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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

Otsuka Pharmaceutical Co., Ltd announces that its subsidiary Otsuka Pharmaceutical Europe Ltd. and H. Lundbeck A/S (Lundbeck) 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® 400mg) in 266 adults, of whom 185 were diagnosed with schizophrenia[1,2].

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.'

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.'

References

1. Harlin, M, et al. *CNS Drugs* 2023; doi: 10.1007/s40263-023-00996-8.
2. Citrome, L, et al. *J Clin Psychiatry* 2023; doi:10.4088/JCP.23m14873.