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ALL-CAUSE DISCONTINUATION AND SAFETY OF ARIPIPRAZOLE ONCE-MONTHLY FOR THE TREATMENT OF SCHIZOPHRENIA: A POOLED ANALYSIS OF TWO DOUBLE-BLIND, RANDOMIZED, CONTROLLED TRIALS

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Objective: To evaluate the initial (3 months) all-cause discontinuation and safety of aripiprazole once-monthly 400mg (AOM-400mg), an extended release injectable suspension of aripiprazole, stratified by previous treatment.

Methods: These two studies (NCT00705783 & NCT00706654) were double-blind, placebo- or active-controlled assessing the efficacy and safety of AOM-400mg. Detailed study designs have been reported previously (1, 2). This analysis was conducted on the pooled population in the first 3 months after initiating AOM-400mg treatment, on patients who received at least one dose of AOM-400mg. Outcome measures are reported for groups stratified by prior treatment.

Results: During the first 3 months of treatment, discontinuation due to all-causes (except for those who discontinued due to the sponsor stopping the NCT00705783 study early after pre-specified efficacy parameters were met) as well as due to adverse events are presented in Table 1. The rates of insomnia and akathisia are shown in Table 1

Table 1		Prior treatment		
	Overall n=841	Antipsychotic other than oral aripiprazole (converted) n=581	Oral aripiprazole n=191	Not on antipsychotic treatment n=69
All-cause discontinuations	111/841 (13.2%)	76/581 (13.1%)	23/191 (12.0%)	12/69 (17.4%)
Discontinuations due to adverse events	21/841 (2.5%)	14/581 (2.4%)	3/191 (1.6%)	4/69 (5.8%)
Insomnia	71/841 (8.4%)	57/ 581 (9.8%)	6/191 (3.1%)	8/69 (11.6%)
Akathisia	59/ 841 (7.0%)	39/581 (6.7%)	15/191 (7.9%)	5/ 69 (7.2%)

Conclusion: Aripiprazole once-monthly 400mg appeared equally safe and effective (as measured by all cause discontinuation) in the first 3 months after initiation, regardless of treatment prior to entering trials.

(1)Kane. J Clin Psychiatry 2012;73:617. (2)Fleischhacker. Poster presented at ACNP 2012

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