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Dr. Eric Abadie
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17 November 2009

Subject: Withdrawal of ABILIFY (aripiprazole) Tablets, Orodispersible tablets and Oral solution - EMEA/H/C/000471/II/0063

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Otsuka Pharmaceutical Europe Ltd has taken the decision to withdraw the application for a new indication for ABILIFY (aripiprazole) Tablets, Orodispersible tablets and Oral solution (EU/1/04/276/001-020; 024-035) in the treatment of Major Depressive Episodes, as adjunctive therapy, in patients who have had an inadequate response to previous treatment with antidepressants.

This withdrawal is based on the CHMP consideration that the long-term data provided in support of the proposed indication were considered insufficient, as long-term randomised controlled data are needed before licensing this indication.

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

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