Concomitant Medication Subgroup Analyses

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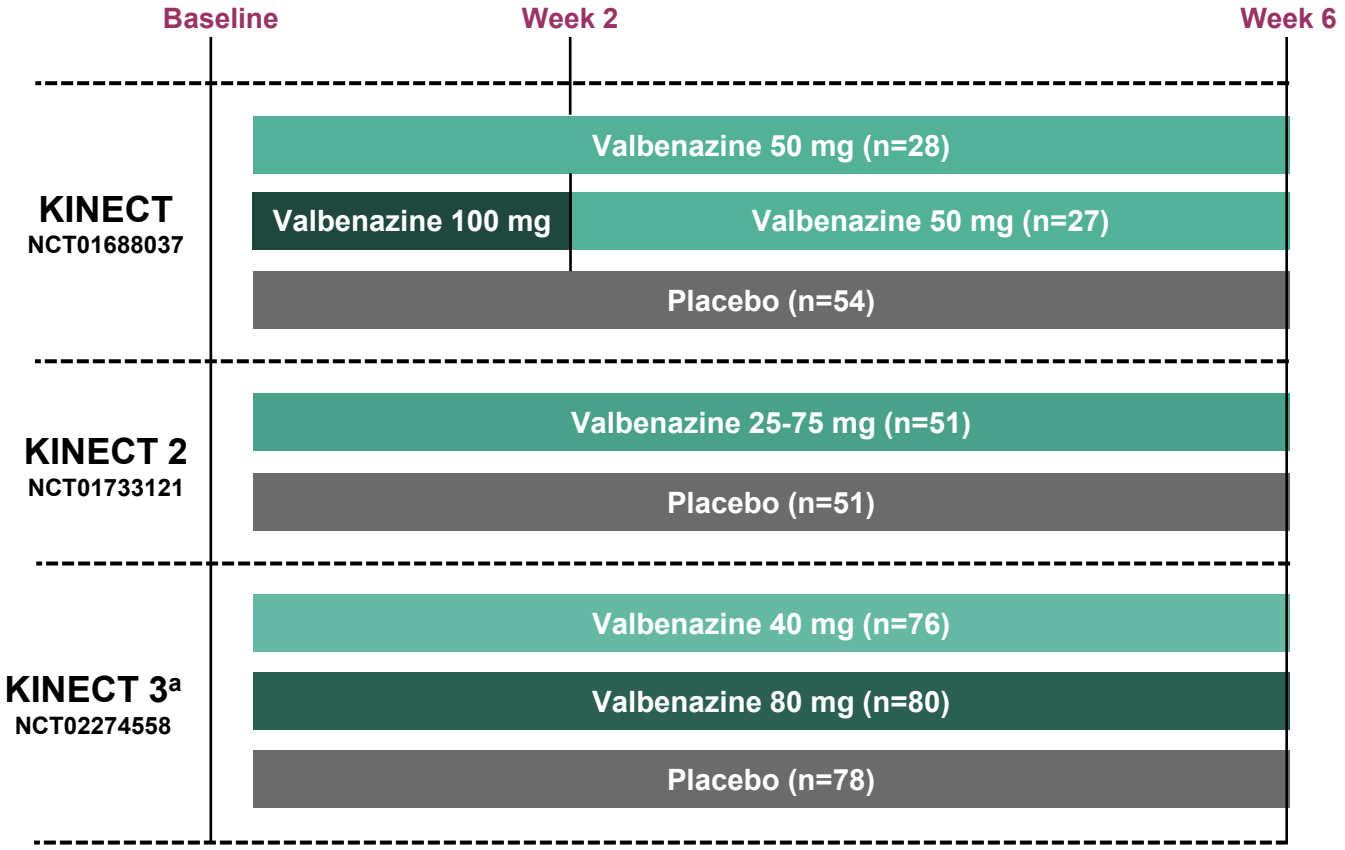
KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis

KINECT, KINECT 2, & KINECT 3: Study Design



- Pooled valbenazine 80 mg group included participants from KINECT 3 (80 mg group) and KINECT 2 (75 mg group)
- Pooled valbenazine 40 mg group included participants from in KINECT 3 (40 mg group) and KINECT (50 mg group)
- Participants who received only valbenazine 25 mg in KINECT 2 study were excluded from analyses

[a]KINECT 100 mg group received 100 mg for the first two weeks then decrease to 50 mg. [b]KINECT 3 80 mg group received 40 mg for the first week.
N-values indicate the number of participants who were randomized to treatment.

Meyer J, et al. NEI Congress 2017; Colorado Springs, CO.

KINECT, KINECT 2 & KINECT 3: Assessments

- All participants who received ≥1 dose of study drug and had ≥1 post-baseline Abnormal Involuntary Movement Scale (AIMS) assessment were included in the pooled intent-to-treat population
- Concomitant medication subgroups were defined as follows:
  - Antipsychotic use at baseline: yes, no
  - Antidepressant use at baseline: yes, no
  - Antidepressant category: selective serotonin reuptake inhibitor (SSRI), tricyclic antidepressant (TCA), serotonin-norepinephrine reuptake inhibitor (SNRI), or other (e.g., bupropion, mirtazapine, trazodone, vilazodone)
  - Anxiolytic use at baseline: yes, no
  - Anticholinergic use at baseline: yes, no
- TD improvement was assessed using AIMS total score (sum of items 1-7) mean change from baseline to Week 6 and AIMS response, defined as ≥50% total score improvement from baseline to Week 6
- Clinical relevance of AIMS mean score change was evaluated using Cohen's d effect size
- Clinical relevance of AIMS response was evaluated using numbers needed to treat (NNTs) and odds ratios (ORs) with 95% confidence intervals (95% CIs); valbenazine dose groups were combined for OR analyses

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 –Concomitant Medication Subgroup Analysis: Baseline Characteristics

	Placebo n=158	Valbenazine 40 mg n=114	Valbenazine 80 mg n=101
Antipsychotics, n (%)			
Yes	130 (82.3)	102 (89.5)	77 (76.2)
No	28 (17.7)	12 (10.5)	24 (23.8)
Common antispychotics[a]			
Quetiapine	33 (20.9)	32 (28.1)	21 (20.8)
Risperidone	27 (17.1)	12 (10.5)	17 (16.8)
Olanzapine	21(13.3)	18 (15.8)	9 (8.9)
Aripiprazole	18 (11.4)	12 (10.5)	14 (13.9)
Haloperidol	12 (7.6)	15 (13.2)	9 (8.9)
Ziprasidone	5 (3.2)	7 (6.1)	11 (10.9)
Lithium	2 (1.3)	5 (4.4)	8 (7.9)
Perphenazine	6 (3.8)	7 (6.1)	2 (2.0)
Paliperidone	2 (1.3)	8 (7.0)	3 (3.0)
Clozapine	8 (5.1)	3 (2.6)	2 (2.0)
Antidepressants, n (%)			
Yes	101 (63.9)	70 (61.4)	61 (60.4)
No	57 (36.1)	44 (38.6)	40 (39.6)
SSRI	62 (39.2)	41 (36.0)	35 (34.7)
SNRI	10 (6.3)	10 (8.8)	8 (7.9)
TCA	2 (1.3)	2 (1.8)	3 (3.0)
Other	47 (29.7)	40 (35.1)	28 (27.7)
Common antidepressants[a]			
Trazodone	27 (17.1)	23 (20.2)	20 (19.8)
Citalopram	22 (13.9)	14 (12.3)	12 (11.9)
Sertraline	21 (13.3)	13 (11.4)	13 (12.9)
Mirtazapine	12 (7.6)	12 (10.5)	4 (4.0)
Bupropion	9 (5.7)	8 (7.0)	8 (7.9)
Fluoxetine	11 (7.0)	7 (6.1)	3 (3.0)
Escitalopram	5 (3.2)	7 (6.1)	4 (4.4)
Duloxetine	5 (3.2)	5 (4.4)	5 (5.0)

[a]Reported in ≥5% of participants in any treatment group; includes any concomitant medications at baseline or after study drug initiation
SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; TCA, tricyclic antidepressant

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis: Baseline Characteristics

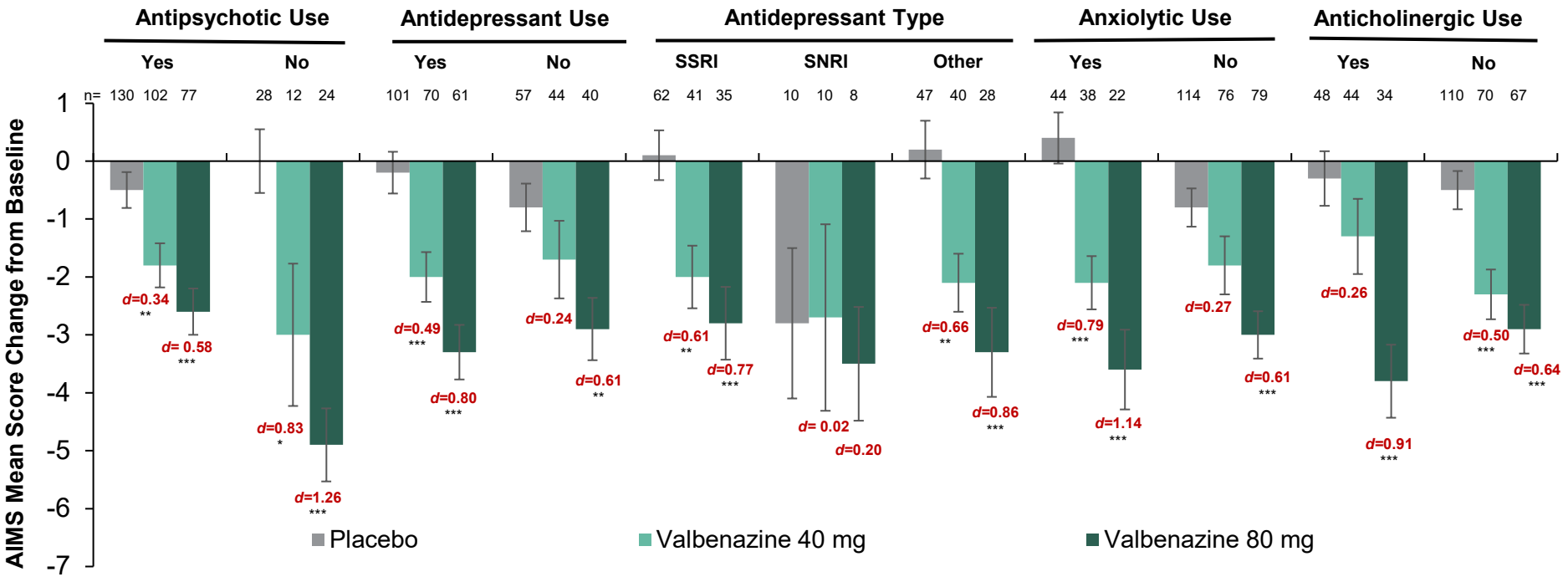
	Placebo n=158	Valbenazine 40 mg n=114	Valbenazine 80 mg n=101
Anticholinergics, n (%)			
Yes	48 (30.4)	44 (38.6)	34 (33.7)
No	110 (69.6)	70 (61.4)	67 (66.3)
Common anticholinergics[a]			
Benztropine	41 (25.9)	42 (36.8)	29 (28.7)
Diphenhydramine	8 (5.1)	4 (3.5)	6 (5.9)
Anxiolytics, n (%)			
Yes	44 (27.8)	38 (33.3)	22 (21.8)
No	114 (72.2)	76 (66.7)	79 (78.2)
Common anxiolytics[a]			
Lorazepam	15 (9.5)	11 (9.6)	11 (10.9)
Hydroxyzine	13 (8.2)	11(9.6)	8 (7.9)
Alprazolam	7 (4.4)	13 (11.4)	3 (3.0)
Buspirone	6 (3.8)	6 (5.3)	4 (4.4)

[a]Reported in ≥5% of participants in any treatment group; includes any concomitant medications at baseline or after study drug initiation

- Among all participants, 83% were taking a concomitant antipsychotic, 62% were taking a concomitant antidepressant, and 34% were taking a concomitant anticholinergic

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis: AIMS Mean Changes from Baseline to Week 6

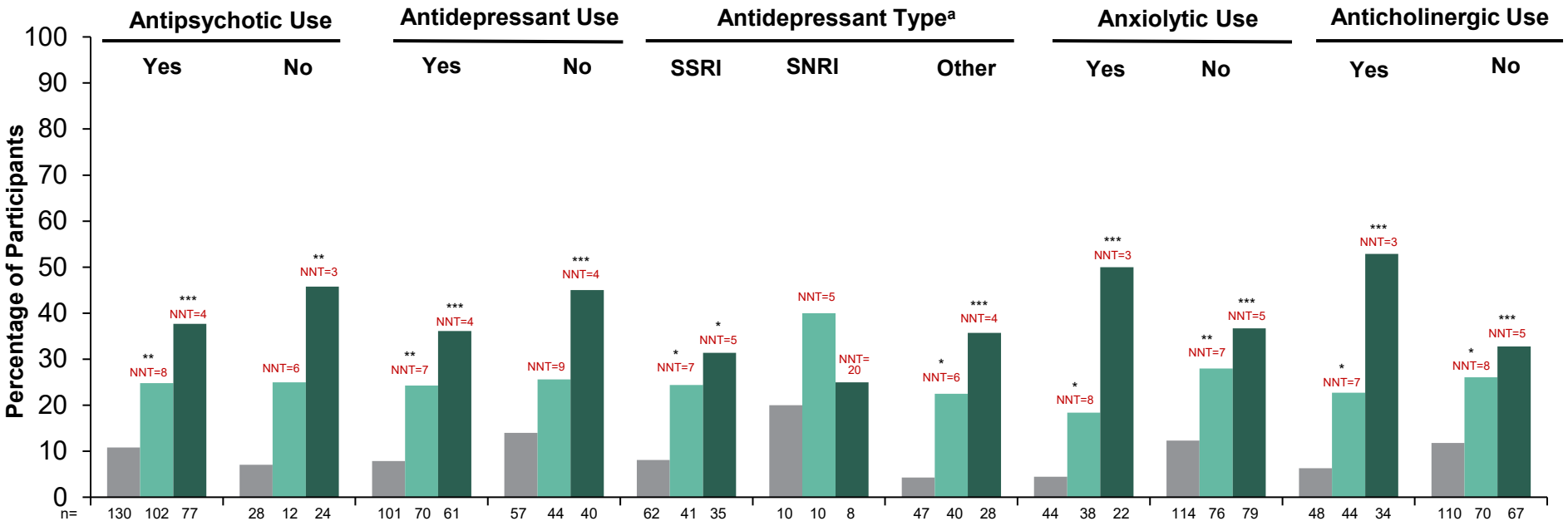


*P<0.05; **P≤0.01; ***P≤0.001 vs placebo. Cohen's *d* effect sizes (AIMS change from baseline) and numbers needed to treat (AIMS response) are in red. A negative value indicates a lower AIMS response rate with valbenazine vs placebo; AIMS, Abnormal Involuntary Movement Scale; SEM, standard error of the mean; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

- Mean changes from baseline to Week 6 in AIMS total score indicated a significantly greater improvement with valbenazine (40 and/or 80 mg) vs placebo in some subgroups that had concomitant use ("yes") of any antipsychotic, antidepressant, anxiolytic, or anticholinergic
- Subgroups with the largest effect sizes (d≥0.8) for valbenazine 80 mg were: no antipsychotic use (also 40 mg), any antidepressant use, other antidepressant use, any anxiolytic use, and any anticholinergic use

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis: >50% AIMS Improvement from Baseline at Week 6

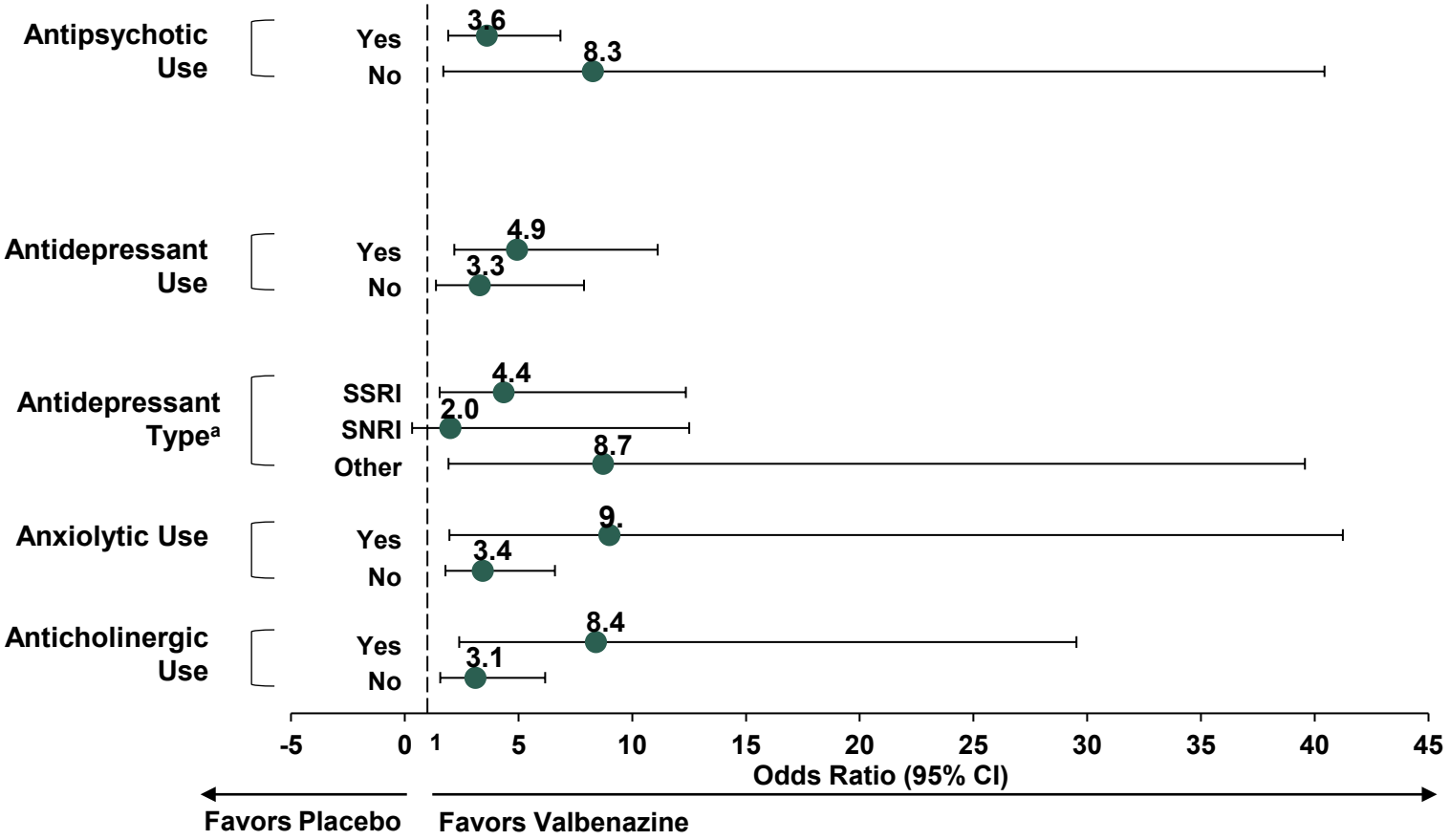


*P<0.05; **P≤0.01; ***P≤0.001 vs placebo. [a]Analyses were not conducted in the tricyclic antidepressant subgroup due to small sample size (n=7)
AIMS, Abnormal Involuntary Movement Scale; SEM, standard error of the mean; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

- The percentage of participants with an AIMS response (≥50% total score improvement from baseline) was significantly higher with valbenazine (40 and/or 80 mg) relative to placebo in some concomitant medication subgroups, except for SNRI use, which had ≤10 participants in each treatment group
- All subgroups treated with valbenazine 80 mg had an NNT ≤5 except for SNRI use; however, this subgroup had an NNT=5 for valbenazine 40 mg

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis: Odds Ratios for AIMS Response at Week 6



[a]Analyses were not conducted in the tricyclic antidepressant subgroup due to small sample size (n=7)
AIMS, Abnormal Involuntary Movement Scale; CI, confidence interval; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

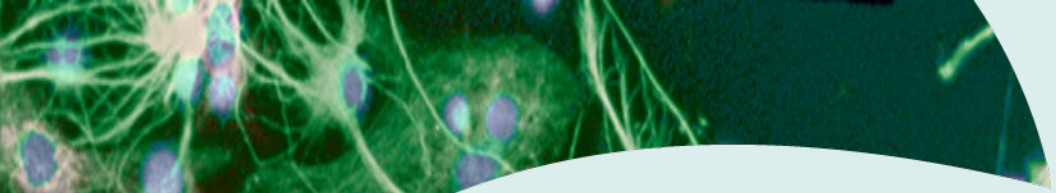
- At Week 6, ORs for AIMS response (>50% improvement in AIMS total score from baseline) indicated favorable effects with valbenazine (40 mg and 80 mg combined) vs placebo in all subgroups

Meyer J, et al. CPNP 2018; Indianapolis, IN.

KINECT, KINECT 2 & KINECT 3 – Concomitant Medication Subgroup Analysis: Summary

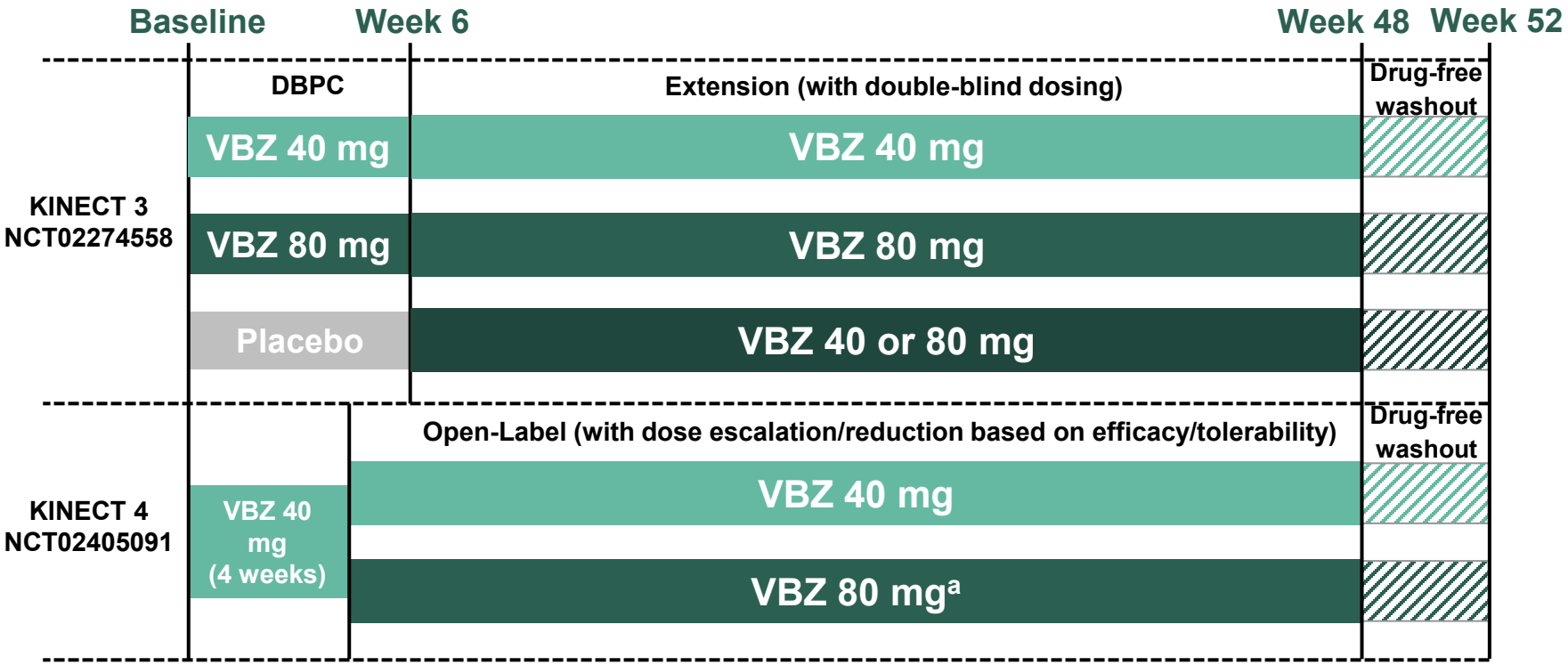
- Mean changes from baseline to Week 6 in AIMS total score indicated a significantly greater improvement with valbenazine (40 and/or 80 mg) vs. placebo in all subgroups that had concomitant use (“yes”) of any antipsychotic, antidepressant, anxiolytic, or anticholinergic[1]
  - Any antipsychotic: VBZ 40 mg: -1.8, P≤0.01; VBZ 80 mg: -2.6, P≤0.001; PBO: -0.5
  - Antidepressant: VBZ 40 mg: -2.0, P≤0.001; VBZ 80 mg: -3.3, P≤0.001; PBO: -0.2
  - Anxiolytic: VBZ 40 mg: -2.1, P≤0.001; VBZ 80 mg: -3.6, P≤0.001; PBO: 0.4
  - Anticholinergic: VBZ 80 mg: -3.8, P≤0.001; PBO: -0.3
- The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >Placebo) include anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia[2]

1. Meyer J, et al. CPNP 2018; Indianapolis, IN. 2. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.



KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis

KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: Study Design



[a]Includes participants who had a dose reduction to 40 mg due to tolerability issues
DBPC, double-blind placebo-controlled; VBZ, valbenazine

Comella C, et al. AAN 2019; Philadelphia, PA.

KINECT 3 & KINECT 4: Assessments

- All participants who received ≥1 dose of study drug and had ≥1 post-baseline Abnormal Involuntary Movement Scale (AIMS) assessment were included in the pooled intent-to-treat population
  - The AIMS was scored by blinded central video raters (KINECT 3) or site raters (KINECT 4)
- Analyses at Week 48 (end of long-term treatment) and Week 52 (end of 4-week washout) included:
  - Mean change from baseline in AIMS total score (sum of items 1-7)
  - Response, defined as ≥50% total score improvement from baseline
- Concomitant medication subgroups were defined by use at baseline as follows:
  - Antipsychotic use (yes, no)
  - Antidepressant use (yes, no)
  - Anticholinergic use (yes, no)
  - Anxiolytic use (yes, no)
  - Combinations: antidepressant + atypical antipsychotics; antipsychotic + anxiolytic; antipsychotic + anticholinergic; antidepressant + anxiolytic
  - Subgroup categories were not mutually exclusive

Comella C, et al. AAN 2019; Philadelphia, PA.

KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: Concomitant Medications at Baseline or at Any Time During the Study

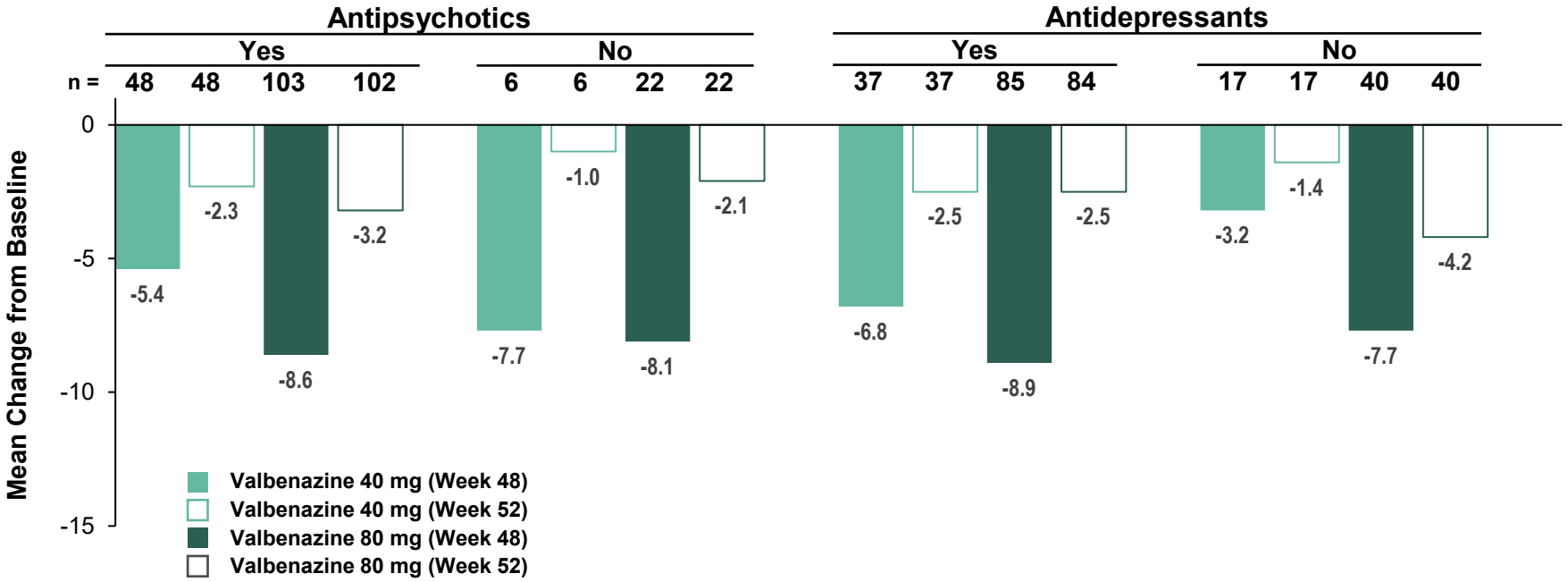
	Valbenazine 40 mg n=107	Valbenazine 80 mg n=197	All N=304
Any antipsychotic, n (%)[a]	98 (91.6)	169 (85.8)	267 (87.8)
Quetiapine	29 (27.1)	50 (25.4)	79 (26.0)
Risperidone	19 (17.8)	32 (16.2)	51 (16.8)
Aripiprazole	14 (13.1)	28 (14.2)	42 (13.8)
Olanzapine	17 (15.9)	24 (12.2)	41 (13.5)
Haloperidol	14 (13.1)	20 (10.2)	34 (11.2)
Ziprasidone	6 (5.6)	13 (6.6)	19 (6.3)
Any antidepressant, n (%)[a]	71 (66.4)	129 (65.5)	200 (65.8)
Trazodone	26 (24.3)	45 (22.8)	71 (23.4)
Mirtazapine	13 (12.1)	20 (10.2)	33 (10.9)
Sertraline	13 (12.1)	20 (10.2)	33 (10.9)
Citalopram	13 (12.1)	19 (9.6)	32 (10.5)
Bupropion	4 (3.7)	21 (10.7)	25 (8.2)
Escitalopram	7 (6.5)	14 (7.1)	21 (6.9)
Fluoxetine	8 (7.5)	13 (6.6)	21 (6.9)
Duloxetine	9 (8.4)	10 (5.1)	19 (6.3)
Venlafaxine	5 (4.7)	11 (5.6)	16 (5.3)
Any anxiolytic, n (%)[a]	42 (39.3)	59 (29.9)	101 (33.2)
Lorazepam	13 (12.1)	23 (11.7)	36 (11.8)
Hydroxyzine	11 (10.3)	18 (9.1)	29 (9.5)
Alprazolam	10 (9.3)	16 (8.1)	26 (8.6)
Buspirone	11 (10.3)	14 (7.1)	25 (8.2)
Any anticholinergic, n (%)[a]	41 (38.3)	68 (34.5)	109 (35.9)
Benztropine	40 (37.4)	61 (31.0)	101 (33.2)

[a]Common medications, as reported in ≥5% of all participants, are listed

- In all participants who received ≥1 dose of study drug (N=304), 87.8% were taking an antipsychotic medication at baseline

Comella C, et al. AAN 2019; Philadelphia, PA.

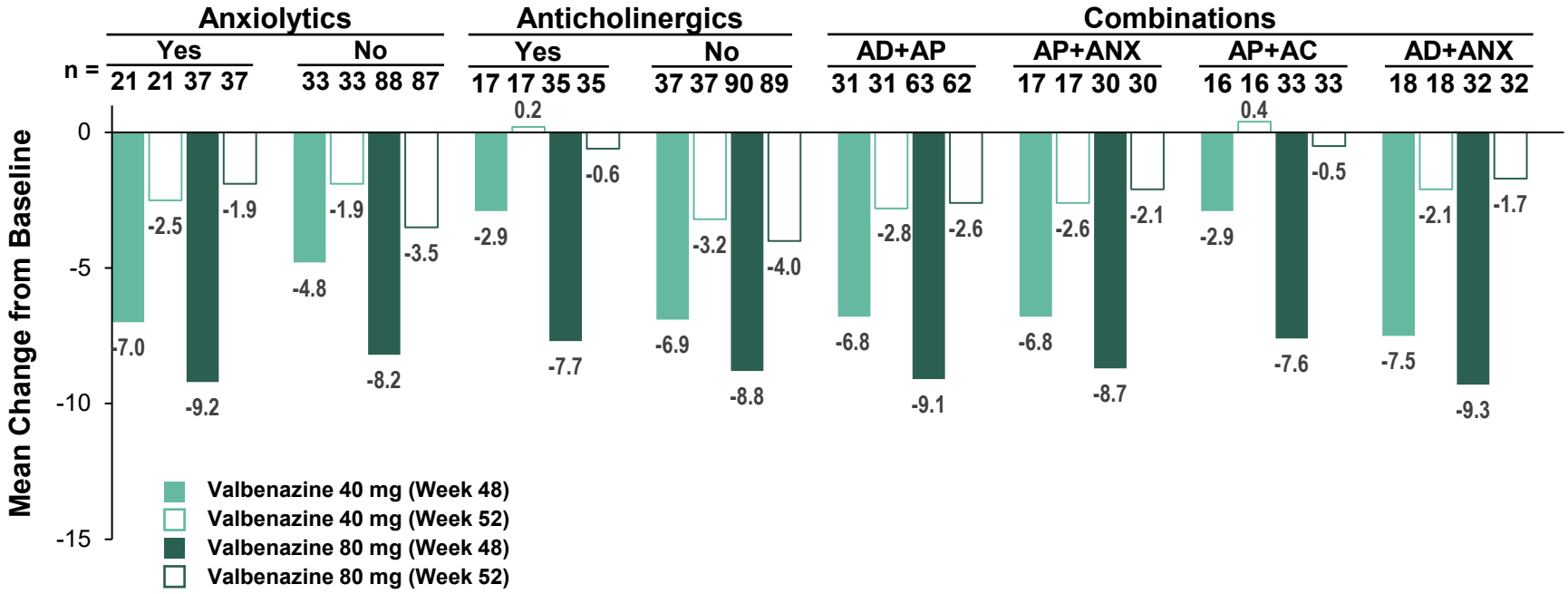
KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: AIMS Mean Changes from Baseline to Week 48 & Week 52



All Week 48 mean changes were significant vs. baseline ($P<0.05$), except in the following subgroups: no antipsychotics (40 mg).
AIMS, Abnormal Involuntary Movement Scale; AC, anticholinergic; AD, antidepressant; ANX, anxiolytic; AP, antipsychotic; Benzo, benzodiazepine; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

Comella C, et al. AAN 2019; Philadelphia, PA.

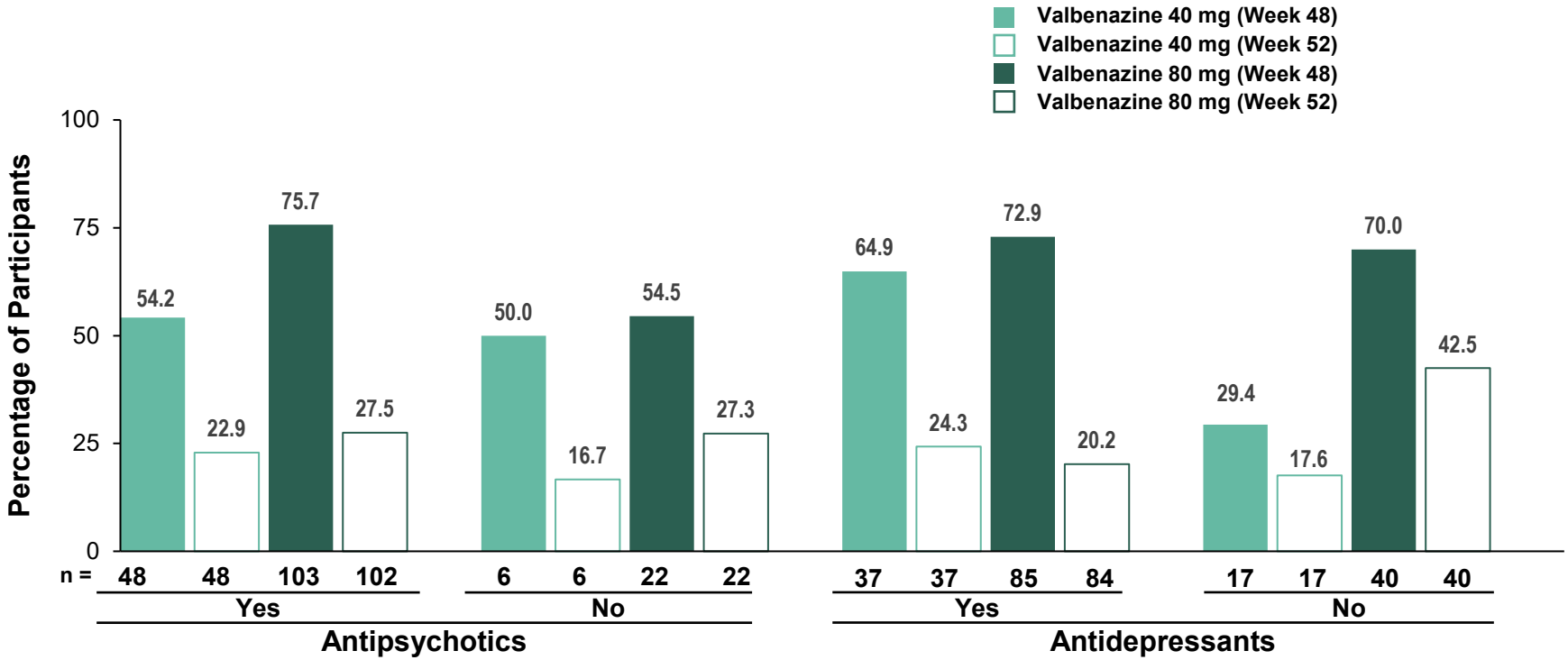
KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: AIMS Mean Changes from Baseline to Week 48 & Week 52



All Week 48 mean changes were significant vs. baseline ($P<0.05$), except in the following subgroups: no antipsychotics (40 mg). AD+AP includes participants who received an atypical antipsychotic or both (atypical + typical)
AIMS, Abnormal Involuntary Movement Scale; AC, anticholinergic; AD, antidepressant; ANX, anxiolytic; AP, antipsychotic; Benzo, benzodiazepine; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

Comella C, et al. AAN 2019; Philadelphia, PA.

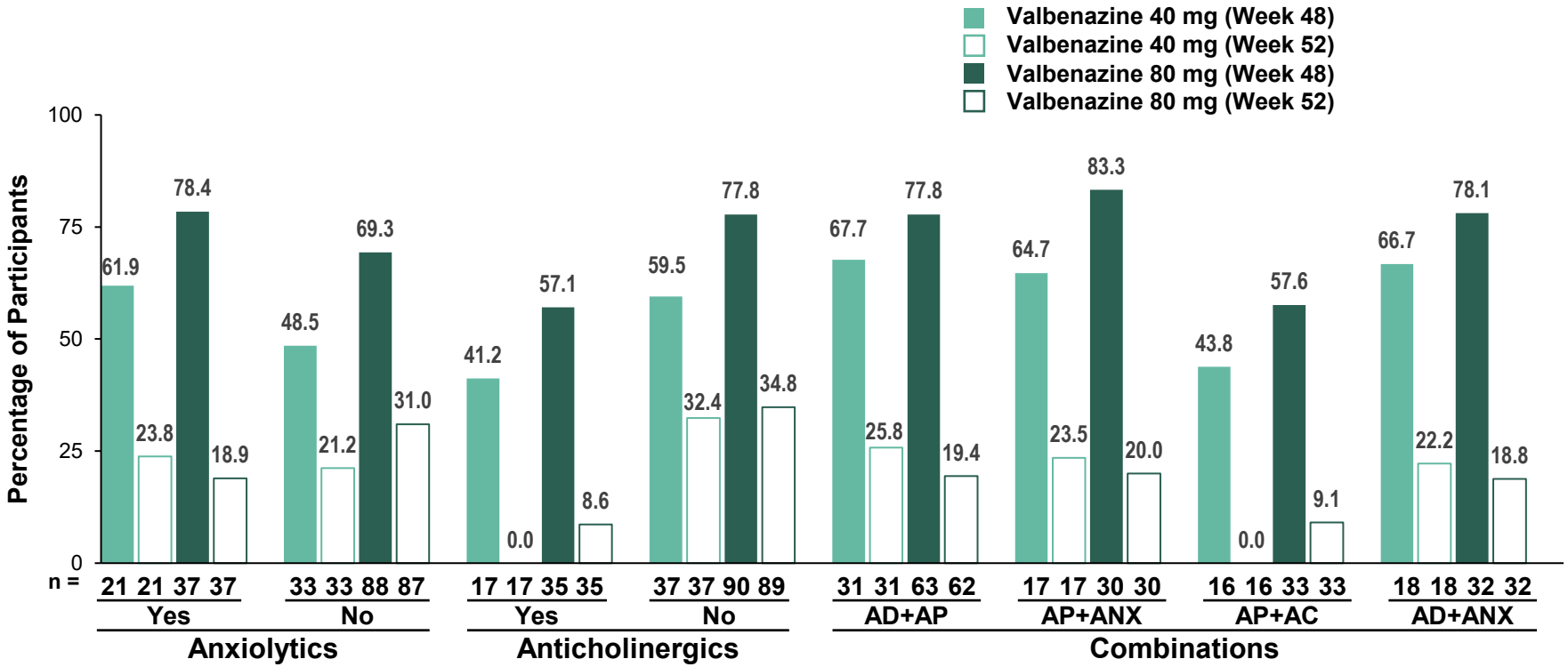
KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: ≥50% AIMS Improvement from Baseline at Week 48 & Week 52



AIMS, Abnormal Involuntary Movement Scale

Comella C, et al. AAN 2019; Philadelphia, PA.

KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: ≥50% AIMS Improvement from Baseline at Week 48 & Week 52



AIMS, Abnormal Involuntary Movement Scale; AC, anticholinergic; AD, antidepressant; ANX, anxiolytic; AP, antipsychotic.

Comella C, et al. AAN 2019; Philadelphia, PA.

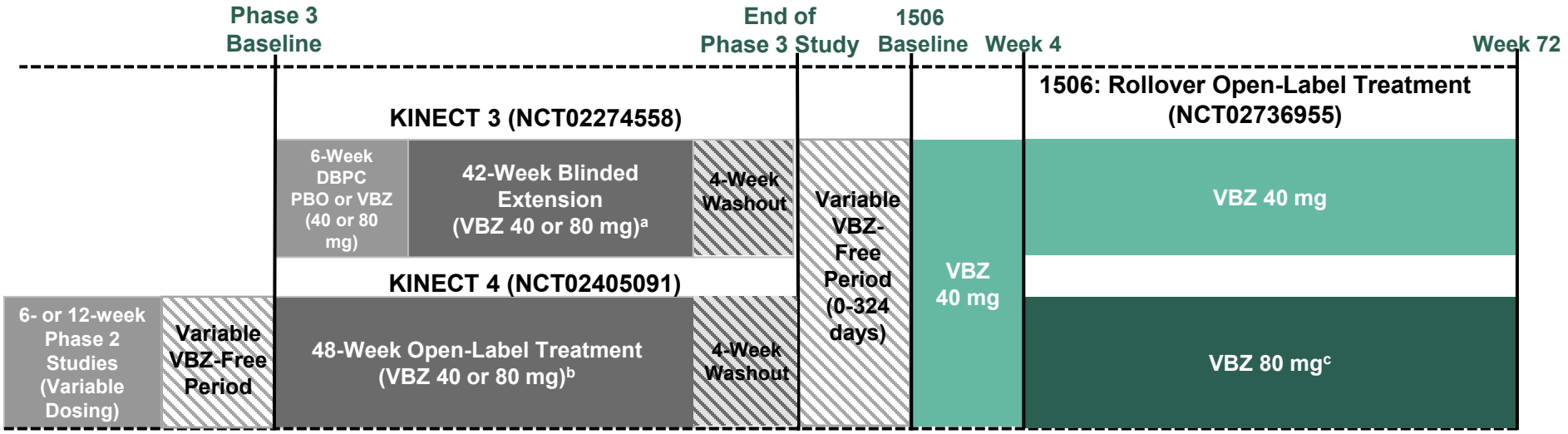
KINECT 3 & KINECT 4 – Concomitant Medication Subgroup Analysis: Summary

- Results from two long-term valbenazine trials indicate sustained TD improvements at Week 48 as indicated by mean AIMS change from baseline in patients taking concomitant antipsychotics, antidepressants, anxiolytics, and/or anticholinergics[1]
  - Antipsychotics: -5.4 (VBZ 40 mg) and -8.6 (VBZ 80 mg)
  - Antidepressants: -6.8 (VBZ 40 mg) and -8.9 (VBZ 80 mg)
  - Anxiolytics: -7.0 (VBZ 40 mg) and -9.2 (VBZ 80 mg)
  - Anticholinergics: -2.9 (VBZ 40 mg) and -7.7 (VBZ 80 mg)
- At Week 52 (after 4-week washout), mean AIMS scores generally reverted towards baseline levels and AIMS response decreased in all subgroups[1]
- The most commonly reported TEAEs (≥ 8%) in all participants taking VBZ (n= 304) were headache (8.9%) and urinary tract infection (8.9%)[2]

1. Comella C, et al. AAN 2019; Philadelphia, PA. 2. Marder SR, et al. US Psych Congress 2018; Orlando, FL.

1506 : Rollover Phase 3b Study – Concomitant Medication Subgroup Analysis

1506: Study Design



[a]All KINECT 3 participants randomized to valbenazine in the DBPC period or re-randomized from placebo to valbenazine in the extension period were initiated at 40 mg for 1 week. [b]All KINECT 4 participants were initiated at 40 mg for 4 weeks; [c]Included participants who had a dose reduction to 40 mg due to tolerability issues; DBPC, double-blind placebo-controlled; PBO, placebo; VBZ, valbenazine.

- The open-label rollover study included patients who completed KINECT 3 or KINECT 4 (48 weeks of valbenazine treatment and 4 weeks of valbenazine-free washout)
  - KINECT 4 included ~50 participants from an earlier phase 2 study
  - All participants restarted once-daily valbenazine at 40 mg for 4 weeks
  - Dosage was escalated to 80 mg at the end of Week 4 based on clinician judgment of safety/tolerability and TD improvement; those not escalated remained on 40 mg
  - One dose reduction to 40 mg was allowed after Week 4 if 80 mg was not tolerated
  - Participants unable to tolerate 40 mg were discontinued from the study
- Participants received treatment for up to 72 weeks or until valbenazine became commercially available
- Stable doses of concomitant medications to treat psychiatric disorders and comorbid medical conditions were allowed

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506: Key Inclusion/Exclusion Criteria

- Key inclusion criteria:
  - Adults with neuroleptic-induced TD and a *Diagnostic and Statistical Manual of Mental Disorders* (e.g., DSM-IV) psychiatric diagnosis (i.e., schizophrenia, schizoaffective disorder, or mood disorder) who completed KINECT 3 or KINECT 4
  - Psychiatrically stable prior to study entry (Brief Psychiatric Rating Scale score <50 at screening)
- Key exclusion criteria:
  - Active, clinically significant, and unstable medical condition
  - Clinically significant parkinsonism per investigator judgment
  - Significant risk for active suicidal ideation or suicidal behavior (Columbia-Suicide Severity Rating Scale [C-SSRS]) or violent behavior

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: Assessments

- Data from the rollover study (1506) were analyzed post hoc to provide clinical insights into the effect of valbenazine in conjunction with common psychoactive medications
- Clinical Global Impression of Severity-Tardive Dyskinesia (CGIS-TD) data were analyzed descriptively in participants who received ≥1 dose of valbenazine and had available data
- Analyses included:
  - Mean change from baseline in CGIS-TD
    - Range, 1 “normal, not at all ill” to 7 “extremely ill”
  - Percentages of participants with a CGIS-TD score ≤2 (“normal, not at all ill” or “borderline ill”)

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: Assessments

- Concomitant medication subgroups were defined by use at baseline as follows:
  - Antipsychotic use (yes, no)
  - Antidepressant use (yes, no)
  - Anxiolytic use (yes, no)
  - Anticholinergic use (yes, no)
  - Combinations:
    - Antidepressant + Atypical Antipsychotics
    - Antipsychotic + Anxiolytic
    - Antipsychotic + Anticholinergic
    - Antidepressant + Anxiolytic
  - Subgroup categories were not mutually exclusive and only reflected concomitant medication use in the rollover study
  - Concomitant medication use in the prior studies were not considered, nor was the mean daily antipsychotic dose of the subgroups

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: Assessments

- Of the 224 participants who completed KINECT 3 or KINECT 4, 161 (71.9%) enrolled in the rollover study
  - 71 from KINECT 3; 90 from KINECT 4
  - 1 participant without post-baseline data was excluded
    - 138 (85.7%) were ongoing in the study when it was terminated
    - Few reached Week 60 (n=4) and none reached Week 72 because valbenazine became commercially available before reaching those visits
    - Reasons for discontinuation prior to study termination were withdrawal of consent (n=8), adverse events (n=5), death (n=4, not related to treatment),non-compliance (n=3), investigator decision (n=2), and lost to follow-up (n=1)
- In all 160 participants who received ≥1 dose of study drug, 82.5% were taking an antipsychotic medication at baseline or during the study
- Concomitant use of antidepressants, anxiolytics, and anticholinergics were reported in 69.4%, 36.3%, and 27.5% of participants, respectively

Farahmand K, et al. ACNP 2019; Orlando, FL.

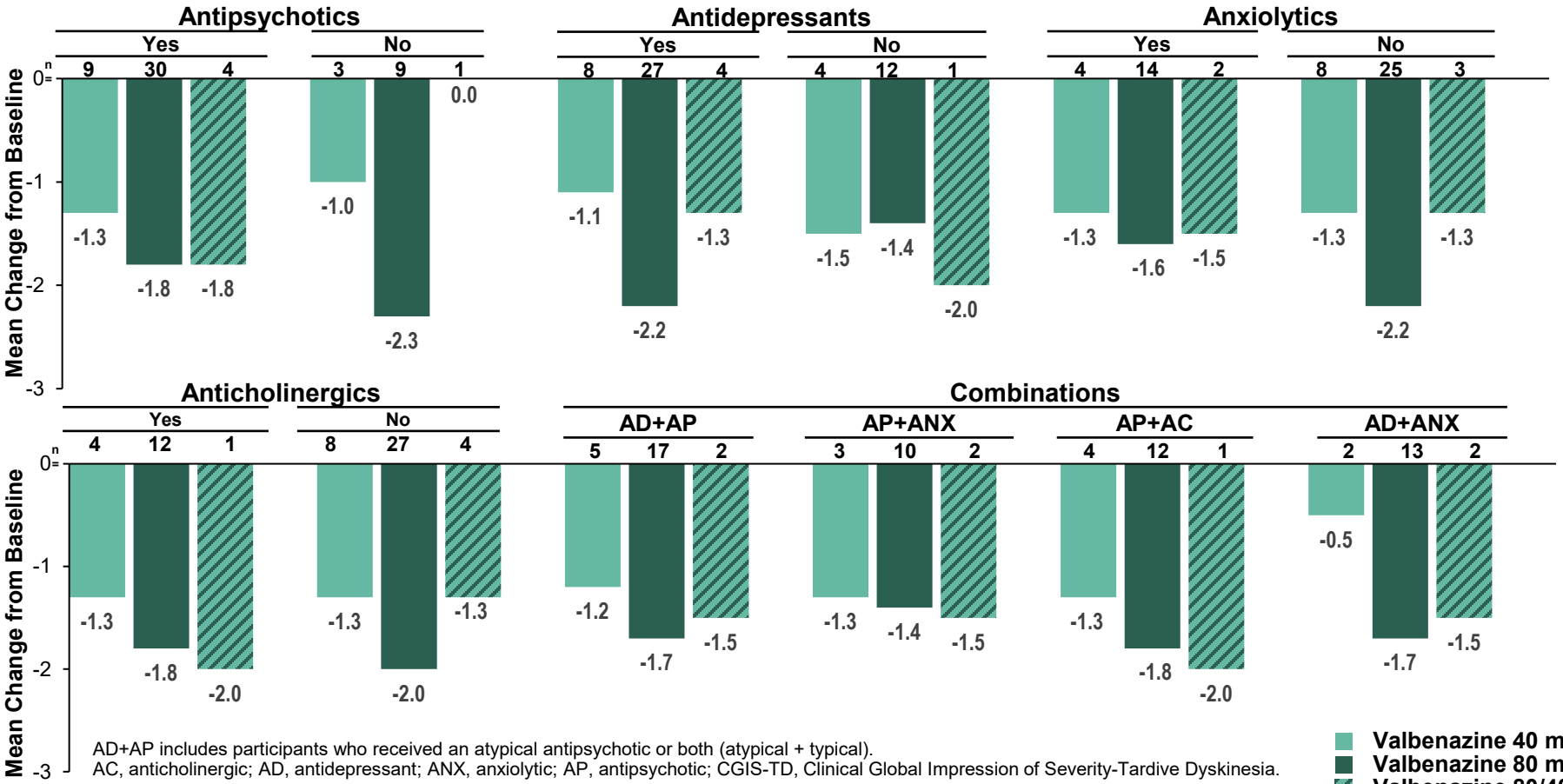
1506 – Concomitant Medication Subgroup Analysis: Concomitant Medication Use[a]

	Valbenazine 40 mg (n=35)	Valbenazine 80 mg (n=117)	Valbenazine 80/40 mg (n=8)
Any antipsychotic, n (%)[b]	28 (80.0)	97 (82.9)	7 (87.5)
Quetiapine	6 (17.1)	30 (25.6)	0
Haloperidol	2 (5.7)	7 (6.0)	2 (25.0)
Olanzapine	5 (14.3)	14 (12.0)	2 (25.0)
Aripiprazole	3 (8.6)	23 (19.7)	1 (12.5)
Risperidone	7 (20.0)	13 (11.1)	1 (12.5)
Ziprasidone	3 (8.6)	7 (6.0)	1 (12.5)
Lithium	1 (2.9)	7 (6.0)	1 (12.5)
Any antidepressants, n (%)[b]	22 (62.9)	85 (72.6)	4 (50.0)
Trazodone	7 (20.0)	24 (20.5)	2 (25.0)
Fluoxetine	2 (5.7)	9 (7.7)	2 (25.0)
Bupropion	3 (8.6)	13 (11.1)	0
Sertraline	7 (20.0)	13 (11.1)	0
Mirtazapine	2 (5.7)	17 (14.5)	0
Citalopram	3 (8.6)	8 (6.8)	1 (12.5)
Duloxetine	1 (2.9)	10 (8.5)	0
Escitalopram	1 (2.9)	8 (6.8)	0
Venlafaxine	2 (5.7)	7 (6.0)	0
Any anxiolytic, n (%)[b]	11 (31.4)	45 (38.5)	2 (25.0)
Alprazolam	3 (8.6)	15 (12.8)	0
Hydroxyzine	1 (2.9)	15 (12.8)	1 (12.5)
Lorazepam	4 (11.4)	10 (8.5)	1 (12.5)
Buspirone	3 (8.6)	11 (9.4)	1 (12.5)
Any anticholinergic, n (%)[b]	13 (37.1)	29 (24.8)	2 (25.0)
Benztropine	11 (31.4)	26 (22.2)	2 (25.0)

[a]At baseline or at any time during the study; [b]Reported in ≥5% of participants.

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: CGIS-TD Mean Change from Baseline at Week 48

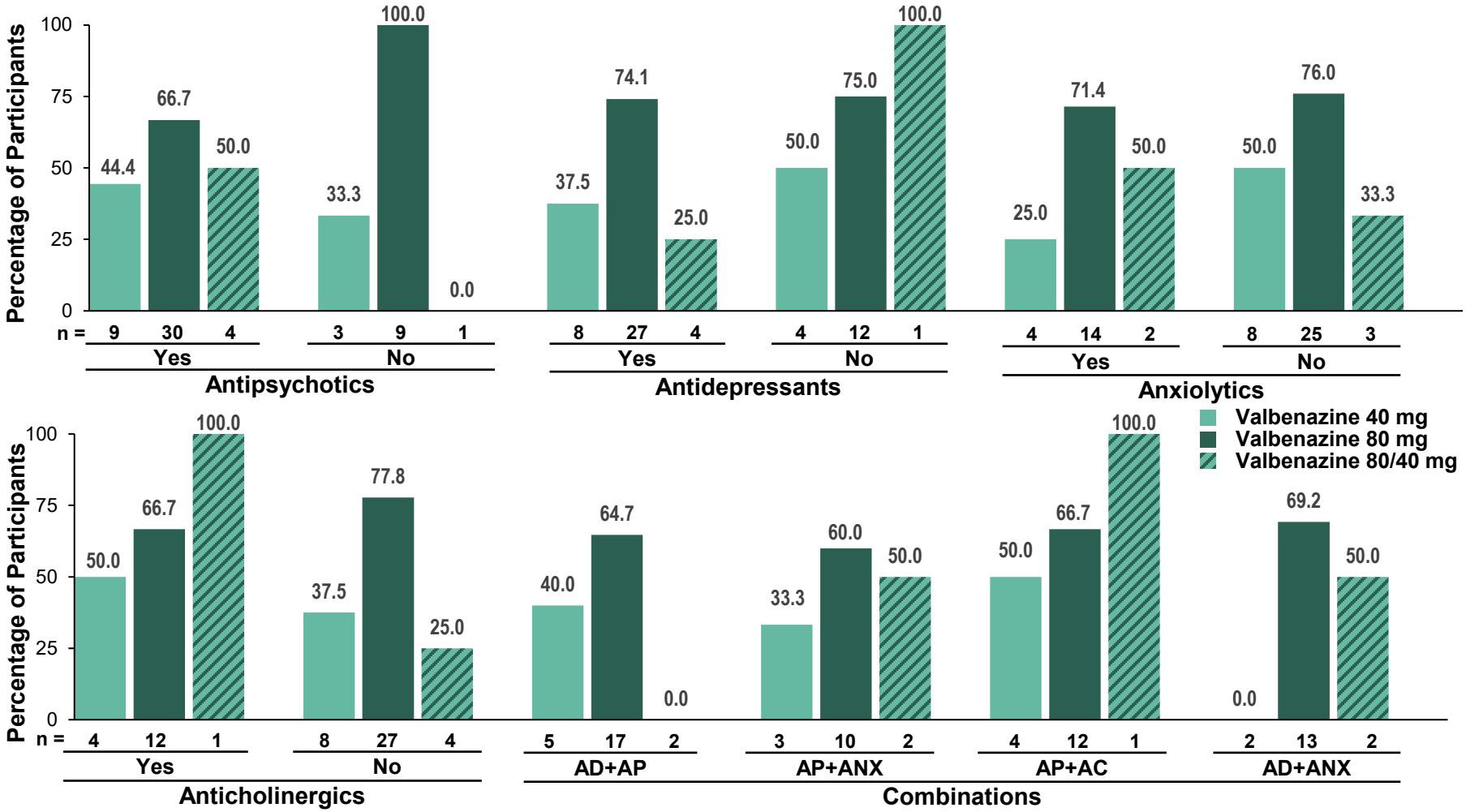


AD+AP includes participants who received an atypical antipsychotic or both (atypical + typical).
AC, anticholinergic; AD, antidepressant; ANX, anxiolytic; AP, antipsychotic; CGIS-TD, Clinical Global Impression of Severity-Tardive Dyskinesia.

- At Week 48 in the overall population (n=56), the mean change from baseline in CGIS-TD score was -1.8 for all doses combined; comparable mean improvements were found in all concomitant medication subgroups

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: Percentage of Participants with CGI-TD Score ≤2* at Week 48



*CGIS-TD score ≤2 ("normal, not at all ill" or "borderline ill"); AD+AP includes participants who received an atypical antipsychotic or both (atypical + typical); AC, anticholinergic; AD, antidepressant; ANX, anxiolytic; AP, antipsychotic; CGIS-TD, Clinical Global Impression of Severity-Tardive Dyskinesia.

Farahmand K, et al. ACNP 2019; Orlando, FL.

1506 – Concomitant Medication Subgroup Analysis: Summary

- In all 160 participants who received ≥1 dose of study drug, 82.5% were taking an antipsychotic medication at baseline or during the study[1]
  - Concomitant use of other medications:
    - Antidepressants (69.4%), anxiolytics (36.3%) and anticholinergics (27.5%)
- Week 48 in the overall population (n=56), the mean change from baseline in CGIS-TD score was -1.8 for all doses combined[1]
  - Comparable mean improvements were found in all concomitant medication subgroups
- 64.3% of all participants had a CGIS-TD score ≤2[1]
  - Similar results were found in almost all concomitant medication subgroups
- Treatment-emergent adverse events occurring in ≥4% of all valbenazine treated participants in the rollover study were urinary tract infection (4.5%) and upper respiratory tract infection (4.5%)[2]

1. Farahmand K, et al. ACNP 2019; Orlando, FL; 2. Lindenmayer JP, et al. ASCP 2018; Miami, FL.