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LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in Bermuda with limited liability)

(Stock Code: 02186)

VOLUNTARY ANNOUNCEMENT

RYKINDO[®] ENTERED COMMERCIAL OPERATION IN THE UNITED STATE MARKET

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces the first batch of RYKINDO[®] (risperidone) for extended-release injectable suspension for export to the United States (the “**U.S.**”) has been successfully shipped, which means that the product has officially entered the commercialization stage in the U.S. market.

The Group developed RYKINDO[®] on its proprietary microsphere technology platform. In January 2023, RYKINDO[®] has received marketing approval from the U.S. Food and Drug Administration (the “**FDA**”) as a treatment for schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. The drug is administered bi-weekly by intramuscular injection and delivers the active ingredient, risperidone, via long-acting and extended-release microsphere technology. The most common adverse reactions in patients with schizophrenia ($\geq 5\%$) were headache, parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremity, and dry mouth. The most common adverse reactions in patients with bipolar disorder were (5% in monotherapy trial) weight increased and ($\geq 10\%$ in adjunctive therapy trial) tremor and parkinsonism.

Schizophrenia and bipolar disorder are both severe mental disorders, and according to recent figures, affecting an estimated 24 million and 40 million people worldwide, respectively. In the U.S., the estimated prevalence of schizophrenia and related psychotic disorders ranges between 0.25% and 0.64%, while an estimated 4.4% of U.S. adults experience bipolar disorder at some point in their lives. The two diseases both have high relapse rates, with poor treatment adherence known to be one of the key associated risk factors.

Data from the IQVIA has shown that long-acting antipsychotics generated sales of approximately US\$7.5 billion in the global market and US\$5.0 billion in the U.S. market in 2022.

The Group will continue to promote the commercialization of RYKINDO[®] in the U.S. market, so that the product can serve the unmet clinical needs of adult patients with schizophrenia and bipolar I disorder as soon as possible.

ABOUT RYKINDO[®]

What is RYKINDO[®](risperidone)?

RYKINDO[®](risperidone) is used for the treatment of schizophrenia and for the longer-term treatment of bipolar I disorder in adults.

IMPORTANT SAFETY INFORMATION FOR RYKINDO[®] (risperidone)

RYKINDO[®] can cause serious side effects, including an increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis). RYKINDO[®] is not for treating dementia-related psychosis.

Do not receive RYKINDO[®] if you are allergic to risperidone, paliperidone or any of the ingredients in RYKINDO[®].

Cerebrovascular problems (stroke) that can lead to death have been reported in elderly patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS) is a rare but very serious problem that can happen in people who receive RYKINDO[®]. NMS can cause death and must be treated in a hospital. Call your healthcare provider right away if you become severely ill and have any of these symptoms: high fever, severe muscle stiffness, confusion, loss of consciousness, or changes in your breathing, heartbeat and blood pressure.

Tardive Dyskinesia (TD) is a serious, sometimes permanent side effect reported with RYKINDO[®] and similar medications. TD includes uncontrollable movements of the face, tongue, and other parts of the body. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. Elderly female patients appear to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. This condition can develop after a brief period of therapy at low doses, although this is much less common. Symptoms may go away partially or completely if therapy is stopped.

Atypical antipsychotic drugs have been associated with metabolic changes that can increase cardiovascular/cerebrovascular risks. These changes may include:

High blood sugar and diabetes have been reported with RYKINDO[®] and similar medicines. If you already have diabetes or have risk factors such as being overweight or a family history of diabetes, blood sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening. Call your healthcare professional if you develop signs of high blood sugar or diabetes, such as being thirsty all the time, having to urinate or “pass urine” more often than usual, or feeling weak or hungry.

Changes in cholesterol and triglycerides have been noted in patients taking atypical antipsychotics. Check with your healthcare professional while on treatment.

Weight gain has been reported in patients taking atypical antipsychotics. Monitor weight gain while on treatment.

RYKINDO[®] and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and problems with erection.

Some people taking RYKINDO[®] may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional’s dosing instructions, this side effect can be reduced.

Patients (particularly the elderly) taking antipsychotics with certain health conditions or those on long-term therapy should be evaluated by their healthcare professional for the potential risk of falls.

Blood problems such as low numbers of white blood cells have been reported in patients taking risperidone and similar medications. In some cases, it has been serious and life-threatening. Depending upon your medical condition, your healthcare professional may choose to test your blood as you start therapy with RYKINDO[®].

RYKINDO[®] may affect your ability to make decisions, think clearly, or react quickly. Do not drive, operate heavy machinery, or do other dangerous activities until you know how RYKINDO[®] affects you.

RYKINDO[®] should be used cautiously in people with a seizure disorder, who have had seizures in the past, or who have conditions that increase their risk for seizures.

RYKINDO[®] may increase difficulty in swallowing that may cause food or liquid to get into your lungs.

Painful, long lasting erections have been reported with the use of RYKINDO[®]. Call your healthcare professional immediately if you think you are having this problem.

Tell your healthcare professional if you are pregnant or plan to become pregnant. It is not known if RYKINDO[®] will harm your unborn baby. If you become pregnant while taking RYKINDO[®], talk to your healthcare professional about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry>. Infants born to women who are treated with RYKINDO[®] may experience symptoms such as tremors, irritability, excessive sleepiness, eye twitching, muscle spasms, decreased appetite, difficulty breathing, or abnormal movement of arms and legs. Let your healthcare professional know if these symptoms occur. Tell your healthcare professional if you are breastfeeding or plan to breastfeed. RYKINDO[®] can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive RYKINDO[®].

RYKINDO[®] may impair fertility, which is reversible. Speak to your healthcare provider if you plan to become pregnant.

RYKINDO[®] may make you more sensitive to heat. You may have trouble cooling off, or be more likely to become dehydrated, so take care when exercising or when doing things that make you warm.

Some medications interact with RYKINDO[®]. Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while taking RYKINDO[®].

In studies of people taking RYKINDO[®], the most common side effects in the treatment of schizophrenia were headache, slow movements (including tremor shaking, stiffness, and a shuffling walk), dizziness; feeling of inner restlessness or needing to be constantly moving; tiredness, constipation, indigestion, sleepiness, weight gain, pain in the limbs, and dry mouth.

In studies of people taking RYKINDO[®], the most common side effects in the treatment of bipolar disorder were weight gain (when used alone) and slow movements (including with tremor shaking, stiffness, and a shuffling walk) and tremor (when used with lithium or valproate).

This is not a complete list of all possible side effects. Ask your healthcare professional or treatment team if you have any questions or want more information.

If you have any questions about RYKINDO[®] or your therapy, talk with your healthcare professional.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please visit https://www.luye.cn/lvye_en/rykindo.pdf to read the full Prescribing Information, including BOXED WARNING, for RYKINDO[®] and discuss any questions you have with your healthcare professional.

By Order of the Board
LUYE PHARMA GROUP LTD.
Liu Dian Bo
Chairman

Hong Kong, 17 August 2023

As at the date of this announcement, the executive directors of the Company are Mr. LIU Dian Bo, Mr. YANG Rong Bing, Mr. YUAN Hui Xian and Ms. ZHU Yuan Yuan; the non-executive directors of the Company are Mr. SONG Rui Lin and Mr. SUN Xin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit, Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.