

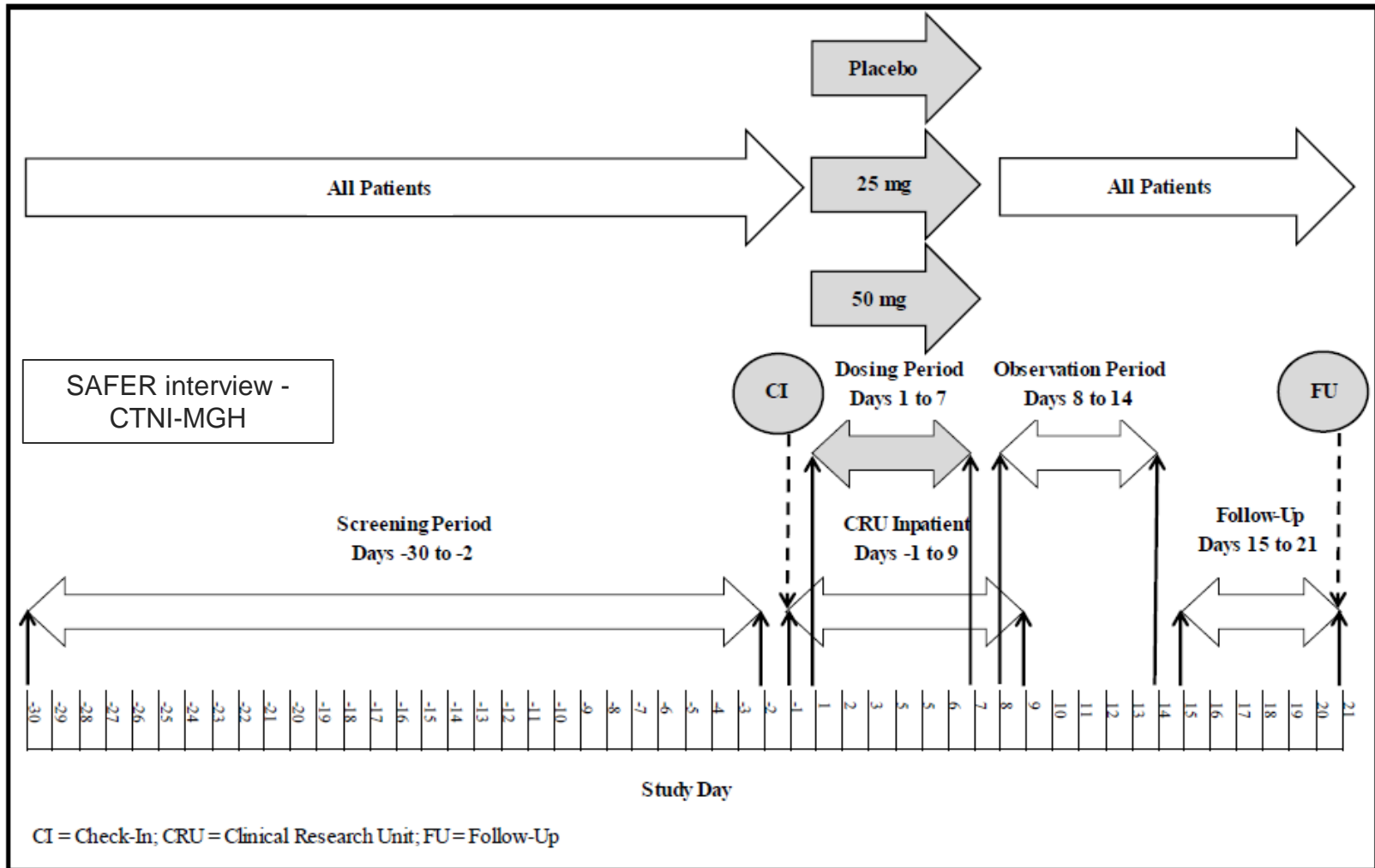


RELMADA
THERAPEUTICS

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



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

Primary Objectives	Primary Endpoints
<p>Safety and tolerability of 25 mg and 50 mg of REL-1017 vs Placebo as adjunctive treatment</p>	<p>PE, Laboratory studies, ECG, AEs CADSS (dissociative symptoms) 4-item PSRS (psychotomimetic symptoms) COWS (opiate withdrawal symptoms) C-SSRS (suicidality)</p>
Secondary Objectives	Secondary Endpoints
<p>To characterize pharmacokinetic (PK) profile of REL-1017 25 mg and 50 mg x 7 days</p> <p>To explore the efficacy of 25 mg and 50 mg of REL-1017 as adjunctive treatment in patients with TRD</p>	<p>PK parameters for both 25 and 50 mg qday</p> <p>Change from BSL at Day 2, 4, 7 and 14 on:</p> <ul style="list-style-type: none"> • MADRS • SDQ • CGI-S <p>Difference in CGI-I score placebo vs treatment groups Day 2 to 14</p>

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

Study REL-1017-202 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

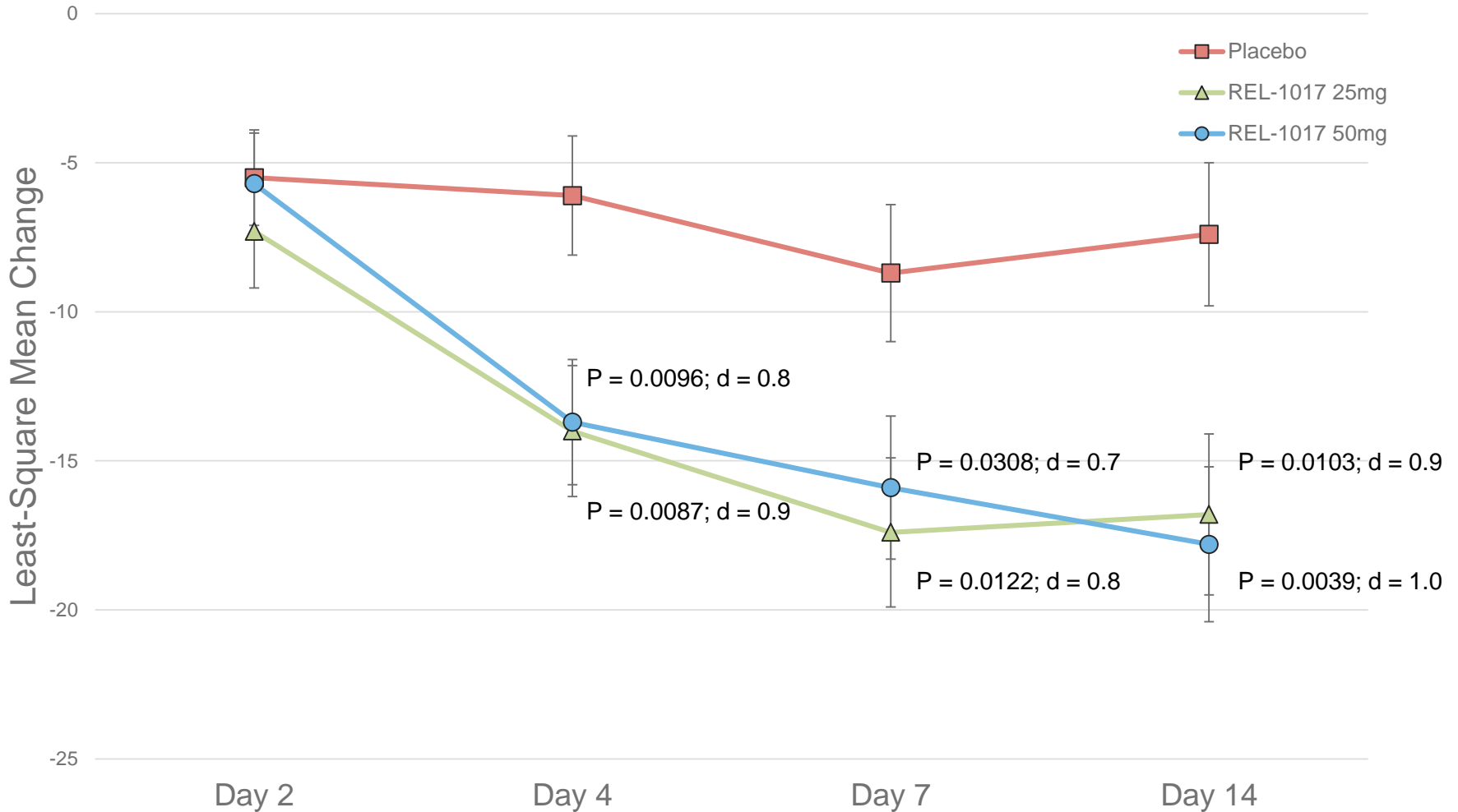
SDQ scores with moderate effect size differences (d=0.4 and 0.5) from Day 4 to Day 7 and with both statistically significant differences and large effect size for both 25 mg (P = 0.0066; d = 0.9) and 50 mg (P= 0.0014; d = 1.1) arms at Day 14

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



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

