**About Us**

**Luye Pharma Group**

*Luye Pharma Group* (02186.HK), a member of Luye Life Sciences Group, is an international pharmaceutical company dedicated to the R&D, manufacturing and sale of innovative medications.

**Luye Life Sciences Group**

Founded in 1994, the *Luye Life Sciences Group* is committed to providing high-quality innovative products and professional services in the life sciences area with the mission of “Advanced Technologies for Better Quality of Life”. The Group is comprised of three major business divisions: Luye Pharma, Luye Medical and Luye Investment.
Corporate Culture

Mission
Advanced Technologies for Better Quality of Life

Customer Focus
Operational Excellence
Employee Development

Business Philosophy

Vision
To Be a Leading Global Pharmaceutical Company

Core Values
Integrity
Cooperation
Innovation
Excellence

Passionate for Life
Milestones

1994-2010

1994  • The founding of Luye Pharma
2000  • Recognized as national high-tech enterprise, post-doctorate scientific research work station
2007  • Acquired Nanjing Kanghai Pharmaceutical, Sike Pharmaceutical and a sizable stake in Beijing WPU
2010  • Designated as a “State Key Laboratory of Long-acting and Targeting Drug Delivery System” by the Ministry of Science and Technology of China

2011-2016

2011  • Acquired Sichuan Baoguang Pharmaceutical
2013  • Shandong Luye Microsphere Formulation Workshop passed EU GMP inspections
       • Shandong Luye obtained CNAS certification
       • Multiple microsphere formulations made periodic progresses
2014  • Listed on the main board of Hong Kong stock exchange
2015  • LY03004 became the first Chinese innovative formulation to conduct all clinical trials in the U.S.
2016  • Acquired Acino’s TDS business

2017-2019

2017  • Acquired two biological antibody drugs, established a biological antibody technology development platform
       • Invested in Exicure for the development of novel nucleic acid therapeutics
       • Collaborated with ABPRO on the development of novel bispecific antibodies
       • Collaborated with Excel Biopharm on the development of therapeutic antibodies for next-generation immuno-oncology treatment.
2018  • Collaborated with ELPIS Biopharm on CAR-T therapy
       • Acquired AstraZeneca’s CNS products, Seroquel and Seroquel XR in 51 countries and regions
       • Acquired Bayer’s contraceptive patch product Apleek, along with all associated global rights
2019  • Granted exclusive promotion rights for Xuezhikang Capsules in mainland China to AstraZeneca and signed MOU to promote Xuezhikang Capsules on the global market
       • Rykindo (LY03004) Filed NDA in the U.S. FDA
Business Overview

Luye Pharma has made **global R&D, global manufacturing, and the global market** its three main strategic priorities, with a focus on targeting four therapeutic areas — central nervous system, oncology, cardiovascular and metabolism, among which **central nervous system** and **oncology** are considered the core strategic areas.

**Global R&D**

- **R&D centers** in China, the U.S. and Europe with a **robust pipeline** of 40 drug candidates in China and 10+ drug candidates overseas
- **Several new drugs and new formulations** in central nervous system and oncology therapeutic areas are being studied in the U.S. and Europe

**Global Manufacturing**

- **6 manufacturing sites** in Yantai, Nanjing, Beijing and Luzhou of China, among which the oral formulation workshop passed Australian TGA GMP inspections, the solid formulation workshop passed EU GMP inspections, the microsphere injection workshop passed the EU QP quality audit
- **1 manufacturing site** in Germany passed EU GMP, FDA GMP and Japanese GMP inspections

**Global Market**

- **Key products** covering four therapeutic areas — oncology, cardiovascular, metabolism and central nervous system, among which **central nervous system** and **oncology** are considered core strategic areas.
- **30+ products** covering 80+ countries and regions around the world, including large pharmaceutical markets - China, the U.S., Europe and Japan, as well as fast growing emerging markets
Luye Pharma has reached a high level international standard in advanced drug delivery technologies such as microspheres, liposomes and transdermal drug delivery systems, with the company making active efforts to develop innovative compounds and antibodies, cell and gene therapies, as well as smart formulations.
R&D Centers

R&D centers in **China**, the **U.S.** and **Europe**

Over **550 R&D professionals**, unique product offering enabled by increased R&D capability and efficiency through integration of global R&D system and resources

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**R&D Center in China**

- The first state key laboratory of long-acting and targeting drug delivery system in China
- Key R&D Capabilities: Long-acting and Extended Release Technology, Liposome and Targeted Drug Delivery Technology, Biological Antibody Technology

**R&D Center in the U.S.**

- Key R&D Capabilities: International R&D Collaboration, Exploratory Study for Innovative Drugs

**R&D Center in Europe**

- Key R&D Capabilities: Transdermal Drug Delivery Technology

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**Passionate for Life**
Platforms and Technologies

**Liposome and Targeted Drug Delivery Technology**
( >5 investigational products )
- Efficacy improvement of marketed drugs
- Toxicity reduction
- Site-specific targeting

**Long-acting and Extended Release Technology**
( >11 investigational products )
Microsphere and nano-particle technologies
- Customized drug release rate and period according to specific clinical needs
- Reduce frequency of drug intake
- Balanced drug release to improve efficacy and to reduce side effects

**New Compounds**
( >10 investigational products at the early R&D phase )
Discover and develop new compounds by improving existing pharmaceuticals. Focus on:
- Rapid simulation and follow-up
- Comparative research
- Deficiency reduction

**CAR-T Immunotherapy**
Revolutionize cancer treatment with a potential to cure
- Next generation CAR-T Immunotherapy therapeutics
- Opportunity to treat solid tumors
- Potentially improved efficacy
- Mitigate side-effects

**Gene Therapy**
Potential cure for genetic diseases
- Targeting gene specific rare diseases
- Precision gene editing
- Safety proved virus delivery technology
- No need of frequent administration

**Transdermal Drug Delivery System**
( >8 investigational products )
- Constant and stable release of active ingredient to reduce side effects
- Drug release interrupted by removing the patch
- Patient compliance enhancement
- Applicable to various indications

**Biological Antibody Technology**
( Joint development with partners, with 4 investigational drugs under clinical trials stage)
- Integrated R&D and manufacturing capacity from DNA to biomedicine
- GMP standard pilot plant for antibodies
- Novel bispecific monoclonal antibody platform

**Stem Cell Therapy**
Regenerate diseased tissues
- Focus on neuro-degeneration diseases
- Novel therapeutic approach
- Ability to proliferate and create normal functional tissues
- Long sustainable therapeutic effects

**Digitalization and Smart Formulations**
- Leverage AI to discover and develop new drugs
- Smart formulations and new extended release technology
- Environmentally responsive drug delivery
- Microneedle drug delivery
- Long-term extended release drug delivery

**Innovative New Compounds & Antibodies**

**Gene & Cell Therapy Technologies and Digitalization**
## Innovation Capability

| Patents | 254 patents granted in China and another 56 applications in progress  
|         | 444 patents granted overseas while 116 applications in progress |
| Scientific Awards | 26 awards on national and provincial levels, including a 2nd prize of National Technology Invention Award, a 2nd prize of National Science & Technology Progress Award  
|         | One 1st prize of Science & Technology Progress award presented by Chinese Pharmaceutical Association |
| R&D Capability | Undertaking 50+ national-level key research projects  
|         | Several papers published in international peer-reviewed journals |
| Innovation Base | A National Innovation-driven Company  
|         | State Key Laboratory of Long-acting and Targeting Drug Delivery System  
|         | Cooperation Base for International Science and Technology  
|         | Industrialization Base of National 863 Program  
|         | State Intellectual Property Exemplary Company  
|         | Post-doctorate Scientific Research Work Station  
|         | The first wave of national enterprises to export intellectual property rights |
State Key Laboratory of Long-acting and Targeting Drug Delivery System

The first State Key Laboratory of Long-acting and Targeting Drug Delivery System in China

Focus
- Research into long-acting drug delivery system and drug release technology
- Research into targeting drug delivery system and drug release technology
- Research into high-end carrier materials for long-acting and targeting drug delivery

Achievement
- The first and only marked paclitaxel liposome drug in the world
- The first breakthrough in the commercialization of liposome drug in China
- Develop microsphere continuous dynamic formulation technology with independent intellectual property rights
- Leading the use of long-acting technology for neurodegenerative diseases
- Rykindo ® (LY03004) became the first Chinese innovative formulation to conduct all clinical trials in the U.S., and filed NDA in the U.S. FDA
- LY03003, as China’s first innovative formulation, entered clinical trials in the U.S.
- LY01005 is China’s first long-acting formulation product for the treatment of cancer, to conduct clinical trials in the U.S.
Overseas R&D Pipelines

As one of the first Chinese pharmaceutical companies conducting clinical trials in the global market, Luye Pharma has several investigational products in central nervous system and oncology therapeutic areas under clinical trials in the U.S. and Europe.

<table>
<thead>
<tr>
<th>Therapeutic Areas</th>
<th>Indications</th>
<th>Product No.</th>
<th>Progress</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNS</td>
<td>Parkinson’s disease</td>
<td>LY03003</td>
<td>PC IND Ph I Ph II Ph III NDA</td>
<td>USA, JAPAN (Ph I)</td>
</tr>
<tr>
<td>CNS</td>
<td>Schizophrenia and bipolar disorder</td>
<td>Rykindo (LY03004)</td>
<td>PC IND</td>
<td>USA, EU (Ph I)</td>
</tr>
<tr>
<td>CNS</td>
<td>Moderate to severe depression</td>
<td>LY03005</td>
<td>PC IND</td>
<td>USA</td>
</tr>
<tr>
<td>CNS</td>
<td>Mild to moderate dementia</td>
<td>30410</td>
<td>PC IND</td>
<td>EU</td>
</tr>
<tr>
<td>CNS</td>
<td>Schizophrenia</td>
<td>LY03010</td>
<td>PC IND</td>
<td>USA</td>
</tr>
<tr>
<td>Oncology</td>
<td>Prostate cancer</td>
<td>LY01005</td>
<td>PC IND</td>
<td>USA</td>
</tr>
<tr>
<td>Oncology</td>
<td>Oncology Immune</td>
<td>LY01013</td>
<td>PC IND</td>
<td>USA</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Hypercholesterolemia</td>
<td>LY02405</td>
<td>PC IND</td>
<td>USA</td>
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<tr>
<td>orthopaedics</td>
<td>Osteoporosis</td>
<td>LY06006</td>
<td>PC IND</td>
<td>USA, EU</td>
</tr>
<tr>
<td>Gyneceology</td>
<td>Female contraception</td>
<td>Apleek</td>
<td>PC IND</td>
<td></td>
</tr>
</tbody>
</table>

- NDDS
- Small molecule innovative
- Antibody
- Others
## R&D Pipelines in China

R&D pipelines of 40 drug candidates in China, including 15 oncology drugs, 15 CNS drugs.

<table>
<thead>
<tr>
<th>Products / Generic Names</th>
<th>Indications</th>
<th>Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>LY01005</td>
<td>Prostate cancer, breast cancer</td>
<td>PC IND Ph I Ph II Ph III NDA</td>
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<tr>
<td>LY01007</td>
<td>Prostate cancer, endometriosis</td>
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<tr>
<td>LY01008</td>
<td>Colorectal cancer, NSCLC</td>
<td></td>
</tr>
<tr>
<td>LY01011</td>
<td>Myeloma and bone metastasis</td>
<td></td>
</tr>
<tr>
<td>LY01013</td>
<td>Tumor</td>
<td></td>
</tr>
<tr>
<td>LY01610</td>
<td>Rectal cancer, pancreatic cancer</td>
<td></td>
</tr>
<tr>
<td>LY03003</td>
<td>Parkinson's disease</td>
<td></td>
</tr>
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<td>Rykindo (LY03004)</td>
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<tr>
<td>LY03011</td>
<td>Mild to moderate dementia</td>
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<tr>
<td>LY021701</td>
<td>Severe pain</td>
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<tr>
<td>LY021702</td>
<td>Moderate to severe pain</td>
<td></td>
</tr>
<tr>
<td>LY03012</td>
<td>Chronic pain</td>
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<tr>
<td>LY03401</td>
<td>Parkinson's disease</td>
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<tr>
<td>LY09004</td>
<td>Age-related macular degeneration</td>
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<tr>
<td>LY02404</td>
<td>Hypercholesterolemia</td>
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### Notes:
- `▲` NDDS
- `★` Small molecule innovative
- `☆` Antibody
- `★` Others
Rykindo® filed NDA in the U.S. FDA

Luye Pharma successfully submitted its first New Drug Application (NDA) to the U.S. FDA for Rykindo® (LY03004) on 28 March 2019. This is the first NDA submission of an innovation drug of formulation to the U.S. FDA by a Chinese pharmaceutical company.

Rykindo® can differentiate itself by providing simplicity and efficiency during treatment initiation and mitigating risk of prolonged side effects

- No oral supplementation required during treatment initiation
- Steady state concentrations are reached faster than comparators with the same active metabolite which would be beneficial to the stable treatment of patients
- The concentration of Rykindo® decreases faster than comparators which would lower side effect risk
Global Manufacturing

Luye Pharma is building a global supply chain with 7 manufacturing sites worldwide.

The company has established a GMP quality management and control system with international standards.
Manufacturing Sites

- 7 manufacturing sites with 30+ production lines
- International practices are followed from product design to construction of facilities
- The microsphere reactor and other main equipment are all independently developed by the company. As one of the world's most advanced microsphere production lines, it successfully tackles the challenges posed in commercial application of microsphere technology.
- One of the largest independent TDS manufacturers in Europe, boasting highly sophisticated process and high barrier technologies
Quality Management System

CHINA

• Passed EU GMP inspections
• Passed Australian TGA GMP inspections
• Passed China 2010 GMP inspections
• Obtained ISO9001:2008 QMS certification
• Obtained ISO14001:2004 EMS certification
• Obtained OHSAS18001:2007 certification
• Obtained CNAS certification

EUROPE

• One of the largest independent TDS manufacturers in Europe, boasting highly sophisticated process and high barrier technologies
• Passed FDA GMP inspections
• Passed EU GMP inspections
• Passed Japanese GMP inspections
Global Market

Luye Pharma is focused on four therapeutic areas – central nervous system, oncology, cardiovascular and metabolism, among which the central nervous system and oncology areas are considered most strategically significant. The company’s key products hold a leading position in their respective market segments.
Key Products

CMNa
The only chemical sensitizer for cancer radiotherapy in China

Lipusu
The only marketed paclitaxel liposome injection in the world indicated for multiple cancers

Seroquel and Seroquel XR
Atypical anti-psychotic medicines with antidepressant properties

Rivastigmine Transdermal Patch
The first-to-file generic product approved by the U.S. FDA, for treatment of Alzheimer’s disease

Maitongna
Obtained novel compounds patent in China for treatment of cerebral edema, swelling caused by trauma or surgery and venous reflux disorders

Xuezhikang
The first evidence-based and internationally recognized Chinese lipid-adjusting drug which has completed phase II clinical trials required by FDA

Beixi
The only Acarbose capsule in China managing Type 2 diabetes adjunct to diet control
Marketing Network

Marketing network covers over 80 countries and regions including large global pharmaceutical markets and fast growing emerging markets

Chinese market: Marketing strategies are determined at group level and executed by the sales teams with support from functional departments. Products distributed in more than 30,000 hospitals and medical institutions.

Overseas market: A highly engaged full-service team covering marketing, pharmacovigilance, business development functions, has established deep relationships with dozens of customers.
Acquisition of AstraZeneca’s Seroquel and Seroquel XR in 51 Countries and Regions

The acquisition completed in June 2018. Acquired assets including:

- Marketing authorizations, regulatory information, certain patents, relevant business materials and data, manufacturing know-how and sales networks, etc. in the 51 countries and regions
- Exclusive, permanent, free and sublicensable trademark licensing, along with other licensing rights
- Luye Pharma will be the future production base for the global supply of Seroquel and Seroquel XR

Seroquel (Quetiapine Fumarate, immediate release, IR) and Seroquel XR (extended release formulation)

- The two products are atypical, antipsychotic medicines with antidepressant properties. The main indications for Seroquel are the treatment of schizophrenia and bipolar disorder.
- Seroquel XR is also approved in some markets for major depressive disorder and generalized anxiety disorder.

Strategy behind the Acquisition

- Building a product portfolio with a global competitive edge in central nervous system therapeutic area
- Enhancing the synergy across international markets
- Enhancing brand equity
In January 2019, Luye Pharma granted AstraZeneca exclusive rights to promote Xuezhikang Capsules in mainland China.

- AstraZeneca is responsible for the exclusive promotion of Xuezhikang Capsules in mainland China, while Luye Pharma retains asset rights, commercial sales rights, the registration permit, all intellectual property rights and other product-related rights aside from product promotion.
- This is the first time that a multinational pharmaceutical company has gained exclusive authorization in China to promote an innovative drug developed by a Chinese pharmaceutical company.

In March 2019, Luye Pharma and AstraZeneca signed a Memorandum of Understanding for intent to form a new strategic partnership jointly exploring opportunities for Xuezhikang Capsules in global markets other than China.

- Luye Pharma and AstraZeneca intend to deepen their strategic partnership outside of China by leveraging mutual resources to jointly explore global opportunities for Xuezhikang Capsules.
- Both parties will jointly contribute to the “The Belt and Road” initiative and “Healthy China” development initiatives.
- By tapping into AstraZeneca’s resources in China and abroad, and Luye Pharma’s product advantages respectively, Xuezhikang Capsules are expected to reach more countries and regions globally, further boosting the internationalization effort for innovative domestic drug.
Upholding the philosophy of “Employee Development”, Luye Pharma regards employees as the most valuable resources of the company.

Human Resource Policies
Take proactive measures to attract and retain talents both at home and abroad

Luye Evergreen College
Launch Luye Evergreen College to cultivate future management talents

Multiple Career Development Paths
Establish multiple career development paths for our employees to capitalize on their full potential, and progress together with the company

- Awarded “China’s Healthiest Workplace” by Mercer, the world’s leading consulting company in 2018
- Awarded “China’s Most Socially Responsible Employer” by www.zhilian.com, one of the most prestigious recruitment agencies in China in 2018
- Won “ESG Social Contribution Award” by SynTao, a Chinese leading corporate social responsibility consulting company in 2018
- Awarded “Outstanding Employer – Best Company to Work for in China” by Fortune China in 2011
Four Strategies to Drive Future Growth

Global R&D
- Chinese market focus on Central Nervous System, Oncology, Metabolism and Cardiovascular
- Overseas market focus on Central Nervous System and Oncology
- Focus on both new drug innovation and formulation innovation, with biopharmaceutical and cutting-edge biological technologies leading the way to expand R&D capabilities from identified drug targets to innovative new global targets
- Gradually increase investment in R&D, with the goal of building up differentiated innovation capability in R&D

Global Manufacturing
- Build up manufacturing sites in China with international quality standards in the short term
- Build up overseas manufacturing sites with a global supply chain management system, implementing overall production capacity planning in the mid to long term
- Build up the global manufacturing footprint, management capability and resources

Global Market
- Strengthen marketing and branding for the Chinese market, set up a national network, expand to grassroots markets and increase market share
- Build up international marketing platforms with a flexible market entry model
- Invest in brand building, promote Luye Pharma’s global market image through current product brand leverage

M&A
- A series of M&As to be carried out in China, the U.S., Europe and Japan.
- M&A deals focus on identifying products with strong potential, to enrich the current R&D pipelines and enhance business operation capabilities
- Strengthen financing, M&A and integration capabilities
For more information, please visit www.luye.cn/luye_en