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

# Aripiprazole once-every-two-months long-acting injectable recommended for approval in the EU by the CHMP for the maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole

- **Subject to final approval by the European Commission, the drug will be the first once-every-two-months long-acting injectable (LAI) antipsychotic licensed in the EU for adult patients with schizophrenia stabilised with aripiprazole.**

**Windsor, United Kingdom/Valby, Denmark, 29 January, 2024** – Otsuka Pharmaceutical Europe Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announce that the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion and recommended granting a marketing authorisation in the European Union (EU) for aripiprazole as a once-every-two-months long-acting injectable (LAI) formulation for the maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole.

Aripiprazole once-every-two-months LAI is a new formulation containing 960mg aripiprazole provided in a single-chamber prefilled syringe that does not require reconstitution[1]. It is intended for dosing once every two months via intramuscular injection into the gluteal muscle[1]. If approved, the drug would be the first once-every-two-months LAI antipsychotic licensed in the EU indicated for the maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole.

Medication adherence in patients with schizophrenia is generally poor[2] and several studies have demonstrated that a predictor for further relapse is nonadherence to antipsychotic medications[3]. An LAI formulation enables continuous exposure to medication, and through a simplified treatment regimen, many of the challenges with poor treatment adherence may be mitigated, resulting in a potential positive impact on patient outcomes[4]. In patients with schizophrenia, LAI formulations have been shown to increase adherence and reduce relapse rates versus oral antipsychotics[4-6].

The CHMP based its positive opinion on the safety and efficacy of the drug, which has been demonstrated in a 32-week pharmacokinetic bridging trial. 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 in 266 adults, of which 185 were diagnosed with schizophrenia[1,7].

**Dr Johan Luthman, Executive Vice President and Head of Research & Development at Lundbeck, said:**
*'This is an important milestone in our efforts to offer adult patients with schizophrenia a new option designed to support treatment goals and offer flexibility. The results from the once-every-two-months formulation trial reinforce the long-standing efficacy and safety profile of the once-monthly aripiprazole long-acting injectable.'*

**Peter Gillberg, Vice President Medical Affairs at Otsuka Europe, added:**
*'New treatment options for patients with schizophrenia are much needed and we will continue to work hard to provide them and their caregivers with additional options in areas of unmet medical need.'*

If approved by the European Commission, the marketing authorisation will be valid in all EU member states, Iceland, Norway, and Liechtenstein. The CHMP positive opinion is one of the final steps before the European Commission makes its decision on the Marketing Authorisation Application. A final decision regarding the approval of the drug is expected from the European Commission in the coming months.

**About aripiprazole**

Aripiprazole is a dopamine D2 partial agonist with weak 5-HT1a partial agonism and 5-HT2A receptor antagonism[8]. It is available as a daily oral tablet, orally disintegrating tablet, and oral solution (Abilify®), or a once-monthly LAI formulation (Abilify Maintena®)[8,9]. Abilify is also available as a short-acting intramuscular (IM) Injection[8].

Aripiprazole was discovered by Otsuka and is being co-developed 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[10]. Schizophrenia affects approximately 24 million people, or 1 in 300 people (0.32%) worldwide[11]. Onset is most often during late adolescence and the twenties, and onset tends to happen earlier among men than women[11]. Schizophrenia is frequently associated with significant distress and impairment in personal, family, social, educational, occupational, and other important areas of life[11]. It is one of the top 15 leading causes of disability worldwide[12].

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**About Lundbeck**

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

Too many people worldwide live with brain diseases – complex conditions often invisible to others that nonetheless take a tremendous toll on individuals, families, and societies. We are committed to fighting stigma and discrimination against people living with brain diseases and advocating for broader social acceptance of people with brain health conditions. Every day, we strive for improved treatment and a better life for people living with brain disease.

We have approximately 5,400 employees in more than 50 countries, and our products are available in more than 100 countries. Our research programs tackle some of the most complex challenges in neuroscience, and our pipeline is focused on bringing forward transformative treatments for brain diseases for which there are few, if any therapeutic options. We have research facilities in Denmark and the United States, and our production facilities are located in Denmark, France and Italy.

Lundbeck generated revenue of DKK 18.2 billion in 2022 (EUR 2.5 billion; USD 2.6 billion). For additional information, we encourage you to visit our corporate website www.lundbeck.com/global and connect with us on Instagram @h_lundbeck, Twitter @Lundbeck and via LinkedIn.

**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 over 550 people and focuses on psychiatric and neurologic disorders, infectious disease, nephrology, oncology, 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 €12.4 billion and a spend of €1.67 billion on research and development in 2022.

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