UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 5, 2020

Minerva Neurosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36517**	**26-0784194**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1601 Trapelo Road **Suite 286** **Waltham, MA**	**02451**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (617) 600-7373

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**NERV**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Minerva Neurosciences, Inc. (the "Company") is filing the corporate presentation slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use from time to time in conversations with third parties. The presentation will also be available in the investor relations section of the Company's website.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation dated June 5, 2020.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MINERVA NEUROSCIENCES, INC.

By: /s/ Geoffrey Race
Name: Geoffrey Race
Title: Executive Vice President, Chief Financial Officer and Chief Business Officer

Date: June 5, 2020

Exhibit 99.1

MINERVA NEUROSCIENCES, INC.

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

June 5th, 2020

MINERVA NEUROSCIENCES, INC.

Nasdaq : NERV

Forward-Looking Statement Safe-Harbor

This presentation 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 presentation 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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Webcast Agenda: Roluperidone phase 3 Top-Line Results (TLR)

Topic	Assigned
Introductions	William Boni, VP IR
Study Results	Remy Luthringer, PhD, Chairman & CEO
Results Discussion by KOL's	Phil Harvey, PhD Brian Kirkpatrick, MD
Concluding remarks & next steps	Remy Luthringer
Q&A	Michael Davidson, MD, CMO Phil Harvey Brian Kirkpatrick Remy Luthringer Geoff Race, CFO & CBO Rick Russell, President Jay Saoud

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Study Design Schema
&
Key Study Elements

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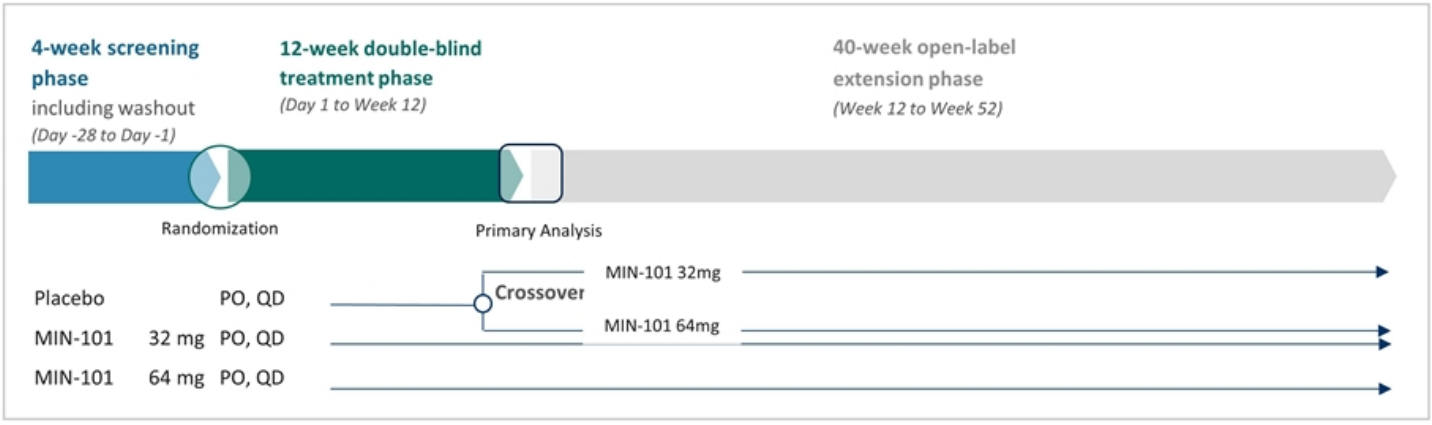
Phase 3: Study Design Schema and Key Study Elements



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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Disposition

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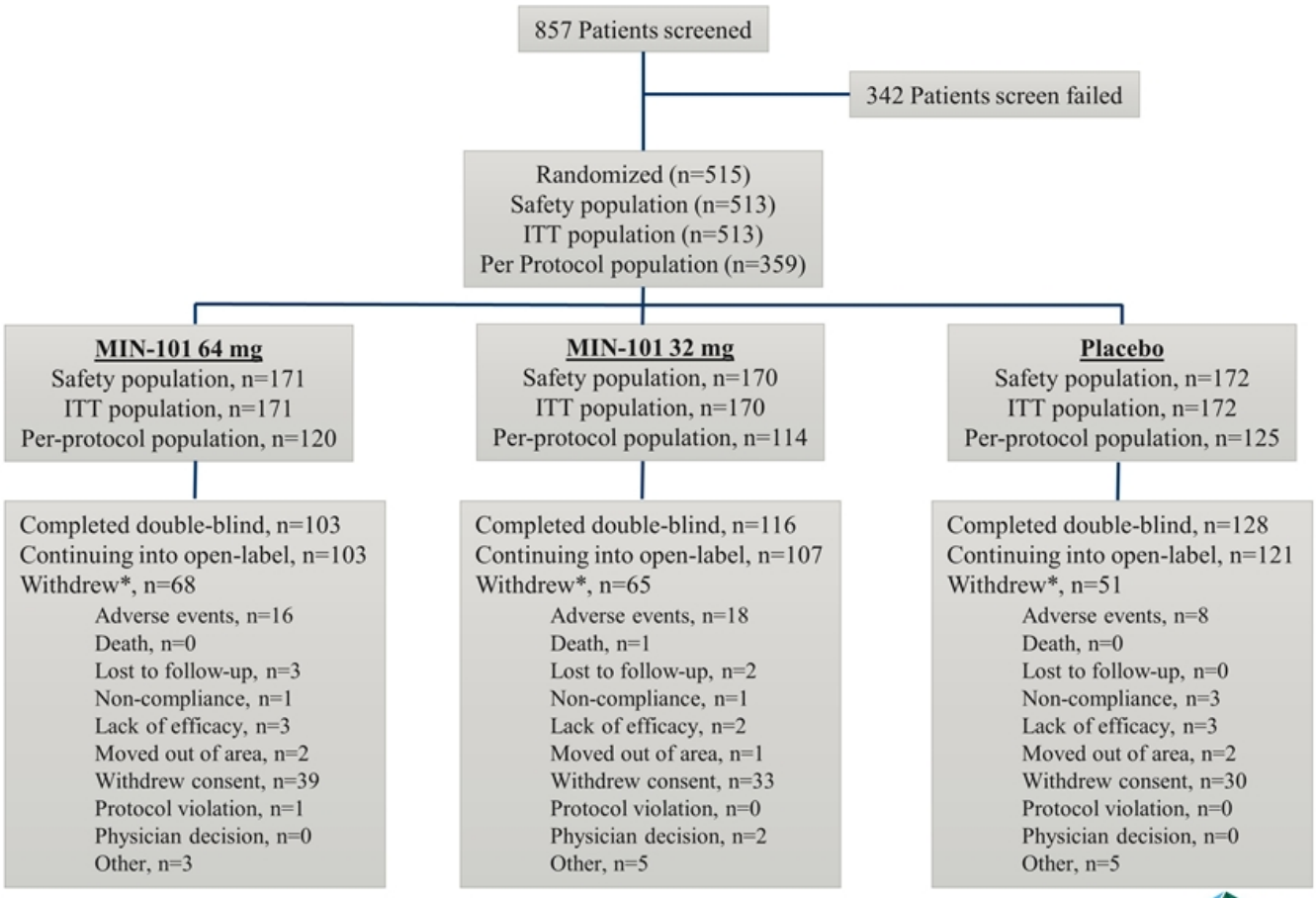
Phase 3: Disposition Flow Chart



* Including patients who withdrew after completing study procedures at Week 12

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Primary Endpoint

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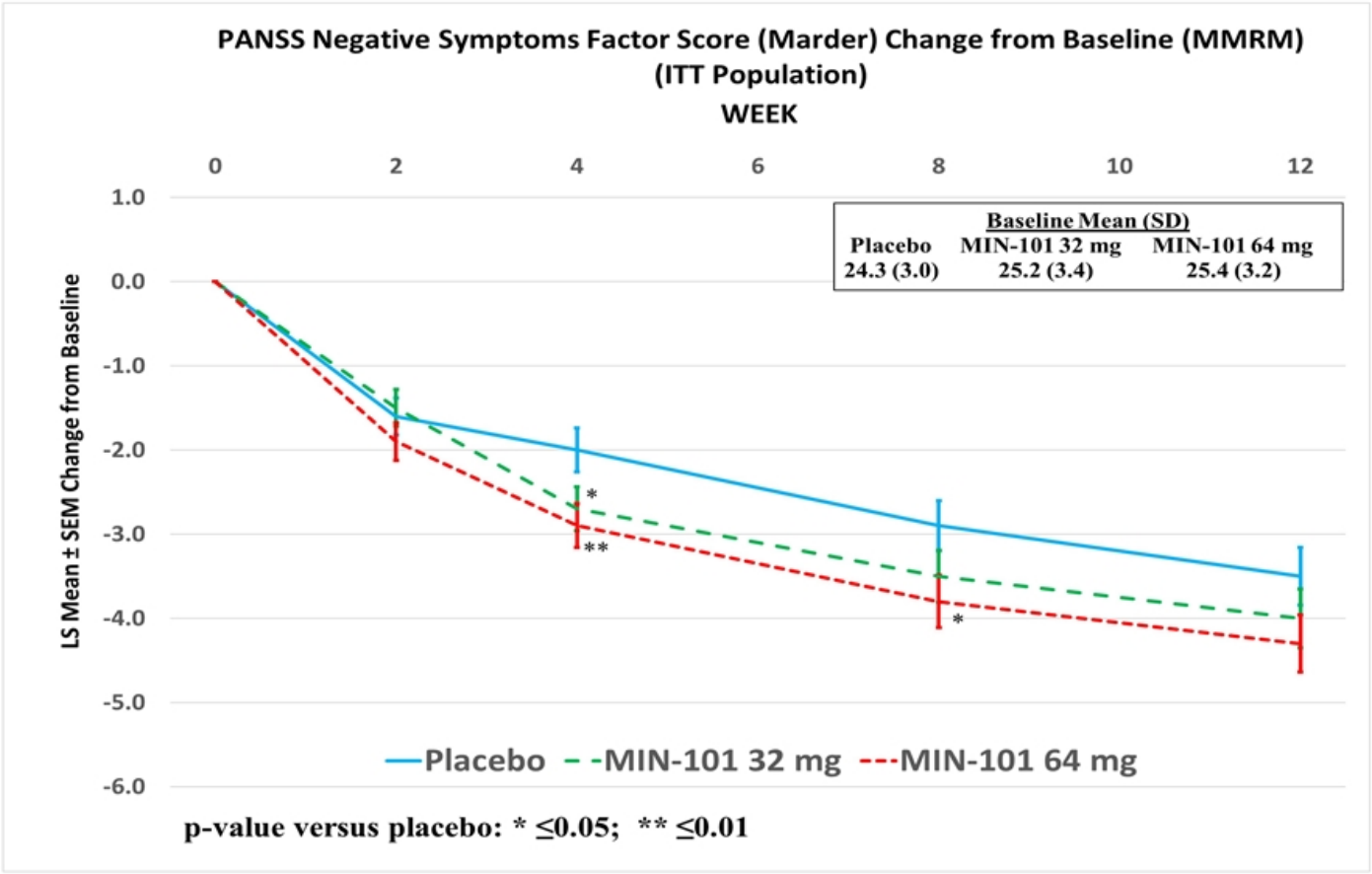
Phase 3: Marder's Negative Symptom Factor Score – Primary Endpoint



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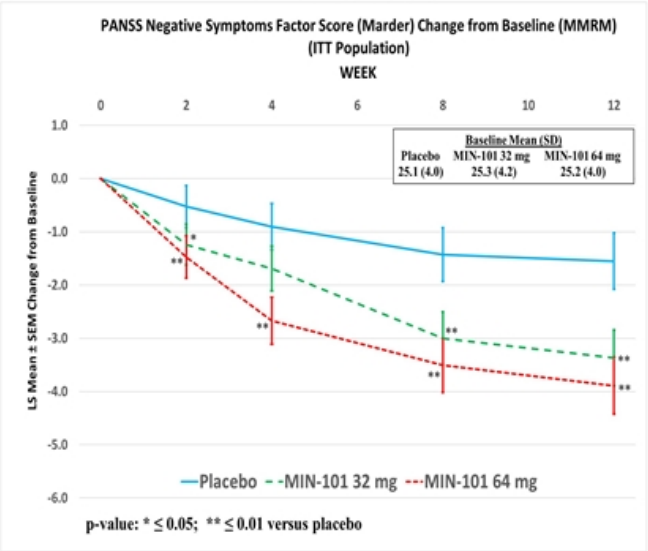
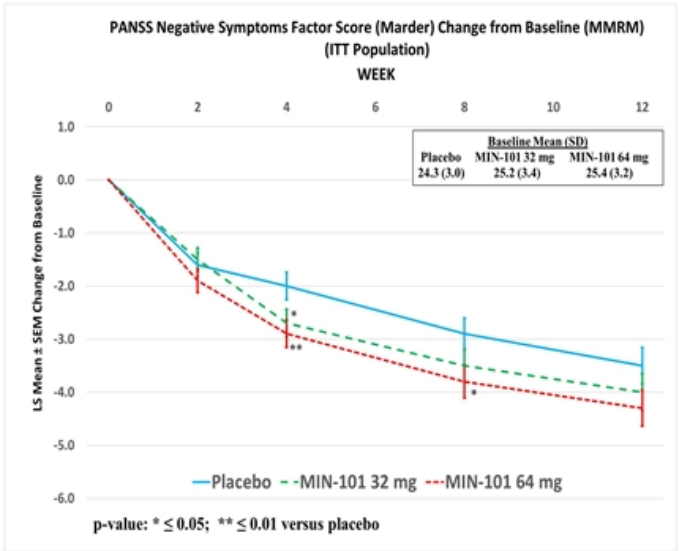
Marder's Negative Symptom Factor Score by Study - comparison of Phase 2b & Phase 3

Phase 2b NSFS



Phase 3 NSFS



Factor	Phase 2b	Phase 3
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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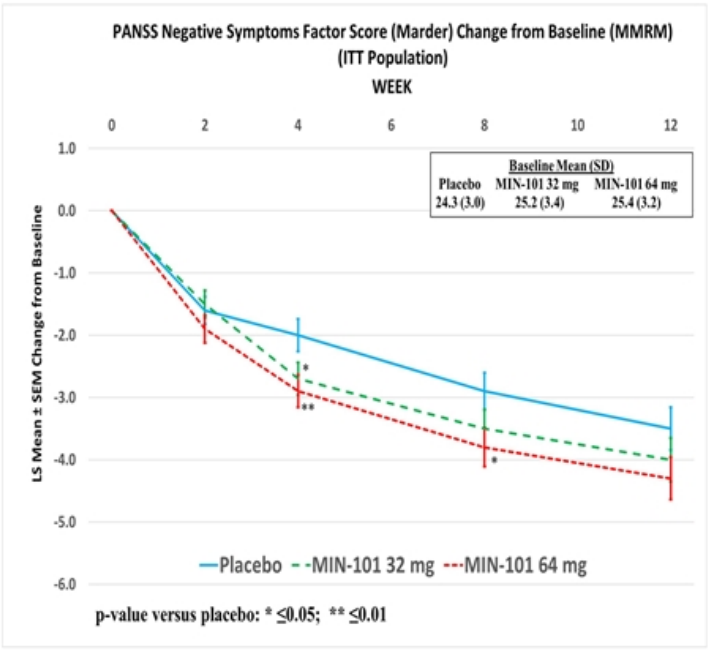
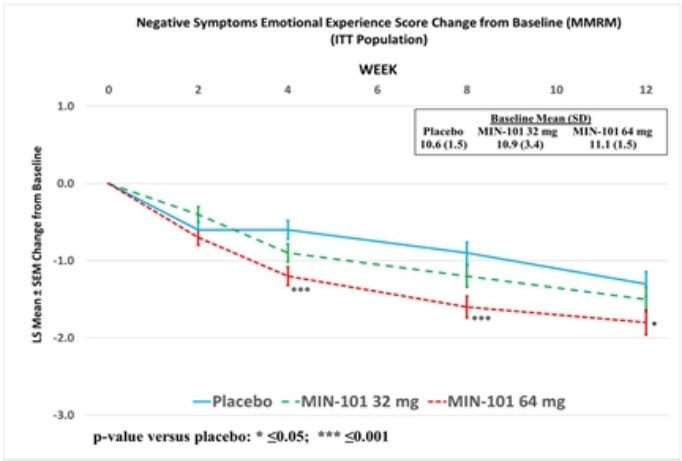
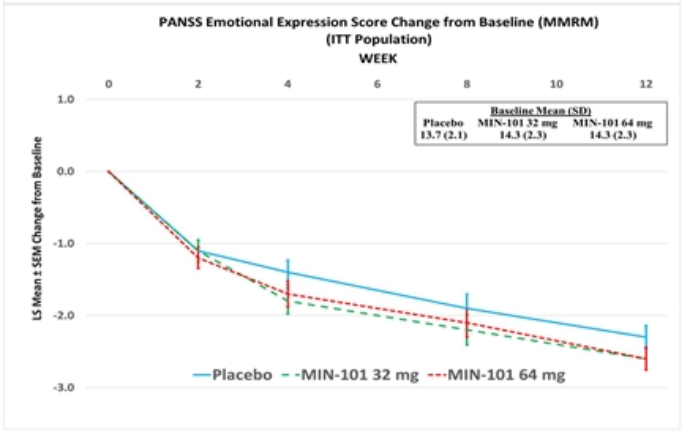
Phase 3: NSFS & Negative Symptom Dimensions[1]







[1] **Roluperidone demonstrated statistically significant superiority to placebo in improving emotional experience and emotional expression:** ***Harvey et al., 2020; Schizophrenia Research***

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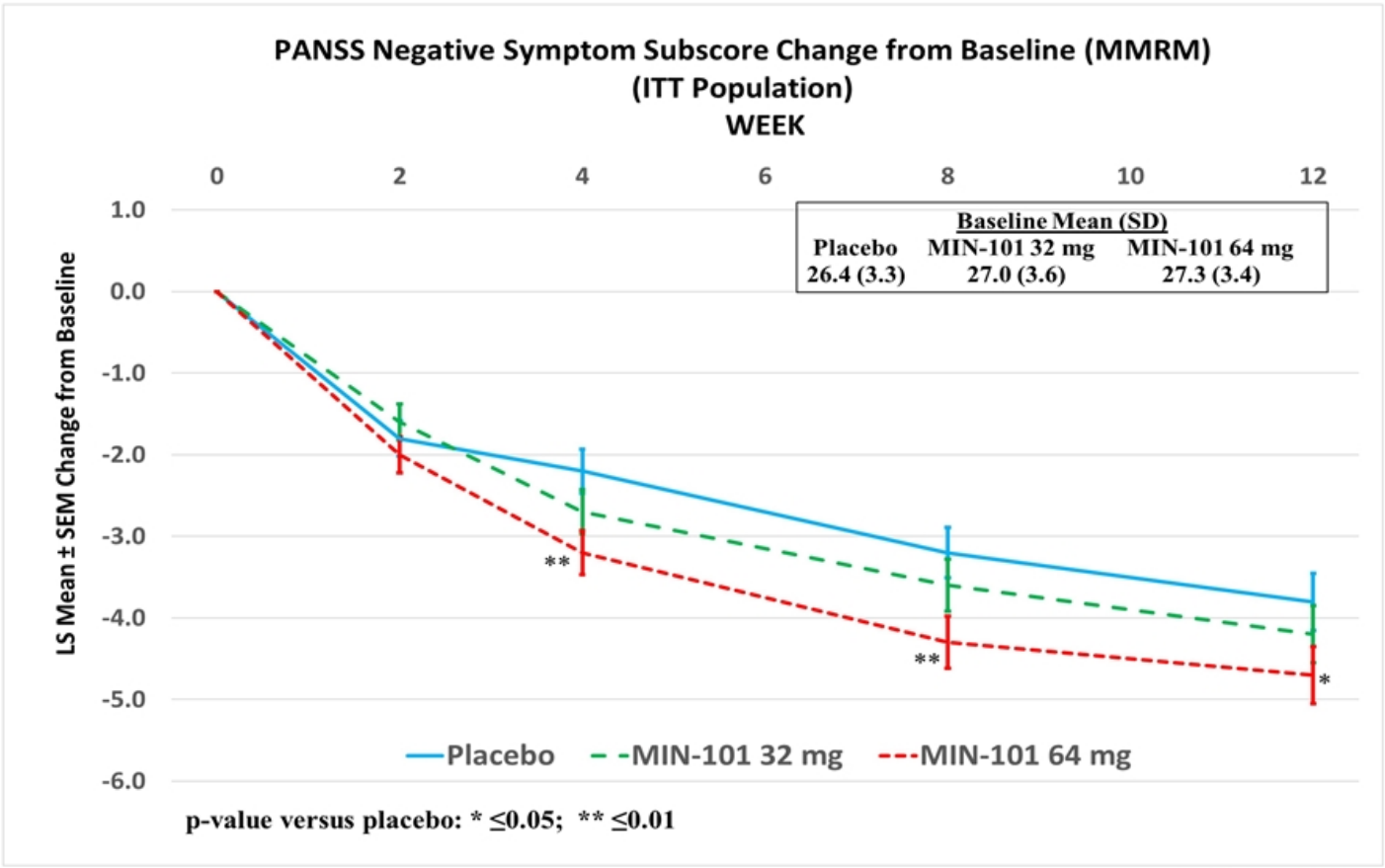
Phase 3: PANSS Negative Symptom Subscore – Sum of the 7 "N" items



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Responder Analysis: PANSS Total & Marder Negative Symptoms Factor Score (NSFS)

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Phase 3: Responder Analysis of PANSS Total and Marder Negative Symptoms Factor Score (NSFS)

		Roluperidone (MIN-101)		
	Placebo (N=172)	**32mg (N=170)**	**64mg (N=171)**	**Total (N=341)**
NSFS at Week 12				
Number of patients with **30%** response in NSFS at Week 12	17/128 (13%)	14/116 (12%)	24/122 (20%)	38/238 (16%)
Logistic Regression p-value [1]		0.807	0.160	0.538
Number of patients with **20%** response in NSFS at Week 12	30/128 (23%)	32/116 (28%)	48/122 (39%)	80/238 (34%)
Logistic Regression p-value		0.418	0.006	0.044
PANSS Total at Week 12				
Number of patients with **30%** response in PANSS Total at Week 12	5/128 (4%)	2/116 (2%)	7/122 (6%)	9/238 (4%)
Logistic Regression p-value [1]		0.327	0.498	0.728
Number of patients with **20%** response in PANSS Total at Week 12	12/128 (9%)	20/116 (17%)	24/122 (20%)	44/238 (18%)
Logistic Regression p-value		0.061	0.021	0.021

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Preliminary Primary Endpoint Integrated Analysis

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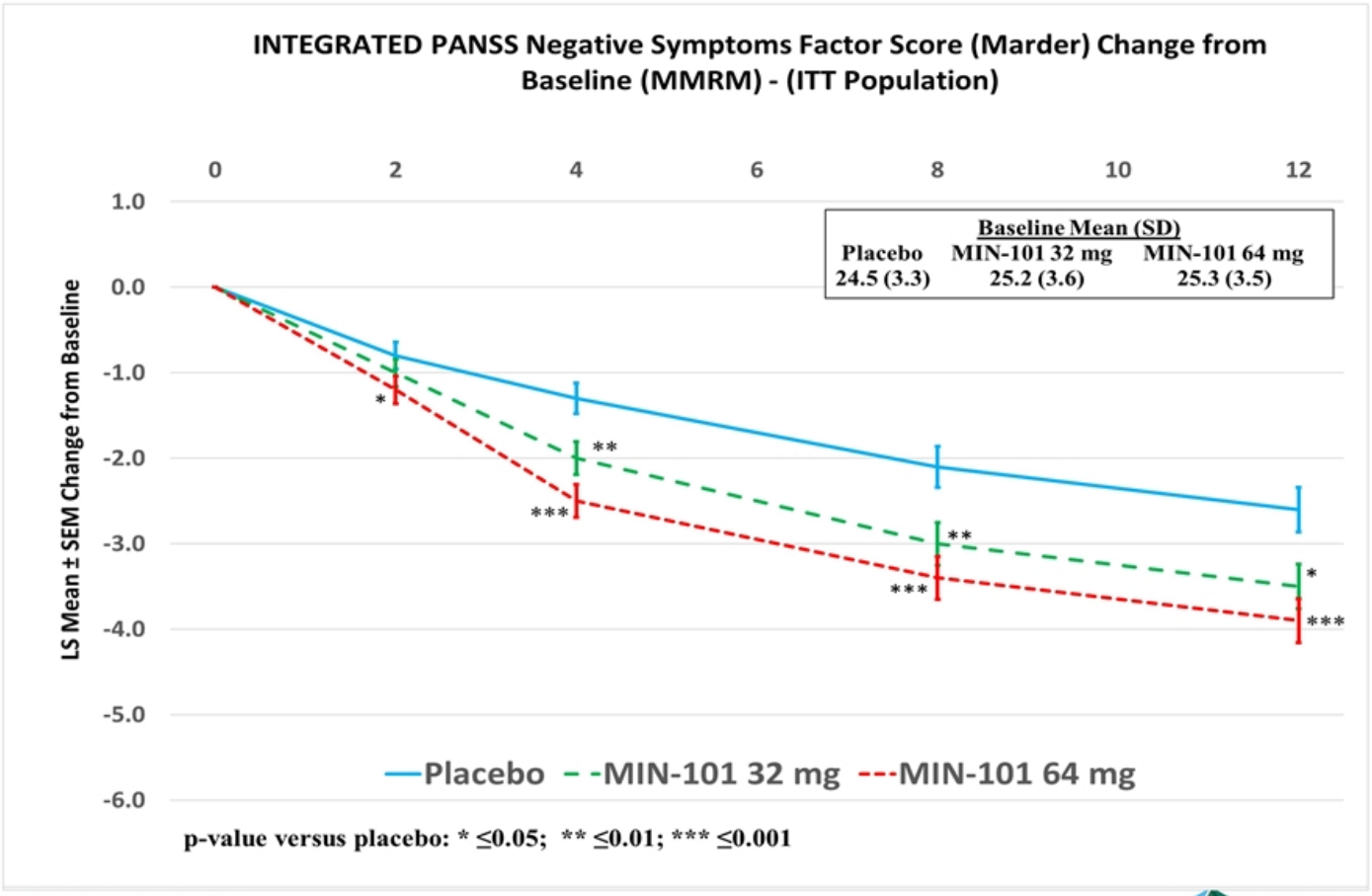
Primary Endpoint Integrated Analysis: Marder's Negative Symptom Factor Score from Phase 2b & Phase 3 Studies – Preliminary Results



ES=0.37; ES=0.26

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Key Secondary Endpoint

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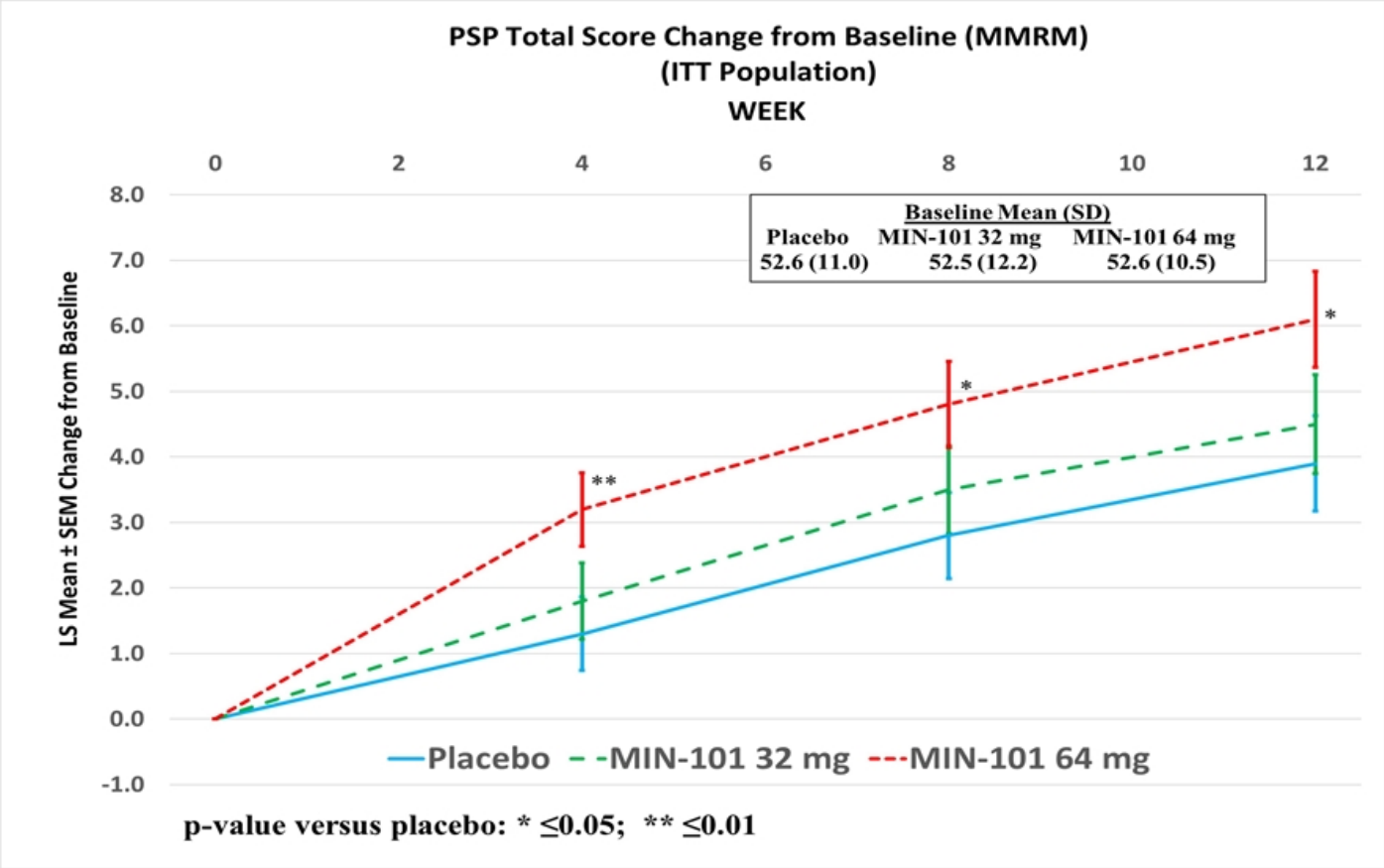
Phase 3: Personal and Social Performance Total Score – Key Secondary Endpoint



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Efficacy Summary

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Phase 3: Summary of Efficacy Findings

Endpoints	Change from Baseline LS Means (Week 12)			32 mg MIN-101 versus Placebo		64 mg MIN-101 versus Placebo	
		MIN-101					
	Placebo	32 mg	64 mg	p-value	effect size	p-value	effect size
Primary							
Marder's Negative Symptom Factor Score (NSFS)	-3.5	-4.0	-4.3	0.259	0.13	0.064	0.21
Key Secondary							
Personal & Social Performance (PSP)	3.9	4.5	6.1	0.542	0.07	0.021	0.27
Secondary & Exploratory							
Clinical Global Impression of Severity	-0.3	-0.4	-0.5	0.221	0.10	0.073	0.24
PANSS Total Score	-5.5	-7.1	-7.4	0.168	0.17	0.098	0.20
PANSS Negative Subscore	-3.8	-4.2	-4.7	0.392	0.10	0.046	0.23
Marder's Positive Symptoms Factor Score	-0.9	-1.3	-1.6	0.190	0.14	0.039	0.24
NSFS Emotional Experience Score	-1.3	-1.5	-1.8	0.401	0.11	0.020	0.28
NSFS Emotional Expression Score	-2.3	-2.6	-2.6	0.352	0.17	0.349	0.17
PSP Self-Care	-0.3	-0.4	-0.3	0.261	0.15	0.819	0.04
PSP Socially Useful Activities	-0.3	-0.3	-0.4	0.865	0.02	0.047	0.18
PSP Personal and Social Relationships	-0.3	-0.4	-0.3	0.076	0.15	0.501	0.04
* Observed data							

Integrated Analysis	Change from Baseline LS Means (Week 12)			32 mg MIN-101 versus Placebo		64 mg MIN-101 versus Placebo	
		MIN-101					
	Placebo	32 mg	64 mg	p-value	effect size	p-value	effect size
Marder's Negative Symptom Factor Score (NSFS)	-2.5	-3.3	-3.6	0.014	0.26	0.001	0.37

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Phase 3: Summary

- Key findings:
  - Patient populations in the phase 2b and phase 3 are comparable
  - Improvement of negative symptoms as measured by NSFS are similar in both studies
  - Both doses show early separation from placebo at week 4 (both doses) and week 8 (64mg)
  - Due to higher placebo response, roluperidone at both doses separated but did not achieve a statistically significant difference at Week 12
  - Higher number of responders in terms of negative symptoms and total PANSS score in the roluperidone treatment groups
  - The reduction in negative symptoms scores in the 64 mg arm of roluperidone translated into an improvement of PSP total score and sub-scores reflective of functional improvement.
  - Relapse rates are extremely low and confirm that a significant proportion of schizophrenic patients have stable positive symptoms for extended periods of time.
  - The integrated analysis of the phase 3 and phase 2b study data shows a very strong statistically significant difference for both doses of roluperidone at week 12 (and earlier timepoints).
- Safety and efficacy of roluperidone in phase 3 are consistent with phase 2b

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RESULTS DISCUSSION BY KOL'S

Phil Harvey & Brian Kirkpatrick

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CONCLUDING REMARKS
&
NEXT STEPS

Remy Luthringer

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Roluperidone (MIN-101) – CONCLUDING REMARKS & NEXT STEPS

- Further data analyses will continue over the coming weeks:
  - Complete understanding of the data
  - Further explore placebo group and understand the difference seen between the phase 2b and 3 study
  - To continue our dialogue with our regulatory advisors and our KOL's
- Request a meeting with the FDA to present data and obtain input and plan path forward
- The results also confirm the unique mechanism of action of roluperidone targeting those pathways – $5HT_{2A}$, $Sigma_2$, $Alpha_{1A}$ – known to be involved in schizophrenia (1)
- Psychiatrists cite negative symptoms as the top unmet need in the treatment of schizophrenia (2)
- No product is currently approved to treat negative symptoms in the US

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1. Girgis et al., 2018. The past and future of novel, non-dopamine-2 receptor therapeutics for schizophrenia: A critical and comprehensive review. *Journal of Psychiatry Research*..
2. Schizophrenia Market Intelligence Report. Cambridge Healthcare Research. File name: Schizophrenia Intelligence 1 Dec 2017

Q&A

Michael Davidson
Phil Harvey
Brian Kirkpatrick
Remy Luthringer
Geoff Race
Rick Russell
Jay Saoud

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