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Supplementary Material

Article Title: Safety and Efficacy of Maintenance Treatment with Aripiprazole Once-Monthly in Black/African American Adults Diagnosed With Bipolar I Disorder: Post Hoc Analysis of a 52-Week, Open-Label Study

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LIST OF SUPPLEMENTARY MATERIAL FOR THE ARTICLE

DISCLAIMER

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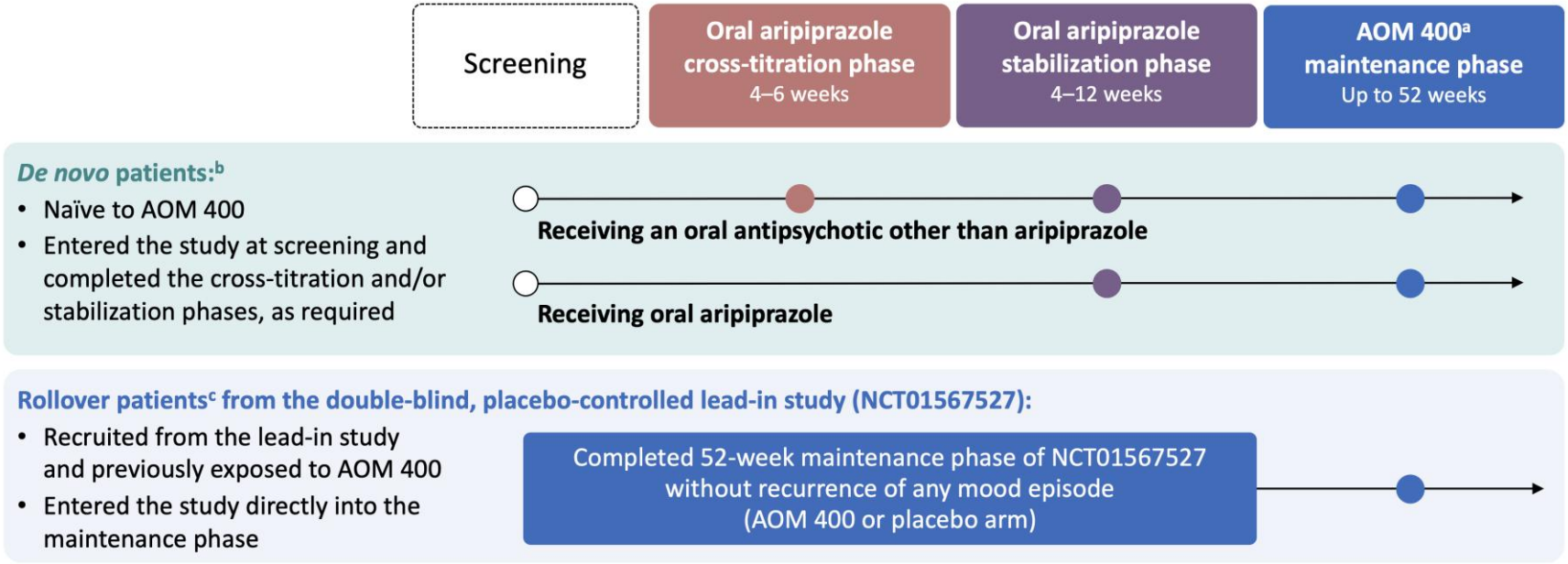
Supplementary Figure 1. Study Design.[1]



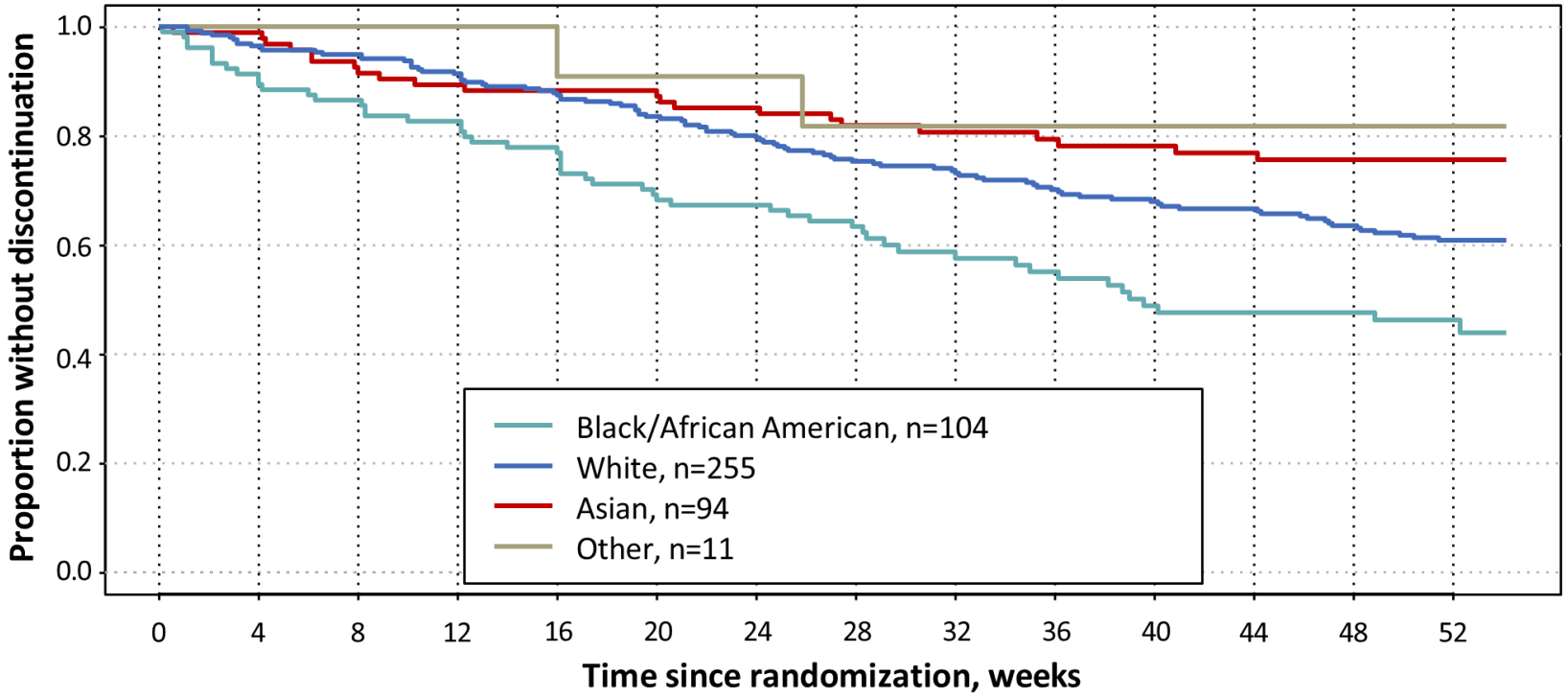
[a]Patients received a starting dose of 400 mg but modification to 300 mg with a return to 400 mg was allowed at any point (rescue therapy to control symptoms was permitted).

[b]*De novo* patients were newly enrolled to the extension study and, depending on their current oral antipsychotic, completed the cross-titration and stabilization phases, or the stabilization phase only. Entry into the maintenance phase occurred when patients demonstrated stability, defined as: outpatient status; a YMRS total score of ≤12; a MADRS total score of ≤12; and no active suicidality (defined as a score of ≥4 for MADRS Item 10 or an answer of "yes" on Questions 4 or 5 of the Columbia-Suicide Severity Rating Scale).

[c]Rollover patients were recruited from the double-blind, placebo-controlled lead-in study (NCT01567527), and entered the study directly into the AOM 400 maintenance phase.

Abbreviations: AOM 400 = aripiprazole once-monthly 400 mg; MADRS = Montgomery–Åsberg Depression Rating Scale; YMRS = Young Mania Rating Scale.

Supplementary Figure 2. Kaplan–Meier Curve of Time From Randomization to Discontinuation According to Patient-Reported Race Across 52 Weeks of Treatment with AOM 400.



B/AA	104	95	90	86	81	72	70	64	48	45	39	37	37	31
White	255	246	242	233	224	213	204	190	170	161	154	151	144	121
Asian	94	93	87	84	83	83	80	76	64	63	62	61	59	58
Other	11	11	11	11	11	10	10	8	8	8	8	8	8	7

Abbreviations: AOM 400 = aripiprazole once-monthly 400 mg; B/AA = Black/African American.

Supplementary Table 1. Reasons for Study Discontinuation According to Patient-Reported Race Across 52 Weeks of Treatment with AOM 400

Reason for discontinuation, n (%)	Overall[a] (N=464)	Black/African American (n=104)	White (n=255)	Asian (n=94)	Other (n=11)
All cause	173 (37.3)	53 (51.0)	96 (37.6)	22 (23.4)	2 (18.2)
TEAE	48 (10.3)	10 (9.6)	30 (11.8)	8 (8.5)	0 (0)
Patient withdrew consent to participate	53 (11.4)	11 (10.6)	31 (12.2)	11 (11.7)	0 (0)
Patient met protocol-specified withdrawal criteria	33 (7.1)	18 (17.3)	11 (4.3)	3 (3.2)	1 (9.1)
Lost to follow-up	29 (6.3)	9 (8.7)	19 (7.5)	0 (0)	1 (9.1)
Protocol deviation	5 (1.1)	2 (1.9)	3 (1.2)	0 (0)	0 (0)
Lack of efficacy	3 (0.6)	1 (1)	2 (0.8)	0 (0)	0 (0)
Patient withdrawn from participation by the investigator	2 (0.4)	2 (1.9)	0 (0)	0 (0)	0 (0)

[a]Data for the overall population are reproduced without any change from Calabrese et al. *Int J Bipolar Disord.* 2018,[1] under the terms of Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/).

Abbreviation: TEAE = treatment-emergent adverse event.

Supplementary Table 2. Reasons for Protocol-Specified Withdrawal According to Patient-Reported Race Across 52 Weeks of Treatment with AOM 400

Reason for protocol-specified withdrawal, n (%)	Overall (N=464)	Black/African American (n=104)	White (n=255)	Asian (n=94)	Other (n=11)
Occurrence of any AE or intercurrent illness that, in the opinion of the investigator, warrants the patient's permanent withdrawal from the trial	–	–	–	–	–
Treatment with a prohibited concomitant medication other than the use of appropriate medications for the treatment of AEs under direction of the investigator	–	–	–	–	–
Patients with 2 positive drug screens for cocaine during the trial. Two positive drug screens for other drugs of abuse must be discussed with the Medical Monitor unless the patient satisfies criteria for dependence, in which case the patient should be excluded from the trial	24 (5.2)	15 (14.4)	8 (3.1)	–	1 (9.1)
Patient non-compliance, defined as refusal or inability to adhere to the trial schedule or procedures.	5 (1.1)	2[a] (1.9)	2 (0.8)	1 (1.1)	–
At the request of the patient, investigator, sponsor, or regulatory authority.	–	–	–	–	–
Patient becomes pregnant	2 (0.4)	–	1 (0.4)	1 (1.1)	–
Patient is lost to follow-up	–	–	–	–	–
Patient does not fulfill stability criteria by week 10 of the oral aripiprazole stabilization phase	1 (0.2)	1 (1.0)	–	–	–

Patients for whom the investigator believes treatment with a medication for their bipolar I disorder (particularly to adequately treat depressive symptoms) other than aripiprazole once-monthly and the allowed rescue therapy (lithium or valproate) is necessary to achieve stabilization	1 (0.2)	–	–	1 (1.1)	–

[a]This included one patient who failed to provide prescription documentation for methadone.

Abbreviation: AE = adverse event.

Supplementary Table 3. Extent of Exposure to AOM 400 or AOM 300 Across 52 Weeks of Treatment According to Patient-Reported Race

Injection number	Overall			Black/African American			White			Asian			Other		
	N	AOM 400 n (%)	AOM 300 n (%)	N	AOM 400 n (%)	AOM 300 n (%)	N	AOM 400 n (%)	AOM 300 n (%)	N	AOM 400 n (%)	AOM 300 n (%)	N	AOM 400 n (%)	AOM 300 n (%)
1	464	462 (99.6)	2 (0.4)	104	103 (99.0)	1 (0.96)	255	255 (100)	0 (0)	94	93 (98.9)	1 (1.1)	11	11 (100)	0 (0)
2	435	392 (90.1)	43 (9.9)	91	85 (93.4)	6 (6.6)	244	220 (90.2)	24 (9.8)	89	76 (85.4)	13 (14.6)	11	11 (100)	0 (0)
3	422	355 (84.1)	67 (15.9)	86	73 (84.9)	13 (15.1)	240	204 (85.0)	36 (15.0)	85	67 (78.8)	18 (21.2)	11	11 (100)	0 (0)
4	402	329 (81.8)	73 (18.2)	83	70 (84.3)	13 (15.7)	225	185 (82.2)	40 (17.8)	83	63 (75.9)	20 (24.1)	11	11 (100)	0 (0)
5	387	307 (79.3)	80 (20.7)	75	62 (82.7)	13 (17.3)	219	174 (79.5)	45 (20.5)	83	61 (73.5)	22 (26.5)	10	10 (100)	0 (0)
6	366	288 (78.7)	78 (21.3)	70	59 (84.3)	11 (15.7)	206	161 (78.2)	45 (21.8)	80	58 (72.5)	22 (27.5)	10	10 (100)	0 (0)
7	353	277 (78.5)	76 (21.5)	66	57 (86.4)	9 (13.6)	198	152 (76.8)	46 (23.2)	79	58 (73.4)	21 (26.6)	10	10 (100)	0 (0)
8	295	226 (76.6)	69 (23.4)	50	42 (84.0)	8 (16.0)	172	130 (75.6)	42 (24.4)	65	47 (72.3)	18 (27.7)	8	7 (87.5)	1 (12.5)
9	284	216 (76.1)	68 (23.9)	48	40 (83.3)	8 (16.7)	165	123 (74.5)	42 (25.5)	63	46 (73.0)	17 (27.0)	8	7 (87.5)	1 (12.5)
10	264	201 (76.1)	63 (23.9)	40	35 (87.5)	5 (12.5)	155	115 (74.2)	40 (25.8)	61	44 (72.1)	17 (27.9)	8	7 (87.5)	1 (12.5)

11	255	192 (75.3)	63 (24.7)	37	33 (89.2)	4 (10.8)	150	109 (72.7)	41 (27.3)	60	43 (71.7)	17 (28.3)	8	7 (87.5)	1 (12.5)
12	247	185 (74.9)	62 (25.1)	36	32 (88.9)	4 (11.1)	144	103 (71.5)	41 (28.5)	59	43 (72.9)	16 (27.1)	8	7 (87.5)	1 (12.5)
13	223	167 (74.9)	56 (25.1)	31	27 (87.1)	4 (12.9)	126	90 (71.4)	36 (28.6)	59	43 (72.9)	16 (27.1)	7	7 (100)	0 (0)

Abbreviations: AOM 300 = aripiprazole once-monthly 300 mg; AOM 400 = aripiprazole once-monthly 400 mg.

Supplementary Table 4. Concomitant use of Benzodiazepines and Anticholinergics Across 52 Weeks of Treatment with AOM 400 According to Patient-Reported Race

Concomitant medication use, %	Overall (N=464)	Black/African American (n=104)	White (n=255)	Asian (n=94)	Other (n=11)
Benzodiazepine derivatives	124 (26.7)	13 (12.5)	64 (25.1)	44 (46.8)	3 (27.3)
Anticholinergic agents	76 (16.4)	15 (14.4)	36 (14.1)	24 (25.5)	1 (9.1)

Abbreviation: AOM 400 = aripiprazole once-monthly 400 mg.

Reference

1. Calabrese JR, Jin N, Johnson B, et al. Aripiprazole once-monthly as maintenance treatment for bipolar I disorder: a 52-week, multicenter, open-label study. *Int J Bipolar Disord*. 2018;6(1):14. doi:10.1186/s40345-018-0122-z