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Date: 02 May 2023

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Asimtufii (aripiprazole) 720 mg and 960 mg prolonged-release suspension for injection in pre-filled syringe - EMEA/H/C/005929

Dear Dr. Harald Enzmann,

We would like to inform you that, at this point of time, Otsuka Pharmaceutical Netherlands B.V., has taken the decision to withdraw the application for Marketing Authorisation of Asimtufii (aripiprazole) 720 mg and 960 mg prolonged-release suspension for injection in pre-filled syringe, which was intended to be used for the maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole.

This withdrawal is based on the following reason: a change in Otsuka's strategy. This is unrelated to product quality or safety.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We agree for this letter to be published on the EMEA website.

Yours sincerely,

[redacted]

Associate Director, Global Regulatory Affairs Region Europe
Otsuka Pharmaceutical Development & Commercialisation Europe GmbH

[redacted]

Managing Director
Otsuka Pharmaceutical Netherlands B.V.