10/26	CXSL2300728	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Chronic heart failure caused by chronic ischemic cardiomyopathy indicated for coronary artery bypass grafting.	Tianshili Pharmaceutical Group Co., Ltd.;	1
37	2023/10/20	CXSL2300718	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Chronic obstructive pulmonary disease with pulmonary interstitial abnormalities	Shanghai Laifu Medical Technology Co., Ltd.;	1
38	2023/10/18	CXSL2300710	BD211 Autologous CD34+Hematopoietic Stem Cell Injection	Hematopoietic Stem Cells	New Drug	Transfusion-dependent $\beta$ - Thalassemia	Shanghai Bendaogen Gene Technology Co., Ltd.;	1
39	2023/10/14	CXSL2300699	KL003 Cell Injection	Hematopoietic Stem Cells	New Drug	Transfusion-dependent $\beta$ - Thalassemia	Kanglin Biotechnology (Hangzhou) Co., Ltd.;	1
40	2023/10/9	CXSL2300670	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to severe atopic dermatitis	Hangzhou Yiwen Sai Biotechnology Co., Ltd.;	1

# Appendix: Stem Cell Therapeutics IND Acceptance/Approval List as of 2024 -3

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
41	2023/10/8	CXSL2300664	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Early (ARCO Stage I or II) Non-traumatic Femoral Head Necrosis	Guizhou Zhongguan Biotechnology Co., Ltd.;	1
42	2023/9/27	CXSL2300659	HGI -001 Injection	Hematopoietic Stem Cells	New Drug	This product is intended for the treatment of transfusion-dependent $\beta$ -thalassemia.	Shenzhen Hemu Gene Biotechnology Co., Ltd.;	1
43	2023/9/26	CXSL2300656	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Shenzhen Yinguan Biotechnology Co., Ltd.;	
44	2023/9/20	CXSL2300637	Injectable human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug		Alpro Regenerative Medicine Technology (Shenzhen) Co., Ltd.;	
45	2023/9/20	CXSB2300101	Allogeneic Endothelial Progenitor Cell (EPCs) Injection	IPSC-derived functional cells	Supplementary Application	This product is intended for the treatment of acute ischemic stroke.	Cenno Regenerative Medicine Technology (Zhuhai Hengqin New Area) Co., Ltd.;	1
46	2023/9/19	CXSL2300630	Human Adipose Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Used for the treatment of localized scleroderma on the head, face, and limbs sclerosis.	Beijing Aige Stem Cell Technology Co., Ltd.;	1
47	2023/9/16	CXSL2300628	Human-derived dopaminergic progenitor cell injection	IPSC-derived functional cells	New Drug	Early-onset Parkinson's disease with onset age below 50 years, This indication was included in the National Health Commission's list in May 2018. A batch of rare disease catalogs	Ruijian Pharmaceutical Technology (Suzhou) Co., Ltd.; Wuhan Ruijian Pharmaceutical Technology Co., Ltd.;	1
48	2023/8/23	CXSL2300562	NCR300 Injection	IPSC-derived functional cells	New Drug	Prevention of relapse following allogeneic hematopoietic stem cell transplantation for acute myeloid leukemia Post-transplant relapse	Anhui Zhongsheng Suyuan Biotechnology Co., Ltd.;	1
49	2023/8/23	CXSL2300562	NCR300 Injection	IPSC-derived functional cells	New Drug	Prevention of relapse following allogeneic hematopoietic stem cell transplantation for acute myeloid leukemia Post-transplant relapse	Anhui Zhongsheng Suyuan Biotechnology Co., Ltd.;	1
50	2023/8/22	CXSL2300561	Allogeneic Endothelial Progenitor Cell (EPCs) Injection	IPSC-derived functional cells	New Drug	This product is intended for the treatment of severe lower limb ischemia	Chengnuo Regenerative Medicine Technology (Beijing) Co., Ltd.;	1
51	2023/8/16	CXSL2300547	Human umbilical cord mesenchymal stem cell (allogeneic) injection	Mesenchymal stem cell	New Drug		Zhejiang Jindai Biological Technology Co., Ltd.;	
52	2023/7/28	CXSL2300523	CEFFE001 Injection	Others	New Drug	Acute respiratory distress syndrome (acute respiratory distress syndrome, ARDS)	Shanghai Samei Cell Technology Co., Ltd.;	1
53	2023/7/25	CXSL2300509	VUM02 Injection	Mesenchymal stem cell	New Drug	Hormone therapy-resistant Grade II to Grade IV acute graft-versus-host disease	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
54	2023/7/21	CXSL2300501	ELPIS Human umbilical cord mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Moderate to severe active inflammatory bowel disease	Huaxiyuan (Shanghai) Biotechnology Co., Ltd.; Jiang West Huaxiyuan Biotechnology Co., Ltd.;	1
55	2023/7/11	CXSL2300461	SCM -181 Injection	Mesenchymal stem cell	New Drug		Yunnan Shunxi Regenerative Medicine Engineering Co., Ltd.;	
56	2023/6/30	CXSL2300446	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis	Wuhan Hamilton Biotechnology Co., Ltd. ; Guangzhou Hamilton Biotechnology Co., Ltd. ;	1
57	2023/6/20	CXSL2300424	IHS002 Human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug	Repair of burns, diabetic foot ulcers, and pressure ulcer wounds	Wuxi Huatai Innovative Pharmaceutical Technology Research Institute Co., Ltd.;	1
58	2023/5/31	CXSL2300385	RY_SW01 Cell injection solution	Mesenchymal stem cell	New Drug	Systemic Sclerosis	Jiangsu Ruiyuan Biotechnology Co., Ltd.;	1
59	2023/5/30	CXSL2300379	Mesenchymal stem cells for blood purification	Mesenchymal stem cell	New Drug	Subacute and acute liver failure (early and middle stages)	Guangdong Qianhui Biotechnology Co., Ltd.;	1
60	2023/5/17	CXSL2300346	Human-derived dopaminergic progenitor cell injection	IPSC-derived functional cells	New Drug	Parkinson's disease	Wuhan Ruijian Pharmaceutical Technology Co., Ltd.;	1

# Appendix: List of stem cell therapeutics IND acceptances/approvals as of 2024

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
61	2023/5/6	CXSL2300309	QN -019a Cell Injection	IPSC-derived functional cells	New Drug	For the treatment of CD19-positive relapsed/refractory B-cell non-Hodgkin lymphoma (B-NHL)	Hangzhou Qihan Biotechnology Co., Ltd.;	1
62	2023/3/29	CXSL2300221	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to severe acute respiratory distress syndrome	Hangzhou Yiwen Sai Biotechnology Co., Ltd.;	1
63	2023/3/28	CXSL2300220	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Interstitial Lung Disease	Shanghai Laifu Medical Technology Co., Ltd.;	1
64	2023/3/24	CXSL2300213	Xinbang Stem Cell Injection	Others	New Drug	Knee osteoarthritis	Shandong Xingrui Biotechnology Co., Ltd.;	1
65	2023/3/24	CXSL2300210	Human-derivedTH-SC01Cell Injection	Mesenchymal stem cell	New Drug	Chronic radiation proctitis	Jiangsu Tuohong Kangheng Pharmaceutical Co., Ltd.;	1
66	2023/3/21	CXSL2300204	Human Adipose Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Hand fibrosis caused by systemic sclerosis Functional impairment (contracture)	Beijing Aige Stem Cell Technology Co., Ltd.;	1
67	2023/3/20	CXSL2300202	Human bone marrow mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	For the treatment of autoimmune pulmonary alveolar proteinosis	Jiuzhitang Meike (Beijing) Cell Technology Co., Ltd.;	1
68	2023/3/14	CXSL2300184	VUM02 Injection	Mesenchymal stem cell	New Drug	Moderate to severe acute respiratory distress syndrome	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
69	2023/3/14	CXSL2300183	VUM02 Injection	Mesenchymal stem cell	New Drug	Subacute acute (subacute) liver failure	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
70	2023/2/23	CXSL2300152	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Mild/Moderate-to-severe acute respiratory distress syndrome	Suzhou Tuohua Biotechnology Co., Ltd.;	1
71	2023/2/15	CXSL2300129	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Alzheimer's disease	Beijing Belai Biotechnology Co., Ltd. ; Beijing Belai Pharmaceuticals Co., Ltd. ;	1
72	2023/2/9	CXSL2300109	NCR300 Injection	IPSC-derived functional cells	New Drug	Myelodysplastic syndrome (MDS)	Anhui Zhongsheng Suyuan Biotechnology Co., Ltd.;	1
73	2023/2/7	CXSL2300091	CASem Cell Injection	Embryonic stem cell-derived functional cells	New Drug	Acute graft-versus-host disease (aGVHD)	Beijing Zehui Chenxing Biotechnology Co., Ltd.;	1
74	2023/2/1	CXSL2300072	CASem Cell Injection	Embryonic stem cell-derived functional cells	New Drug	Acute exacerbation of interstitial lung disease	Beijing Zehui Chenxing Biotechnology Co., Ltd.;	1
75	2023/1/11	CXSL2300030	ELPIS Human umbilical cord mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Moderate to severe intrauterine adhesions	Huaxia Source (Shanghai) Biotechnology Co., Ltd.;	1
76	2023/1/5	CXSL2300006	VUM02 Injection	Mesenchymal stem cell	New Drug	Idiopathic pulmonary fibrosis	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
77	2022/12/29	CXSL2200624	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Acute ischemic stroke	Shenzhen Yinguan Biotechnology Co., Ltd.;	1
78	2022/11/22	CXSL2200587	Huatong's Gel Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis	Shenzhen Boya Perception Pharmaceuticals Co., Ltd.;	1
79	2022/11/22	CXSL2200586	VUM02 Injection	Mesenchymal stem cell	New Drug	Decompensated Cirrhosis	Wuhan Optics Valley Zhongyuan Pharmaceutical Co., Ltd.;	1
80	2022/11/18	CXSL2200581	ELPIS Human umbilical cord mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Subacute acute (subacute) liver failure	Huaxia Source (Shanghai) Biotechnology Co., Ltd.;	1

# Appendix: Stem Cell Therapeutics IND Acceptance/Approval List as of 2024 -5

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
81	2022/11/2	CXSL2200553	Injection of mesenchymal stem cells (umbilical cord)	Mesenchymal stem cell	New Drug	Traumatic spinal cord injury	Tianjin Ansaier Cell Gene Engineering Co., Ltd.;	1
82	2022/10/29	CXSL2200547	Human iPSC-derived cardiomyocyte injection	IPSC-derived functional cells	New Drug	Severe chronic ischemic heart failure	Nanjing Aierpu Regenerative Medical Technology Co., Ltd.;	1
83	2022/10/10	CXSL2200505	CG - BM1 Allogeneic Human Bone Marrow Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Acute-on-chronic liver failure (ACLF)	Guangzhou Saijun Biotechnology Co., Ltd.;	1
84	2022/9/14	CXSL2200457	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Injection administration for decompensated hepatitis B virus cirrhosis	Zhejiang Quansheng Biotechnology Co., Ltd.;	1
85	2022/8/31	CXSL2200430	Human umbilical cord mesenchymal stem cell membrane patch	Mesenchymal stem cell	New Drug	CABG treatment for coronary heart disease with low ejection fraction and poor expected outcome	BOE Regenerative Medical Technology Co., Ltd.;	1
86	2022/8/31	CXSL2200409	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Hangzhou Yiwen Sai Biotechnology Co., Ltd.;	
87	2022/8/16	CXSL2200378	HBG gene-modified autologous CD34+ hematopoietic stem cells Injection	Hematopoietic Stem Cells	New Drug	Transfusion-dependent β- Thalassemia	Guangzhou Ruifeng Biotechnology Co., Ltd.;	1
88	2022/8/10	CXSL2200370	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Idiopathic pulmonary fibrosis	Beijing Belai Biotechnology Co., Ltd.;	1
89	2022/7/28	CXSL2200341	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Shanghai Quansheng Biotechnology Co., Ltd.;	
90	2022/6/30	CXSL2200303	RY_SW01 Cell injection solution	Mesenchymal stem cell	New Drug	Active lupus nephritis	Jiangsu Ruiyuan Biotechnology Co., Ltd.;	1
91	2022/6/28	CXSL2200301	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Injection administration for second-degree burns	Shanghai Quansheng Biotechnology Co., Ltd.;	1
92	2022/6/28	CXSL2200299	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Injection administration for ankylosing spondylitis	Shanghai Quansheng Biotechnology Co., Ltd.;	1
93	2022/6/24	CXSL2200291	NCR100 Injection	IPSC-derived functional cells	New Drug		Anhui Zhongsheng Suyuan Biotechnology Co., Ltd.;	
94	2022/4/28	CXSL2200194	Human-derived dopaminergic progenitor cell injection	IPSC-derived functional cells	New Drug		Wuhan Ruijian Pharmaceutical Technology Co., Ltd.;	
95	2022/4/8	CXSL2200162	Human adipose-derived mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis.	Bopin Gude Biopharmaceutical Technology (Shanghai) Co., Ltd.;	1
96	2022/3/25	CXSL2200145	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis	Guizhou Zhongguan Biotechnology Co., Ltd.;	1
97	2022/3/24	CXSL2200142	ELPIS Human umbilical cord mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Severe lupus nephritis	Huaxia Source (Shanghai) Biotechnology Co., Ltd.;	1
98	2022/3/7	CXSL2200114	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Injection administration for treatment of patients with mild to moderate acute respiratory distress syndrome ( ARDS )	Shanghai Quansheng Biotechnology Co., Ltd.;	1
99	2022/2/18	CXSL2200098	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Ischemic Stroke	Shanghai Aisale Biotechnology Co., Ltd.;	1
100	2022/2/18	CXSL2200097	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Connective Tissue Disease-Associated Interstitial Lung Disease	Shanghai Aisale Biotechnology Co., Ltd.;	1

Note Statistics as of the end of October 2024; does not include imported or generic stem cell therapeutics. Corrections are welcome if omissions are identified.

Source: National Medical Products Administration Center for Drug Evaluation, compiled by Qianzhan Industry Research Institute

# Appendix: List of Stem Cell Therapeutics IND Acceptances/Approvals as of 2024

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
101	2022/2/15	CXSL2200093	Human-derivedTH-SC01Cell Injection	Mesenchymal stem cell	New Drug	Complex Anal Fistula	Jiangsu Tuohong Kangheng Pharmaceutical Co., Ltd.;	1
102	2022/2/14	CXSL2200090	Allogeneic Endothelial Progenitor Cell (EPCs) Injection	IPSC-derived functional cells	New Drug	This product is intended for the treatment of large artery atherosclerosis Type Acute Ischemic Stroke	Chengnuo Regenerative Medicine Technology (Zhuhai Hengqin New Area) Co., Ltd.;	1
103	2021/12/17	CXSL2101489	Human iPSC-derived cardiomyocyte injection	IPSC-derived functional cells	New Drug		Nanjing Aierpu Regenerative Medical Technology Co., Ltd.;	
104	2021/11/30	CXSL2101456	Human Amniotic Epithelial Stem Cell Injection	Others	New Drug	Treatment of steroid-resistant acute graft-versus-host disease after hematopoietic stem cell transplantation	Shanghai Sai'ao Biotechnology Co., Ltd.;	1
105	2021/11/24	CXSL2101443	CASem Cell Injection	Function derived from embryonic stem cells Cell	New Drug	Acute Respiratory Distress Syndrome	Beijing Zehui Chenxing Biotechnology Co., Ltd.;	1
106	2021/10/11	CXSL2101353	Human-derivedTH-SC01Cell Injection	Unipotent stem cells	New Drug	Inactive/mildly active Crohn's disease with anal fistula	Jiangsu Tuohong Kangheng Pharmaceutical Co., Ltd.;	1
107	2021/9/26	CXSL2101334	CG -BM1 Allogeneic Human Bone Marrow Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Moderate to severe adult acute respiratory distress caused by infection syndrome ( ARDS )	Guangzhou Saijun Biotechnology Co., Ltd.;	1
108	2021/9/2	CXSL2101296	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Idiopathic pulmonary fibrosis	Shanghai Laifu Medical Technology Co., Ltd.;	1
109	2021/8/31	CXSL2101297	Allogeneic Human Adipose-Derived Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Treatment of inactive/mildly active complex perianal fistulas in adult patients with Crohn's disease	Jiangsu Dekang Biotechnology Co., Ltd.;	1
110	2021/7/30	CXSL2101224	ELPIS Human umbilical cord mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Moderate to severe chronic plaque psoriasis	Huaxiyuan Cell Engineering Group Co., Ltd.;	1
111	2021/7/15	CXSL2101179	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis (Kellgren-Lawrence grade II or III)	Guangzhou Celera Stem Cell Technology Co., Ltd.;	1
112	2021/7/6	CXSB2101025	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	Supplementary Application	For the treatment of acute graft failure following hormone therapy Graft-versus-host disease	Platinum Shengzhuo Biotechnology (Beijing) Co., Ltd.;	1
113	2021/6/25	CXSL2101146	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Shanghai Huicun Medical Technology Co., Ltd.;	
114	2021/3/12	CXSL2100091	REGEN001 autologous cell reinfusion product	Function derived from embryonic stem cells Cell	New Drug	Chronic obstructive pulmonary disease with impaired pulmonary diffusing capacity Disease	Jiangxi Xianhe Medical Technology Co., Ltd.;	1
115	2021/3/3	CXSL2101001	Uterine blood mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Idiopathic pulmonary fibrosis	Zhejiang Shengchuang Precision Medical Technology Co., Ltd.;	1
116	2021/2/11	CXSL2100056	Injection of mesenchymal stem cells (umbilical cord)	Mesenchymal stem cell	New Drug	Acute Respiratory Distress Syndrome	Tianjin Ansaier Cell Gene Engineering Co., Ltd.;	1
117	2021/1/20	CXSL2100023	Allogeneic Endothelial Progenitor Cell (EPCs) Injection	IPSC-derived functional cells	New Drug		Chengnuo Regenerative Medicine Technology (Zhuhai Hengqin New Area) Co., Ltd.;	
118	2020/11/28	CXSL2000335	Injection of mesenchymal stem cells (umbilical cord)	Mesenchymal stem cell	New Drug	Subacute acute (subacute) liver failure	Tianjin Ansaier Cell Gene Engineering Co., Ltd.;	1
119	2020/8/28	CXSB2000045	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	Supplementary Application	Indicated for the treatment of hormone-refractory acute graft-versus-host disease	Platinum Shengzhuo Biotechnology (Beijing) Co., Ltd.;	1
120	2020/6/5	CXSL2000128	Injectable human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug		/	

# Appendix: List of Stem Cell Therapeutics IND Acceptances/Approvals as of 2024

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
121	2020/4/21	CXSL2000067	M - 021001 Cell Injection	Embryonic stem cell-derived functional cells	New Drug	Meniscal injury	Beijing Zehui Chenxing Biotechnology Co., Ltd.; Institute of Zoology, Chinese Academy of Sciences	1
122	2020/4/21	CXSL2000067	M - 021001 Cell Injection	Embryonic stem cell-derived functional cells	New Drug	Meniscal injury	Beijing Zehui Chenxing Biotechnology Co., Ltd.; Chinese Academy of Institute of Zoology	1
123	2020/1/11	CXSL2000005	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Rheumatoid arthritis	Beijing Belai Biotechnology Co., Ltd.	1
124	2019/11/7	CXSL1900124	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	For the treatment of steroid-resistant acute graft-versus-host disease	Platinum Sheng Zhuoyue Biotechnology (Beijing) Co., Ltd.	1
125	2019/7/10	CXSL1900075	Autologous human adipose-derived mesenchymal progenitor cell injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis ( Knee Osteoarthritis , KOA )	Cibiman Biotechnology (Shanghai) Co., Ltd.; Wuxi Sibiman Biotechnology Co., Ltd.	1
126	2019/3/7	CXSL1900019	REGEND001 autologous cell reinfusion product	Embryonic stem cell-derived functional cells	New Drug	Early and mid-stage idiopathic pulmonary fibrosis (IPF)	Jiangxi Xianhe Medical Technology Co., Ltd.;	1
127	2019/2/28	CXSL1900016	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis	Shanghai Aisaar Biotechnology Co., Ltd.	1
128	2019/2/12	CXSB1900004	Human primitive mesenchymal stem cells	Mesenchymal stem cell	Supplementary Application	Acute graft-versus-host disease following hematopoietic stem cell transplantation and treatment of chronic graft-versus-host disease and prevention.	Tianjin Madison Regenerative Medicine Co., Ltd.;	1
129	2018/12/5	CXSL1700188	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug	Primarily used for inflammatory bowel disease, namely acute and chronic ulcerative colitis, and can prevent ulcerative colitis recurrence.	Qingdao Aoke Biotechnology Development Co., Ltd.	1
130	2018/11/23	CXSL1800117	Human placental mesenchymal stem cell gel	Mesenchymal stem cell	New Drug	Diabetic Foot Ulcer	Beijing Han's United Biotechnology Co., Ltd.	1
131	2018/11/7	CXSL1800109	CBM-ALAM.1 Allogeneic human adipose-derived mesenchymal progenitor cell injection	Mesenchymal stem cell	New Drug	Knee osteoarthritis (Knee Osteoarthritis , KOA)	Wuxi Sibiman Biotechnology Co., Ltd.;	1
132	2018/9/30	CXSL1800101	Injection of mesenchymal stem cells (umbilical cord)	Mesenchymal stem cell	New Drug	Refractory acute graft-versus-host disease (Graft versus Host Disease , GvHD)	Tianjin Onset Cell Gene Engineering Co., Ltd.	1
133	2018/6/7	CXSL1700137	Human dental pulp mesenchymal stem cell injection	Mesenchymal stem cell	New Drug	Chronic periodontitis, including periodontal tissue defects caused by chronic periodontitis	Beijing Sanyouli Heze Biotechnology Co., Ltd.; Capital Medical University	1
134	2014/3/14	CXSL1300091	Injectable human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug		/	
135	2014/3/14	CXSL1300090	Injectable human umbilical cord mesenchymal stem cells	Mesenchymal stem cell	New Drug		/	

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# Appendix: List of Stem Cell Therapeutics IND Acceptances/Approvals as of 2024

Serial Number	Acceptance Date	Application Number	Drug Name	Cell Type	Application Type	Indication	Company Name	Approved
136	2013/8/2	CXSL1200056	Umbilical Cord Mesenchymal Stem Cell Injection for Anti-Hepatic Fibrosis	Mesenchymal stem cell	New Drug	/	/	
137	2013/3/7	CXSL1300001	Human Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		/	
138	2011/10/25	CXSL1000057	Umbilical Cord Mesenchymal Stem Cell Injection for Anti-Hepatic Fibrosis	Mesenchymal stem cell	New Drug		/	
139	2008/12/29	CXSB0800065	Bone Marrow-Derived Primitive Mesenchymal Stem Cells	Mesenchymal stem cell	Supplementary Application		Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences;	
140	2007/2/7	CXSL0600068	Umbilical Cord Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		/	
141	2005/12/23	CXSL0500073	Mesenchymal Stem Cell Injection for Hepatic Fibrosis	Mesenchymal stem cell	New Drug		/	
142	2005/9/1	CXSB0500090	Bone Marrow-Derived Primitive Mesenchymal Stem Cells	Mesenchymal stem cell	Supplementary Application		Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences;	
143	2005/5/2	CXSB0500039	Recombinant Human Stem Cell Factor for Injection	Others	Supplementary Application		Chengdu Diao Jiahong Pharmaceutical Factory; Chengdu Diao Jiahong Pharmaceutical Factory; Chinese Academy of Medical Sciences Institute of Basic Medical Research;	
144	2005/1/5	X0408234	Mesenchymal Stem Cell Injection for Myocardial Infarction	Mesenchymal stem cell	New Drug		Beijing Yuanhe Biotechnology Co., Ltd.; TEDA International Cardiovascular Hospital;	
145	2004/12/11	X0407487	Autologous Bone Marrow Mesenchymal Stem Cell Injection	Mesenchymal stem cell	New Drug		Field Blood Transfusion Research Institute, Chinese PLA Academy of Military Medical Sciences;	
146	2004/10/10	X0400586	Bone Marrow-Derived Primitive Mesenchymal Stem Cells	Mesenchymal stem cell	New Drug		Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences;	
147	2002/10/29	CSL20020071	Recombinant Human Stem Cell Factor for Injection	Others	New Drug		Second Military Medical University of the Chinese PLA;	
148	2001/9/28	CSL01037	Recombinant Human Stem Cell Factor Injection	Others	New Drug		Institute of Bioengineering, Chinese PLA Academy of Military Medical Sciences;	



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