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Luye Pharma shows strong revenue growth and development of R&D product pipelines

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Luye Pharma Group released its financial results for the first half of 2019 on 28 August 2019. The results show the company has achieved a revenue of RMB 3.131 billion, up 42.1% year-on-year; EBITDA reached RMB 1.263 billion, up 44.1% year-on-year, while profit attributed to shareholders reached RMB 767 million, up 36.2% year-on-year.

The pharmaceutical industry experienced vast changes in the first half of 2019. However, Luye Pharma is firmly sticking to its development strategy of "innovation" and "internationalization", focusing on four core therapeutic areas, with a particular attention to the central nervous system (CNS) and oncology therapeutic areas, achieving satisfactory performance returns and laying solid foundations for the global launch and commercial operations for a number of new drugs.

A Number of New CNS Drugs to Be Launched Soon

The U.S. Food and Drug Administration (FDA) has accepted the filing of LY03004's (Extended-Release Microspheres for Injection) new drug application (NDA). LY03004 for the treatment of schizophrenia and bipolar disorder is the first innovative formulation from China to have an NDA accepted by the FDA, indicating that China's first independently-developed microsphere product is likely to be on U.S. market in the near future. The company will file the NDA for LY03004 in China in the second half of this year.

Rivastigmine transdermal patch products in the CNS therapeutic area have also achieved remarkable progress: the multi-day transdermal patch has completed a pivotal study for the treatment of Alzheimer's disease in Germany. The once-a-day transdermal patch will soon be launched in China, while the high dosage strength (13.3mg/24h) once-a-day transdermal patch has received market authorization in Germany.

The registration application for Pramipexole Dihydrochloride Sustained Release Tablet for the treatment of Parkinson's disease has been accepted by China's National Medical Products Administration. Ansofaxine Hydrochloride Extended-Release Tablet for the treatment of depression (LY03005) and Rotigotine Extended-Release Microspheres for Injection for the treatment of Parkinson's disease (LY03003) have filed a clinical trials application and began phase I clinical trials in Japan, respectively. These two investigational drugs have entered the late clinical-stage in China and the U.S.

Outside of the CNS business, four other investigational biosimilar drugs have started clinical trials in China, among which LY01008 (a biosimilar of Avastin®) and LY6006 (a biosimilar of Prolia®) have undergone smooth progress in phase III

clinical trials stage.

R&D expense has increased by 30.6% year-on-year in the first half of 2019, and Luye Pharma will continue increasing its investment in R&D, with more efforts made to speed up new drug registration and launch processes.

Comprehensive Strategic Planning Focused on Core Therapeutic Areas

Luye Pharma has a long-term focus on the four therapeutic areas with the largest scale and fastest growth: oncology, central nervous system (CNS), cardiovascular and metabolism, with a strategic focus given to oncology and CNS. Key products are seeing stable double-digit growth, especially Lipusu, Seroquel, Xuezhikang, Maitongna and Beixi.

In the oncology therapeutic area, of note is the inclusion of the innovative paclitaxel liposome formulation, Lipusu, as a first-line drug in the 2019 Chinese Society of Clinical Oncology (CSCO) Guidelines on Diagnosis and Treatment of Primary Lung Cancer, a strong driver of sales growth for relative indications. Luye Pharma has been actively involved in clinical data collection following the drug's launch, with several research projects completed including "Comparison of the Efficacy of Lipusu with Cisplatin vs. Gemcitabine with Cisplatin for the First-Line Treatment of Advanced Squamous Cell Lung Carcinoma" and "A Study on the Safety and Effectiveness of Sintilimab with Platinum-Based Chemotherapy and Lipusu for the Neoadjuvant Therapy of Esophagus Cancer", among others, bringing greater benefit to more patients.

In the central nervous system therapeutic area, global business integration for Seroquel and Seroquel XR is progressing smoothly to date. A Nervous System Drug Business Unit has been established in China, and a global business network and global pharmacovigilance system also built up, meanwhile, the product's marketing authorization transfer for various countries and regions has been progressing well, laying a solid foundation for global marketing of the Seroquel product series and commercialization of the upcoming new drugs in the central nervous system therapeutic area.

External Collaborations Accelerate Development of R&D Product Pipelines and Commercial Capability

Luye Pharma has embarked on a number of license-in agreements and collaborations in the first half of 2019, based on the company's strategy of internationalization, which supports product pipeline development and improvements to commercial capability.

In April of this year, Luye Pharma and an international biopharmaceutical company PharmaMar entered into a license development and commercialization agreement with respect to an innovative anti-cancer investigational drug, Zepsyre® (Lurbinectedin), which will strengthen Luye Pharma's innovative product pipelines in oncology and generate synergy by leveraging the company's strong marketing capability in mainland China. Zepsyre® was granted orphan drug designation by the U.S. FDA for the treatment of patients with Small Cell Lung Cancer in August 2018. Recently, the FDA also agreed with the company's proposal to file for accelerated approval of Zepsyre®'s New Drug Application (NDA) for monotherapy in the treatment of second-line small cell lung cancer.

Luye Pharma has made increasing efforts to speed up the introduction of new drugs to China and bring the company's original products to overseas markets. Exclusive promotion rights for Xuezhikang Capsules were granted to AstraZeneca in mainland China, following which both parties signed a Memorandum of Understanding to promote Xuezhikang Capsules in international markets. Currently, in addition to mainland China, AstraZeneca is also granted the right to promote the product in Singapore, accelerating Xuezhikang's route to other international markets.

Looking forward to the future, a Luye Pharma Group management representative stated, "We will continue with comprehensive strategic planning focused on innovation and internationalization and will make every effort to accelerate the launch and registration process for our investigational products in global markets. We expect to launch a number of new drugs in the next 3-5 years globally, while in the meantime making in-depth plans for the next generation of products to strengthen our competitive advantage and make great strides in comprehensive development. We are fully confident that we will achieve our targets set for 2019 and our strategic vision for the future."