Supplementary Online Content

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eFigure. Study Design

eTable. Results of Repeated Measures Mixed Model (MMRM) and Seemingly Unrelated Regression (SUR) Sensitivity Analyses of the Primary Endpoint, Modified Intention-to-Treat Population

This supplementary material has been provided by the authors to give readers additional information about their work.

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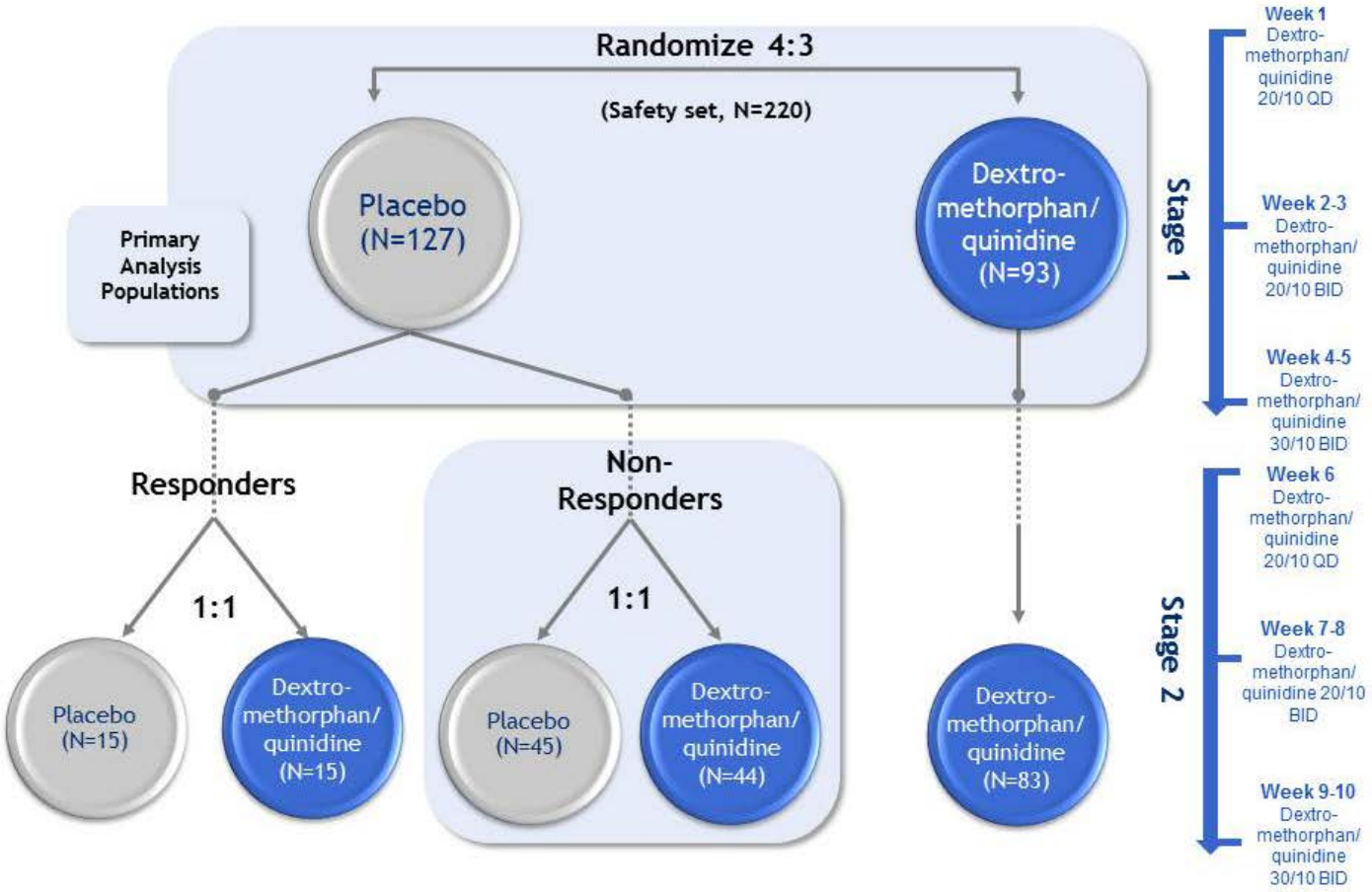
eFigure. Study Design



Shading shows the patient groups included in the primary SPCD analysis (all patients randomized in Stage 1 (mITT population) and placebo nonresponders from Stage 1 that were rerandomized in Stage 2, mITT population stage 2). A “response” in Stage 1 was defined as a CGIS score of 1-3 (inclusive) at Visit 4 (week 5/end of Stage 1) and an NPI Agitation/Aggression domain score decrease of ≥ 25%; patients not meeting these criteria were considered “nonresponders”. BID = twice per day; QD = once daily.

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eTable. Results of Repeated Measures Mixed Model (MMRM) and Seemingly Unrelated Regression (SUR) Sensitivity Analyses of the Primary Endpoint, Modified Intention-to-Treat Population

	Stage	N Dextromethorphan/ quinidine	N Placebo	Dextromethorphan/ quinidine, Mean (SD) Change from Baseline	Placebo, Mean (SD) Change from Baseline	Estimated Treatment Effect (95% CI)	Test Statistic[b]	*P* Value
MMRM Analysis								
NPI–Agitation/ Aggression[a]	1	93	125			-0.74 (-1.17, -0.31)	-3.30	.001
	Wk 1			-2.2 (2.9)	-1.4 (2.7)			
	Wk 3			-2.7 (3.2)	-1.6 (2.9)			
	Wk 5			-3.3 (3.0)	-1.7 (3.1)			
	2	142	60					
	Wk 6			-0.2 (2.8)	-0.9 (2.8)			
	Wk 8			-0.6 (3.1)	-0.7 (2.9)			
	Wk 10			-0.9 (3.4)	-0.5 (3.4)			
SUR Analysis								
NPI–Agitation/ Aggression[a]	1	93	125	-3.3 (3.0)	-1.7 (3.1)		15.5	<0.0001
	2	44	45	-2.0 (3.2)	-0.8 (3.6)			

[a]Assessed at baseline, weeks 1, 3, 5, 6, 8, and 10.

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