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ROLUPERIDONE:
Topline results from the Phase 3 trial: A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Monotherapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of MIN-101 in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 40-Week Open-Label Extension

May 29th, 2020

Nasdaq : NERV

Forward-Looking Statement Safe-Harbor

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this press release, and involve certain risks and uncertainties. Forward-looking statements include statements herein with respect to the timing and scope of future clinical trials and results of clinical trials with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize our therapeutic products; the sufficiency of our current cash position to fund our operations; and management's ability to successfully achieve its goals. These forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether roluperidone will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether any of our therapeutic products will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations on terms acceptable to us; and general economic conditions. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the Securities and Exchange Commission on May 4, 2020. Copies of reports filed with the SEC are posted on our website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.

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MIN-101C07: Phase 3

A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Monotherapy, 12-Week Study to Evaluate the Efficacy and Safety of 2 Fixed Doses of MIN-101 in Adult Patients with Negative Symptoms of Schizophrenia, Followed by 40-Week Open-Label Extension

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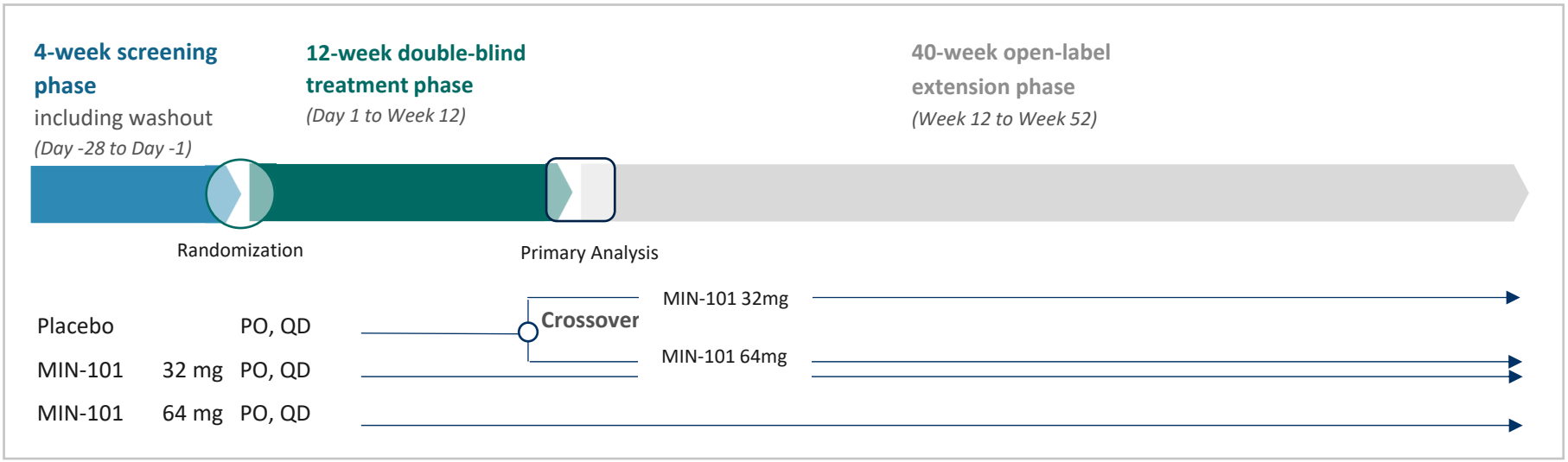
Phase 3: Study Design Schema and Key Study Elements



Primary Endpoint	Change from Baseline to Week 12 in the Positive and Negative Syndrome Scale (PANSS) Negative Symptoms Factor Score (NSFS; Marder score)
Key secondary Endpoint	Change from Baseline to Week 12 in the Personal and Social Performance scale total score (PSP)
Other Endpoints	Change from Baseline to Week 12 in: • Clinical Global Impression of Severity (CGI-S) • Clinical Global Impression of Improvement (CGI-I) • PANSS Total Scores, sub-scores, and Marder's Factor Scores • Cognition • Safety & Tolerability
Number of patients	501 patients randomized 1:1:1 (167 in each arm)
Sample Size Assumptions	Delta versus placebo of 3 points, SD = 6.5, 90% power, and 40% drop-out rate

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Phase 3 : Patient Population, Procedures & Statistical Method

- DSM-5 schizophrenia for at least 1 year
- Baseline score > 20 on the 7 items PANSS negative score
- 18 to 55 years of age
- Outpatient, symptomatically stable and manifesting negative symptoms for 6 months
- Withdrawn from depot antipsychotics for ≥ 1 month and from all psychotropics for ≥ 3 days prior to randomization
- No psychotropic medications except rescue medications given for insomnia or agitation (oral lorazepam, zolpidem, or injectable sodium amytal)
- Assessments for efficacy at Baseline and at Weeks 2, 4, 8 and 12 or upon early discontinuation
- Extensive metabolizers for P450 CYP2D6, as determined by genotyping
- Primary analysis on Intent-To-Treat (ITT) population
- Primary analysis using Mixed Model Repeated Measures (MMRM)
- Truncated Hochberg procedure used to correct for multiplicity for primary and key secondary endpoints

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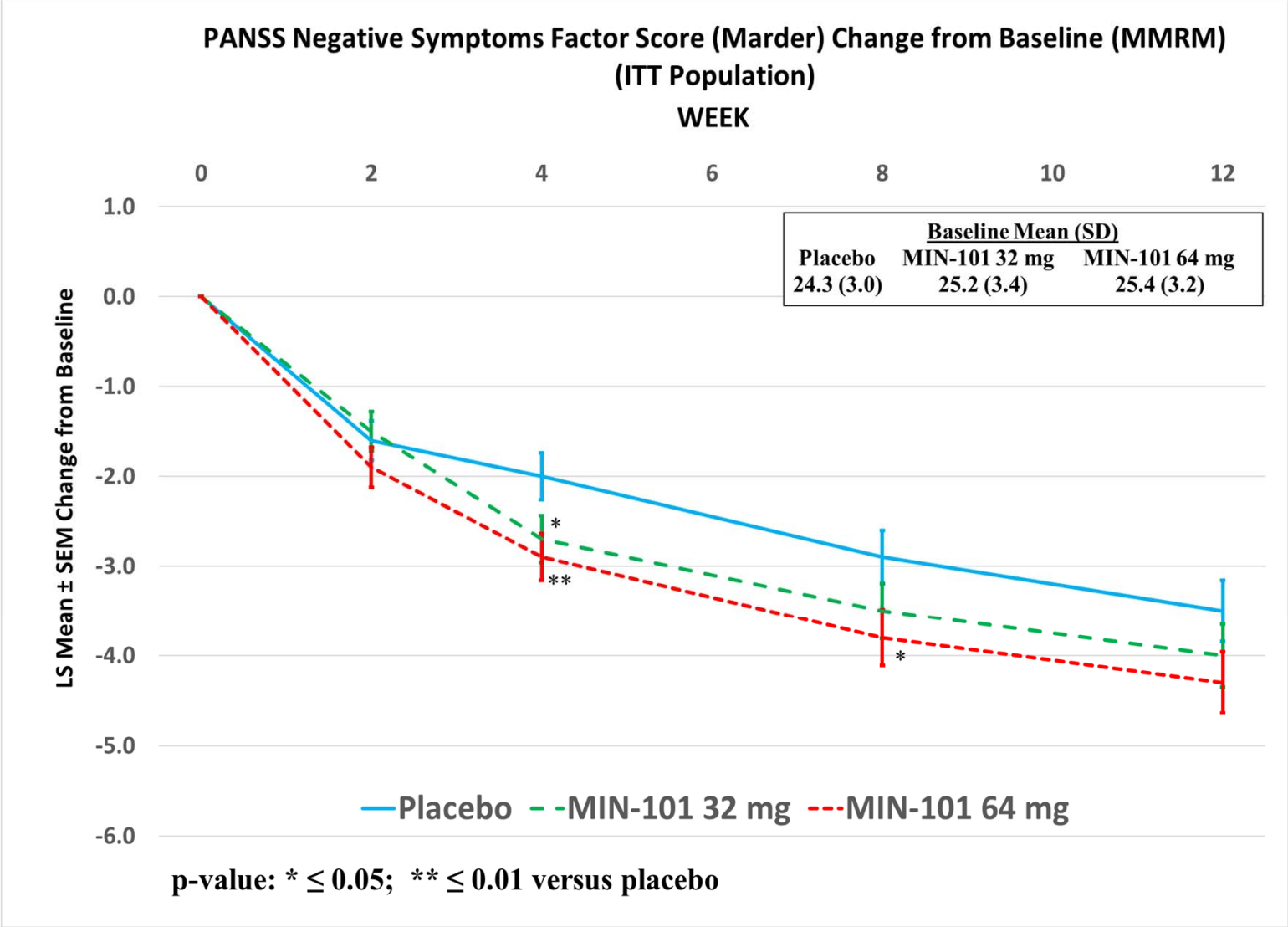
Phase 3 : Efficacy - Primary Endpoint - Marder Negative Symptoms Factor Score (NSFS)



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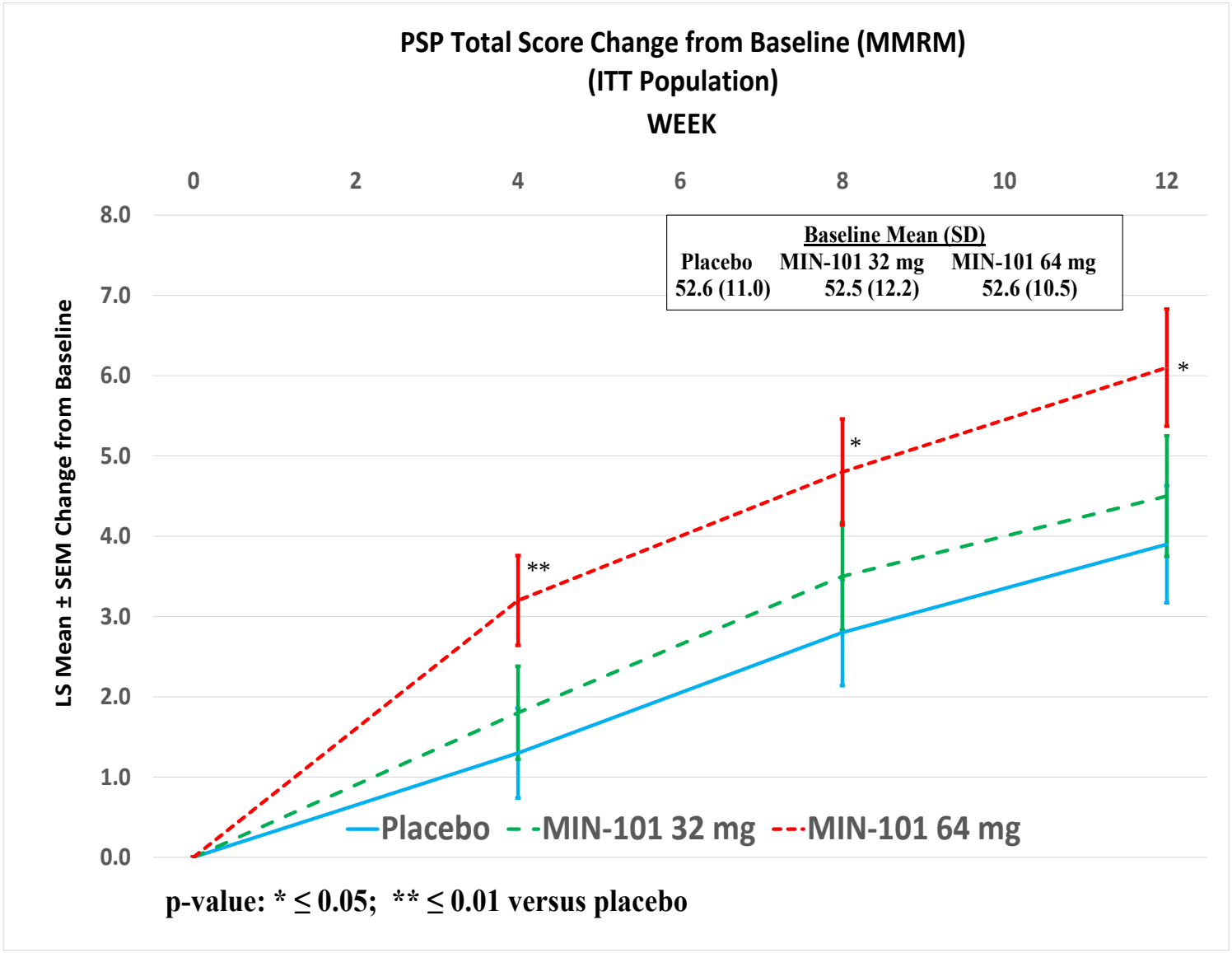
Phase 3 : Efficacy - Key Secondary Endpoint - Personal and Social Performance (PSP) Total Score



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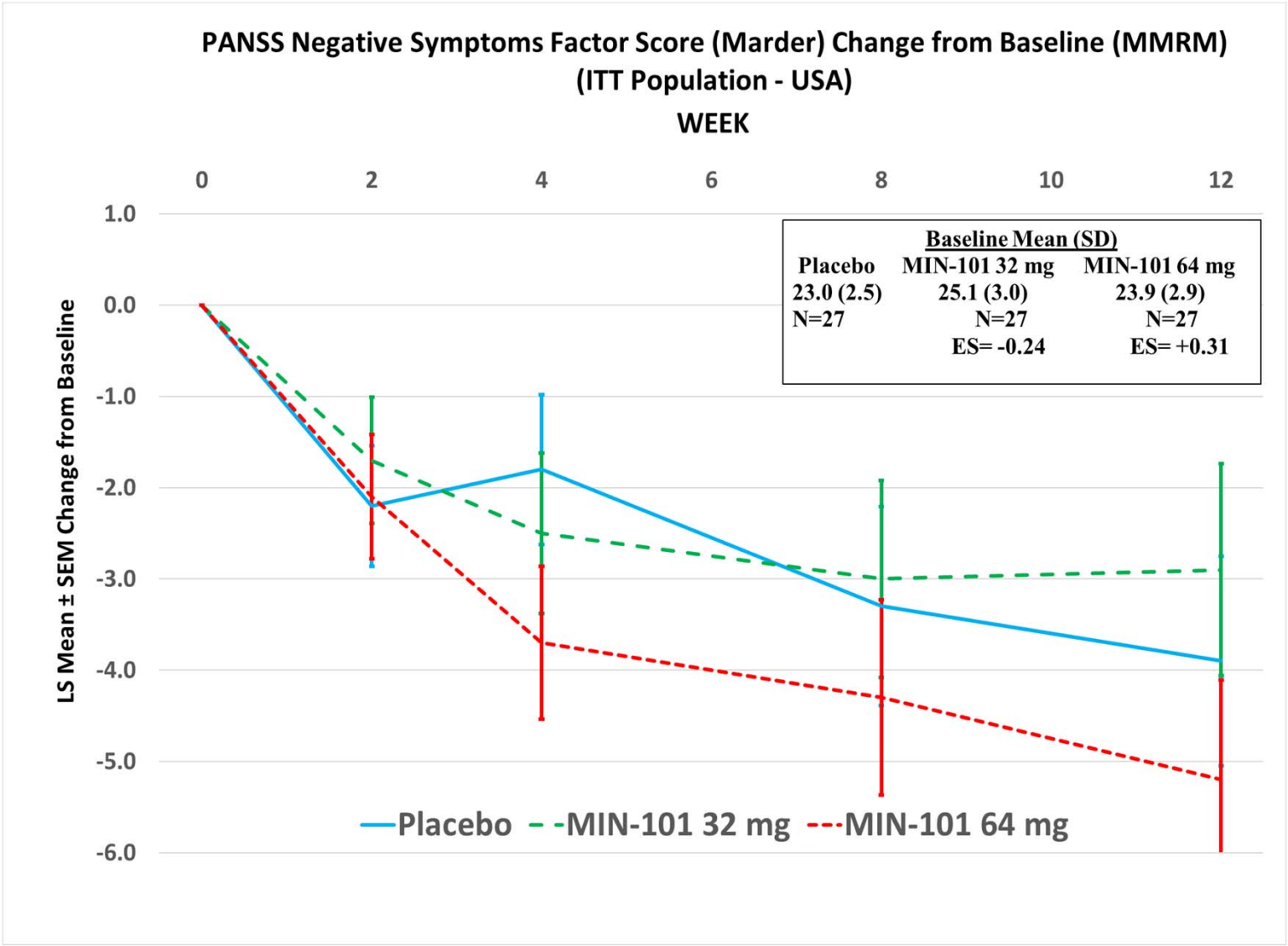
Phase 3 : Efficacy - Marder Negative Symptoms Factor Score (NSFS) – US Sites



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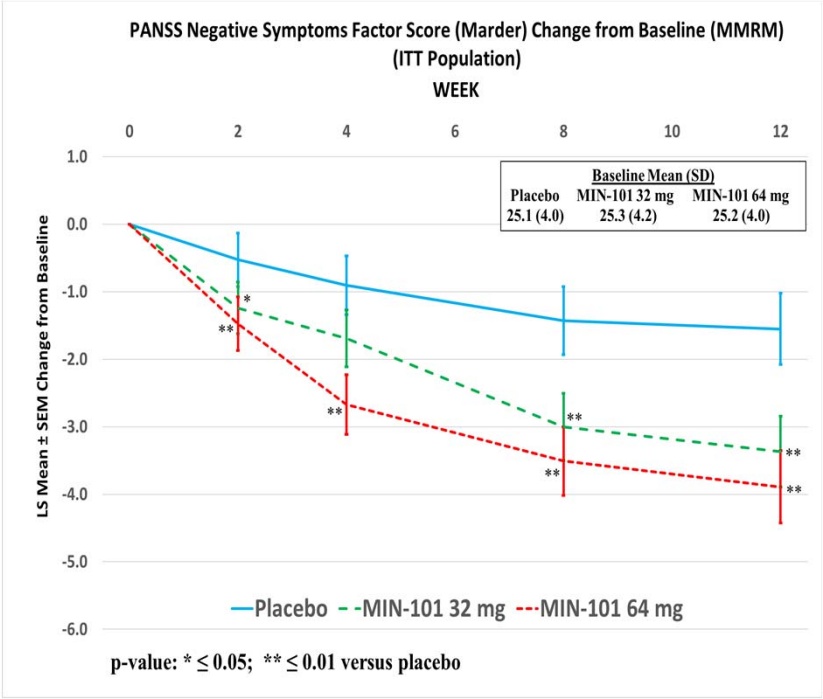
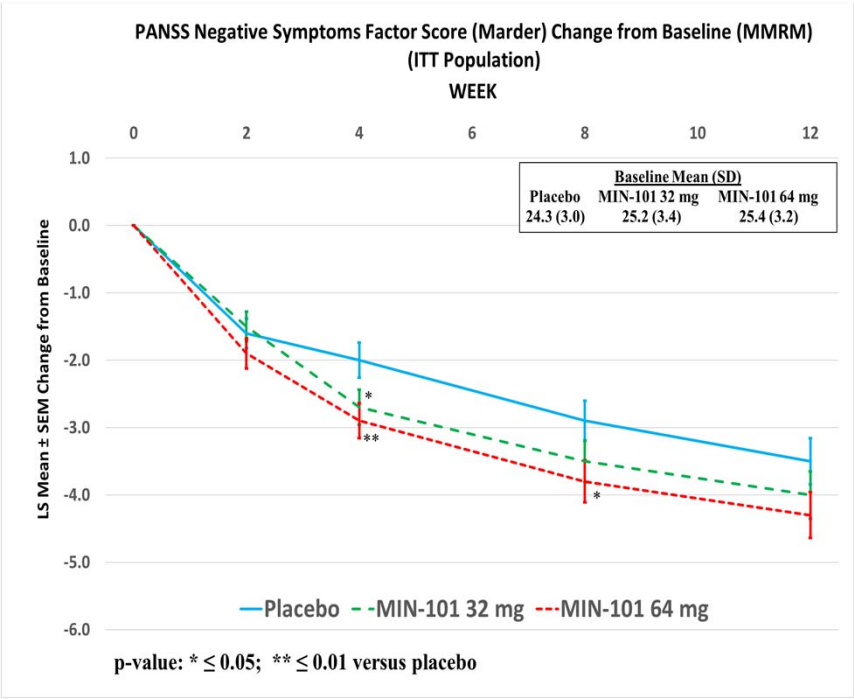
Comparison– Marder Negative Symptoms Factor Score (NSFS): Phase 2b versus Phase 3

Phase 2b NSFS



Phase 3 NSFS



Factor	MIN-101C03	MIN-101C07
Age at Baseline (yrs)	40	41
PANSS NS Subscore	27	27
PANSS Total Score	80	79
Placebo delta in PANSS NSFS (primary)	1.6	3.5
64 mg delta in PANSS NSFS (primary)	3.9	4.3

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Phase 3: Safety – Top Line Summary

Roluperidone was generally well tolerated, and the incidences of patients who reported treatment-emergent adverse events over the duration of 12 weeks of treatment were 37% for the 64 mg group, 42% for the 32 mg group, and 33% for placebo. Only 42 patients discontinued from the study due to adverse events, 16 (9%) in 64 mg arm, 18 (10%) in 32 mg arm, and 8 (5%) in placebo arm. Two treatment-unrelated deaths were reported in the 32 mg treatment arm.

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Phase 3: Key messages

- Improvement of Negative Symptoms is consistent between Phase 3 study and Phase 2b study for both doses
  - Comparable baseline characteristics
  - Comparable time course of improvement over the 12 weeks double-blind phase
  - Comparable improvement after 12 weeks
- The main reason why NSFS didn't reach statistical significance likely due to a stronger placebo effect in the Phase 3 study
- Improvement in negative symptoms seen in the study translates into improvements in PSP total score, a measure of patient daily functioning

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Professor Philip Harvey Statement

"As someone who has spent his career studying everyday functioning in schizophrenia, I see disability as the most important treatment target for people with schizophrenia," stated Philip Harvey, Ph.D., Leonard M. Miller Professor of Psychiatry and Director of the Division of Psychology at the University of Miami Miller School of Medicine. "The substantial improvements in the PSP scale with the 64 mg dose are tremendously encouraging. These study results represent a very important outcome in a study of a potential treatment of negative symptoms, one of the most important drivers of everyday disability and a critical unmet medical need for patients with schizophrenia. The consistency in treatment effects, in terms of overall negative symptoms and of the most important subtype, reduced emotional experience, between the previous Phase 2b study and the current one is encouraging. The increased placebo effect from the first to second study seems to be the only reason that the study did not meet its primary endpoint."

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