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Committee for Medicinal Products for Human Use (CHMP)
Attn: Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

17th July 2020

Subject: Withdrawal of ABILIFY MYCITE (Aripiprazole), 5 mg, 10 mg, 15 mg, 30 mg tablet with sensor (EMEA/H/C/005062)

Dear Dr 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 ABILIFY MYCITE, (Aripiprazole), 5 mg, 10 mg, 15 mg, 30 mg, tablet with sensor, which was intended to be used in adults:

- for the treatment of schizophrenia,
- for the treatment of moderate to severe manic episodes in bipolar I disorder,
- for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.

ABILIFY MYCITE is a drug-device combination product comprised of aripiprazole tablet embedded with an ingestible sensor to track medication ingestion.

This withdrawal is based on the following reason:

Certain major objections cannot be fully addressed at this point in time.

There are no ongoing clinical trials or compassionate use programmes for this product in the European Union.

Otsuka would like to sincerely thank the (Co-)Rapporteurs, EMA, and CHMP members for the time dedicated to reviewing this application and the support provided during the process.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

The applicant agrees for this letter to be published on the EMA website.

Yours sincerely,