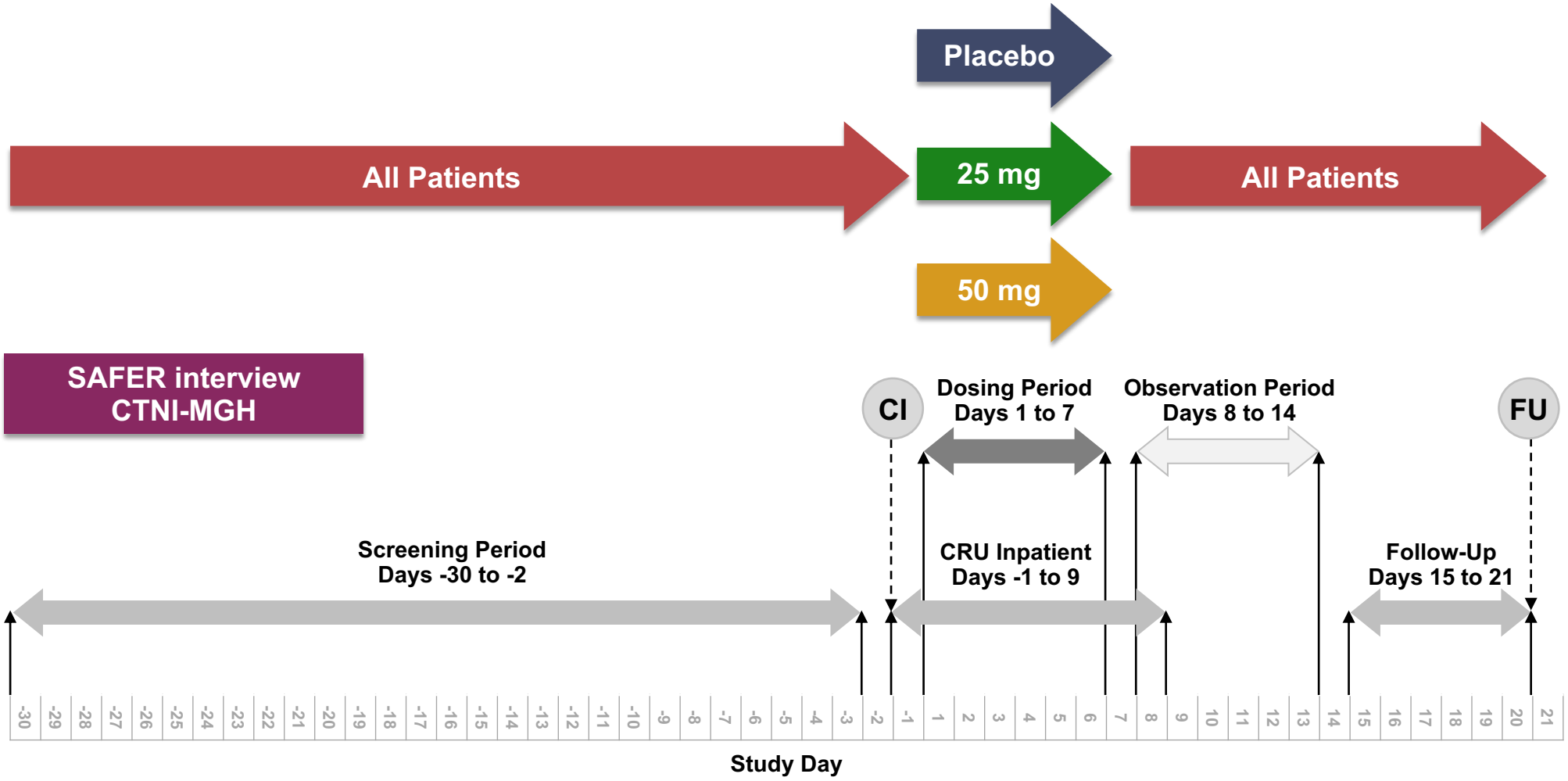
Relmada THERAPEUTICS

REL-1017-202 Phase 2 Study Top Line Results

Conference Call 15 October 2019

REL-1017-202: A Phase 2 Study of REL-1017 at Two Doses in Subjects with Treatment Resistant Depression



CI=Check-In; CRU=Clinical Research Unit; FU=Follow-Up

Study REL-1017-202 Was Designed to Provide Data on Safety, PK and Efficacy of REL-1017 in Treatment Resistant Depression

Primary Objectives

Safety and tolerability of 25 mg and 50 mg of REL-1017 vs Placebo as adjunctive treatment

Primary Endpoints

PE, Laboratory studies, ECG, AEs

CADSS (dissociative symptoms)

4-item PSRS (psychotomimetic symptoms)

COWS (opiate withdrawal symptoms)

C-SSRS (suicidality)

Secondary Objectives

To characterize pharmacokinetic (PK) profile of REL-1017 25 mg and 50 mg x 7 days

To explore the efficacy of 25 mg and 50 mg of REL-1017 as adjunctive treatment in patients with TRD [Note: Maged, original says TRD]

Secondary Endpoints

PK parameters for both 25 and 50 mg qday

Change from BSL at Day 2, 4, 7 and 14 on:

- MADRS
- SDQ
- CGI-S

Difference in CGI-I score placebo vs treatment groups Day 2 to 14

PE=Physical exam; ECG=Electrocardiogram; AEs=Adverse Events; CADSS=Clinician Administered Dissociative States Scale; PSRS=Positive Symptom Rating Scale; COWS=Clinical Opiate Withdrawal Scale; C-SSRS=Columbia Suicide Severity Rating Scale; MADRS=Montgomery Asberg Depression Rating Scale; SDQ=Symptoms of Depression Questionnaire; CGI-S and CGI-I=Clinical Global Impression Severity and Improvement

Subjects' Disposition, Demographic Characteristics and Depression Severity Were Homogeneously Distributed Across Arms

	Placebo	REL-1017 25 mg	REL-1017 50 mg	All Subjects
Randomized Subjects	22	19	21	62
Completed All Visits (Day 21)	20	18	19	57
Received All Doses	21	19	21	61
Age: Mean Years (SD)	49.7 (11.1)	49.4 (12.4)	48.6 (10.9)	49.2 (11.3)
Females	11 (50%)	8 (42.1%)	9 (42.9%)	28 (45.2%)
Subjects ITT	22	19	21	62
Subjects PPP	21	19	21	61
Screening HAMD – Mean (SD)	25.6 (3.5)	25.1 (3.5)	25.0 (3.8)	25.3 (3.6)
Baseline MADRS – Mean (SD)	33.8 (4.0)	32.9 (6.0)	35.2 (3.9)	34.0 (4.7)

ITT=Intent-To-Treat; PPP=Per-Protocol-Population; HAMD=Hamilton Depression Rating Scale; MADRS=Montgomery-Asberg Depression Rating Scale

Study REL-1017-202 Key Safety Findings

REL-1017-202 results confirm the favorable tolerability and safety profile observed in the Phase 1 SAD and MAD studies

- Only Mild and Moderate AEs – no SAEs
- No increased prevalence of specifically relevant organ group AEs in treatment groups vs placebo
- No evidence of treatment induced dissociative symptoms in the treatment groups vs placebo
- No evidence of treatment induced psychotomimetic symptoms in treatment groups vs placebo
- No evidence of opiate withdrawal symptoms in treatment groups vs placebo

AE=adverse event; SAE=serious adverse event
Source: Relmada Phase 2 Top Line Data Presentation at Relmada.com

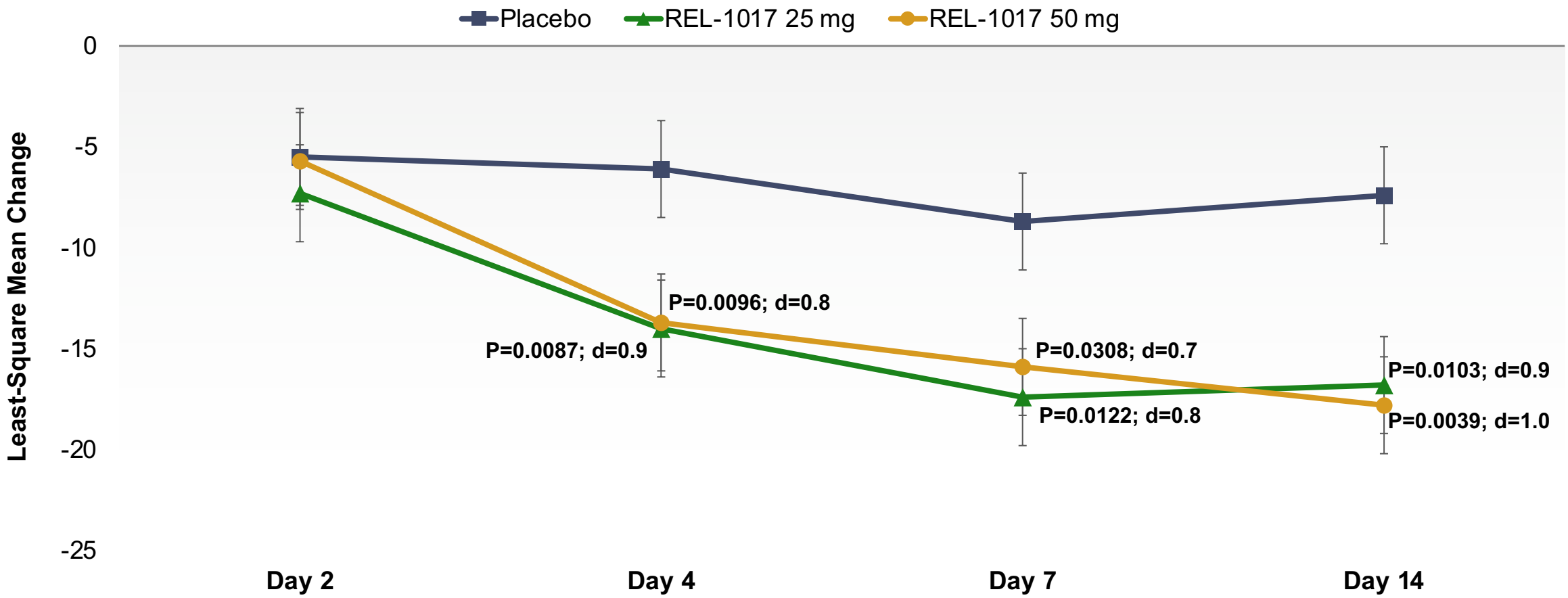
Study REL-1017 Key Efficacy Findings

REL-1017 25 mg and 50 mg show rapid onset and sustained antidepressant efficacy with statistically significant differences compared to placebo on all efficacy measures

- Solid efficacy results on MADRS with P values <0.03 and large effect sizes (0.7-1.0) from Day 4 to Day 14
- CGI-S and CGI-I solid findings consistent with MADRS results with P values and effect sizes of similar magnitude
- SDQ scores with moderate effect size differences (d=0.4 and 0.5) from Day 4 to Day 7 and with both statistically significant differences and large effect size for both 25 mg (P=0.0066; d=0.9) and 50 mg (P=0.0014; d=1.1) arms at Day 14
- Study demonstrates rapid onset and long-lasting antidepressant efficacy
- Findings support continuing clinical development and larger pivotal study

MADRS Scores in the Treatment Groups Achieved Statistically Significant Difference vs Placebo from Day 4 through Day 14

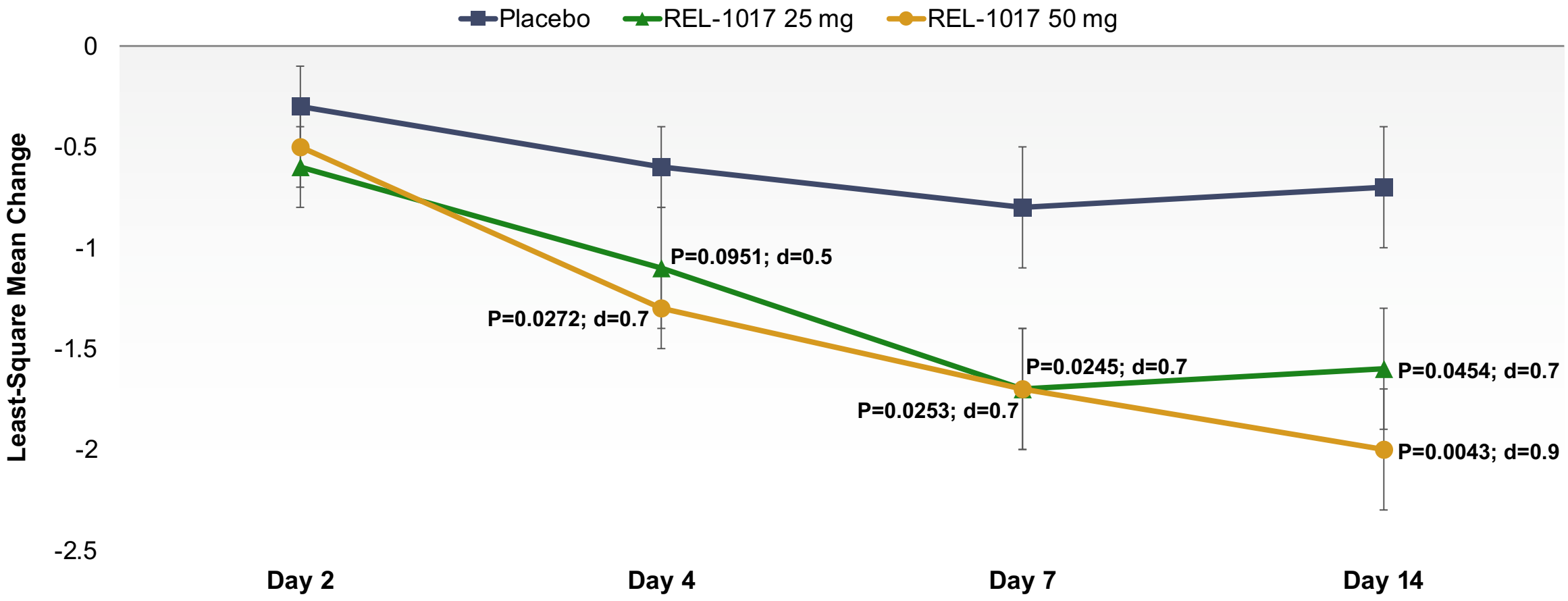
MADRS Change from Baseline – ITT Population



MADRS=Montgomery-Asberg Depression Rating Scale; ITT=Intent-To-Treat; Error Bars=Standard Errors; P and d values as Treatment vs Placebo

CGI-S Scores Achieved Statistically Significant Difference vs Placebo from Day 4 for REL-1017 50 mg and for both Doses on Day 7 and Day 14

CGI-S Change from Baseline – ITT Population



CGI-S=Clinical Global Impression of Severity; ITT=Intent-To-Treat; Error Bars=Standard Errors; P and d values as Treatment vs Placebo