ANNOUNCEMENT FOR EUROPEAN MEDICAL & PHARMACEUTICAL TRADE MEDIA AND EUROPEAN FINANCIAL MEDIA ONLY

Abilify Maintena® 960 mg (aripiprazole) approved in the EU as the first once-every-two-months long-acting injectable for the maintenance treatment of schizophrenia

- **Aripiprazole's new long-acting injectable (LAI) formulation enables continuous exposure to medication for two months**[1]

Windsor, United Kingdom/Valby, Denmark, 27 March, 2024 – Otsuka Pharmaceutical Europe Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) today announced that the European Commission (EC) has approved Abilify Maintena® 960 mg (aripiprazole) as a once-every-two-months long-acting injectable (LAI) formulation for the maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole. The EC decision applies to all European Union (EU) member states, as well as Iceland, Norway and Liechtenstein.

Aripiprazole once-every-two-months LAI is a new formulation containing 960 mg aripiprazole provided in a single-chamber prefilled syringe that does not require reconstitution. It is intended for dosing once every two months via intramuscular injection into the gluteal muscle[1] and is the first once-every-two-months LAI antipsychotic licensed in the EU for this indication.

The EC based its approval on a 32-week pharmacokinetic bridging trial, which also evaluated the safety and efficacy of the drug as primary and secondary endpoint respectively[1]. Aripiprazole once-every-two-months LAI was shown to provide similar plasma concentrations, and therefore similar effectiveness, as well as a similar safety and tolerability profile to aripiprazole once-monthly LAI (Abilify Maintena® 400 mg) in 266 adults, of whom 185 were diagnosed with schizophrenia[1,2].

Dr Johan Luthman, Executive Vice President and Head of Research & Development at Lundbeck, said: *'This approval represents an important step for patients, families, and healthcare providers. It reflects our commitment to addressing unmet medical needs through innovation. Specifically designed for adult patients with schizophrenia who have been stabilised with aripiprazole, this treatment aims to increase patient adherence and convenience, contributing to the careful and comprehensive management of this chronic condition. We extend our appreciation to the patients and researchers who played a crucial role in achieving this milestone.'*

Dr Peter Gillberg, Vice President and Head of Medical Affairs at Otsuka Europe, added: *'We welcome the EC approval of aripiprazole once-every-two-months LAI, which represents a significant milestone in offering adult patients with schizophrenia another, simplified, treatment regimen. We hope that this treatment may help to mitigate challenges with adherence, and potentially allow patients and their healthcare practitioners to focus on other elements of care.'*

About Abilify® (aripiprazole)

Aripiprazole is a dopamine D2 partial agonist and 5-HT1A partial agonist and a 5-HT2A receptor with antagonistic activity[3]. It is available as a daily oral tablet, orally disintegrating tablet, and oral solution (Abilify®), or a once-monthly LAI formulation (Abilify Maintena® 400 mg)[3,4]. Abilify® is

also available as a short-acting intramuscular (IM) Injection[3]. Aripiprazole was discovered by Otsuka and is being co-developed and co-commercialised under a collaboration and license agreement between Otsuka Pharmaceutical Europe Ltd. and H. Lundbeck A/S.

About schizophrenia

Schizophrenia is a chronic, disabling and progressive mental illness, characterised by delusions, hallucinations, and disordered cognition which may occur at varying intervals between periods of relative symptomatic stability[5]. Schizophrenia affects approximately 24 million people, or 1 in 300 people (0.32%) worldwide[6]. Onset is most often during late adolescence and the twenties, and onset tends to happen earlier among men than women[6]. Schizophrenia is frequently associated with significant distress and impairment in personal, family, social, educational, occupational, and other important areas of life[6]. It is one of the top 15 leading causes of disability worldwide[7].

About Otsuka

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: "Otsuka-people creating new products for better health worldwide."

Otsuka researches, develops, manufactures, and markets innovative products, focusing on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health. In pharmaceuticals, Otsuka is a leader in the challenging area of mental health and also has research programs in several under-addressed diseases including tuberculosis, a significant global public health issue.

Otsuka Europe employs around 500 people and focuses on psychiatric and neurologic disorders, nephrology, haemato-oncology, rare diseases and digital medicines. Otsuka Pharmaceutical Europe Ltd. is a part of Otsuka Pharmaceutical Company, Ltd., a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan.

The Otsuka group of companies employed 47,000 people worldwide with consolidated sales of approximately €13.6 billion and a spend of €2 billion on research and development in 2023. For further information on Otsuka, please visit www.otsuka-europe.com.

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About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) Lundbeck is a biopharmaceutical company focused exclusively on neuroscience, with more than 70 years of experience in improving the lives of people with neurological and psychiatric diseases. As a focused innovator, we strive for our research and development programs to tackle some of the most complex challenges. We develop transformative medicines targeting people for whom there are few, if any, treatment options. Our goal is to create long term value and make a positive contribution to people and societies, everywhere we operate. We

are committed to fighting stigma and discrimination, and we act to improve health equity for the people we serve and the communities we are part of.

We are 5,600 employees in more than 50 countries, and our products are available in more than 100 countries. We have research facilities in Denmark and the United States, and our production facilities are located in Denmark, France, and Italy. Whether we work in labs, at desks or in the field, we work closely with patients, healthcare professionals and the neuroscience community to uncover causes, find new treatments and fight stigma and discrimination against people living with brain diseases.

Lundbeck generated revenue of DKK 20 billion in 2023 (EUR 2.6 billion; USD 2.8 billion).

For additional information, we encourage you to visit our corporate website www.lundbeck.com/global and connect with us on LinkedIn.

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