

Italfarmaco Group Enters Into an Agreement with Luye Pharma to Commercialize Alzheimer's Disease Treatment Rivastigmine Multi-Day Transdermal Patch in Four European Countries

- Italfarmaco Group adds innovative Alzheimer's disease therapy to its neurology-based product portfolio -

Milan, Italy, and Basel, Switzerland, March 16th, 2021 - Italfarmaco Group (Italfarmaco) and Luye Pharma Switzerland AG ("Luye Switzerland"), a fully owned subsidiary of Luye Pharma Group (Luye Pharma) announced today that they have entered into an agreement under which Italfarmaco receives exclusive rights to commercialize Rivastigmine Multi-Day Transdermal Patch (Rivastigmine MD) in four European countries. Rivastigmine MD, developed by Luye Pharma, is used to treat mild to moderate dementia associated with Alzheimer's disease and is currently in the final registration phase of marketing approval in Europe. This product represents an important strategic addition to Italfarmaco's central nervous system (CNS) portfolio, building on its depth of knowledge in this therapeutic area.

Under the terms of the agreement, Italfarmaco gains the exclusive rights to commercialize Rivastigmine MD in Germany, Italy, Portugal and Greece. Italfarmaco will also have a preferred right to market Rivastigmine MD in Chile and Vietnam. Italfarmaco will make an upfront payment to Luye Pharma upon the signing of the agreement as well as additional payments when certain sales milestones are achieved. Luye Pharma is also eligible to receive royalties from Italfarmaco. No further financial details are being disclosed.

Antonio Nardi, Vice President of Business and Portfolio Development at Italfarmaco commented: "Alzheimer's is a debilitating disease with a growing patient population and very few treatment options, so we welcome our partnership with Luye Pharma and the addition of an easy-to-administer, innovative product for patients. In addition to our own research expertise, we are looking forward to building our neurology-focused commercial pipeline in this therapeutic area to provide more options for clinicians who are at the frontline of treating individuals with neurodegenerative diseases."

"The collaboration with Italfarmaco represents an important milestone in our commitment to addressing unmet needs for senior patients in Europe. By leveraging Italfarmaco's extensive CNS experience and strong business operation system, we believe we will soon be able to bring this new therapy to patients in Europe," said Bruno Delie, General Manager of Luye Switzerland. "We aim to improve the quality of life for people suffering from dementia, as well as their families, friends and caregivers."

Alzheimer's disease remains a major global health issue, and the number of patients is constantly growing. According to the *World Alzheimer Report 2018*, there is a new case of dementia every three seconds around the world.

50 million people worldwide were living with dementia in 2018, and this number is expected to reach 82 million by 2030ⁱ. While the development of new drugs in this therapeutic area is still a challenge, Rivastigmine is a first-line drug in the treatment of dementia associated with Alzheimer's disease and is currently marketed worldwide.

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About Rivastigmine Multi-Day Transdermal Patch

Rivastigmine Multi-Day Transdermal Patch (Rivastigmine MD) is a twice-weekly innovative patch formulation of Rivastigmine for the treatment of mild to moderate dementia associated with Alzheimer's disease. The product was developed by Luye Pharma on its proprietary transdermal patch platform and is one of the company's core products in the central nervous system therapeutic field.

Rivastigmine is in a class of medicines called cholinesterase inhibitors. These medicines can improve cognitive functions such as memory and thinking by increasing the amount of a certain natural substance in the brain and amplifying the communication channels between nerve cells, which are less active in individuals with mild to moderate Alzheimer's disease. The drug is currently available in the form of tablets and patches.

Rivastigmine MD employs an innovative drug delivery system for Rivastigmine via twice-weekly transdermal administration. Rivastigmine MD has a lower application frequency than the once-daily Rivastigmine patches generally available in the market, enabling it to improve patients' medication adherence. Due to its transdermal route of administration, Rivastigmine MD is convenient for patients who have difficulty swallowing, and it might have the potential to lower the incidence of gastrointestinal adverse reactions such as nausea and vomiting compared with the oral form. Luye Pharma has filed, and been issued a portfolio of international patents protecting Rivastigmine MD.

Rivastigmine MD will be registered in major global markets, including Europe, Japan and China. In May 2020, the Marketing Authorization Application of this product (Rivastigmine MD) in countries within the European Union was accepted for review by competent authorities of the European Union. In September 2020, the product was approved by the Centre for Drug Evaluation of China's National Medical Products Administration to initiate clinical trials in the country. In February 2021, the exclusive development and commercialization rights of Rivastigmine MD in Japan were granted to Towa Pharmaceutical Co., Ltd. ("Towa"). Rivastigmine MD is soon to start phase III clinical trials in Japan. Luye Pharma also plans to register this product in the U.S. and other countries.

About Italfarmaco Group

Italfarmaco is a specialty pharmaceutical company engaged in the discovery,

development, manufacturing and marketing of branded prescription and nonprescription products in more than 60 countries on 5 continents. Italfarmaco's research and development expertise is best demonstrated through its HDAC inhibitor development programs, addressing new therapeutic treatments of specialty and rare diseases.

Through both marketed drugs and compounds in development, Italfarmaco is dedicated to serving patients whose needs remain largely unmet. Italfarmaco employs over 3000 people and expects 2021 annual sales turnover to be close to 800 million euros. Italfarmaco's products mainly address women's health, the central nervous system, cardiovascular, immuno-oncology and musculoskeletal conditions.

Italfarmaco is currently active in neurology-focused indications, especially with the treatment of Amyotrophic Lateral Sclerosis (ALS) patients, which originates from Italfarmaco's own research pipeline.

About Luye Pharma Group

Luye Pharma Group (Luye Pharma), a member of Luye Life Sciences Group, is an international pharmaceutical company dedicated to the R&D, manufacturing, and sale of innovative medications. The company has established R&D centers in China, the U.S. and Europe, with a robust pipeline of over 30 drug candidates in China and more than 10 drug candidates in other international markets. Along with a number of new drugs and new formulations in the central nervous system and oncology therapeutic areas under study in the U.S., Europe and Japan, Luye Pharma has reached high-level international standards in novel drug delivery technologies including microspheres, liposomes, and transdermal drug delivery systems, as well as actively making strategic developments in the fields of biological antibodies, cell therapies and gene therapies, among others.

Luye Pharma is developing a global supply chain of 8 manufacturing sites with over 30 production lines in total, establishing GMP quality management and international standard control systems. With more than 30 products covering the central nervous system, oncology, cardiovascular, metabolism and other therapeutic areas, business is conducted in over 80 countries and regions around the world, including the largest pharmaceutical markets - China, the U.S., Europe and Japan, as well as in fast growing emerging markets.

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¹World Alzheimer Report 2018, Alzheimer's Disease International, September 2018,
<https://www.alzint.org/u/WorldAlzheimerReport2018.pdf>