

**ARIPRAZOLE ONCE-MONTHLY FOR THE TREATMENT OF SCHIZOPHRENIA IN OBESE AND NON-OBESE PATIENTS; A POST-HOC ANALYSIS**

M. De Hert<sup>1</sup>, A. Eramo<sup>2</sup>, W. Landsberg<sup>3</sup>, L.F. Tsai<sup>4</sup>, D. Kostic<sup>5</sup>, R. Baker<sup>6</sup>

<sup>1</sup>University Psychiatric Centre, Catholic University Leuven Campus Kortenberg, Kortenberg, Belgium ; <sup>2</sup>Medical Affairs & Phase IV Clinical Affairs, H. Lundbeck A/S, Deerfield, USA ; <sup>3</sup>Medical, Otsuka Pharmaceutical Europe, Middlesex, United Kingdom ; <sup>4</sup>Biostatics, Otsuka Pharmaceutical Development and Commercialization Inc., Rockville, USA ; <sup>5</sup>Global Medical Affairs, Otsuka Pharmaceutical Development and Commercialization Inc., Princeton, USA ; <sup>6</sup>CNS Global Medical Affairs, Otsuka Pharmaceutical Development and Commercialization Inc., Princeton, USA

**Objective:** To evaluate efficacy and safety of aripiprazole once-monthly 400mg (AOM-400mg), an extended release injectable suspension of aripiprazole, in obese (BMI  $\geq 30\text{kg/m}^2$ ) and non-obese (BMI  $< 30\text{kg/m}^2$ ) patients with schizophrenia.

**Methods:** Data from a 38-week, double-blind, active-controlled, non-inferiority study (NCT00706654); randomisation (2:2:1) to AOM-400mg, oral aripiprazole (10–30mg/day) (ARI), or aripiprazole once-monthly 50mg (AOM-50mg) assessing the efficacy and safety of AOM in patients requiring chronic antipsychotic treatment were used for this post-hoc analysis. We report the overall relapse rates in the 38-week randomized phase. Comparisons of overall relapse rates were analyzed using the Chi-squared test.

**Results:** 662 patients were randomized to: AOM-400mg (n=265); ARI (n=266); or AOM-50mg (n=131). Of these, the following were obese: AOM-400mg: n=95; ARI: n=95; AOM-50mg: n=43. In the obese patients, the overall relapse rate was significantly (p=0.0012) lower with AOM-400mg (7.4%) than with AOM-50mg (27.9%). The difference between AOM-400mg and ARI (8.4%) was not significantly different. In the non-obese patients, the overall relapse was significantly (p=0.0153) lower with AOM-400mg (8.8%) than with AOM-50mg (19.3%). The difference between AOM-400mg and ARI (7.6%) was not significantly different. For patients treated with AOM-400mg, the most common TEAEs (>10% in any group) are presented in Table 1.

TEAE: AOM-400mg	Obese	Non-obese
Insomnia	12.6%	11.2%
Headache	12.6%	8.2%
Injection site pain	11.6%	5.3%
Akathisia	10.5%	10.6%
Upper respiratory tract infection	10.5%	<5%
Weight increase	10.5%	8.2%
Weight decrease	6.3%	11.8%

**Conclusions:** The efficacy and tolerability of aripiprazole once-monthly 400mg were similar in both the obese and non-obese subgroups.

**Disclosure:** Supported by Otsuka Pharmaceutical Development & Commercialization, Inc., and H. Lundbeck A/S