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): January 5, 2022

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 7.01 Regulation FD Disclosure.

On January 5, 2022, Minerva Neurosciences, Inc., or the Company, released a corporate presentation at the 11th Annual LifeSci Partners Corporate Access Event, presented virtually.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information furnished pursuant to Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a determination or admission by the Company that the information in this Current Report on Form 8-K is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Presentation of Minerva Neurosciences, Inc. dated January 5, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: President

Date: January 5, 2022

Exhibit 99.1

MINERVA
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Corporate Presentation

January 2022

Forward-Looking Statement Safe-Harbor

Forward-Looking Safe Harbor Statement

This presentation contains forward-looking statements. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this presentation, and involve certain risks and uncertainties. Forward-looking statements include, but are not limited to, statements herein with respect to the timing and scope of clinical trials and regulatory review and results and outcomes of such clinical trials and regulatory review with roluperidone (MIN-101); the clinical and therapeutic potential of this compound; the likelihood of successful clinical trials, regulatory review, commercialization, and future sales of and potential royalty stream from seltorexant; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the U.S. Food and Drug Administration; 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 or seltorexant 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; changes in expected or existing competition; unexpected litigation or other disputes; the impacts of the COVID-19 pandemic on our business; 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 September 30, 2021, filed with the Securities and Exchange Commission on November 8th, 2021. 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.

5th January 2022

MINERVA NEUROSCIENCES, INC.

Minerva Neurosciences (NASDAQ: NERV)

- Founded in 2014
- Our goal is to transform the lives of patients suffering from CNS disease including schizophrenia, depression, insomnia and Parkinson's disease.
- Roluperidone is our lead program for the treatment of negative symptoms in patients diagnosed with schizophrenia.

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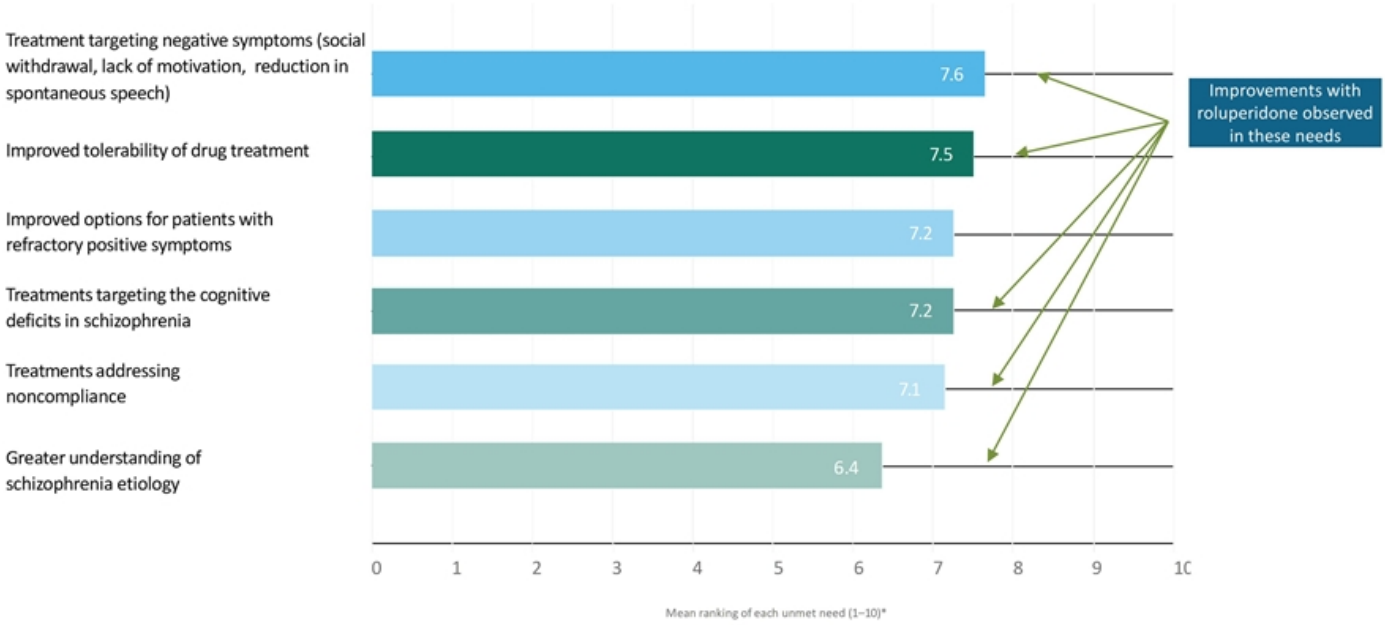
Roluperidone

Treatment of negative symptoms in patients diagnosed with schizophrenia

Physicians Cite Negative Symptoms as One of the Key Unmet Needs in Schizophrenia



*Higher scores denote greater importance assigned to the unmet need.
Source: Datamonitor Healthcare's proprietary schizophrenia survey, September 2017

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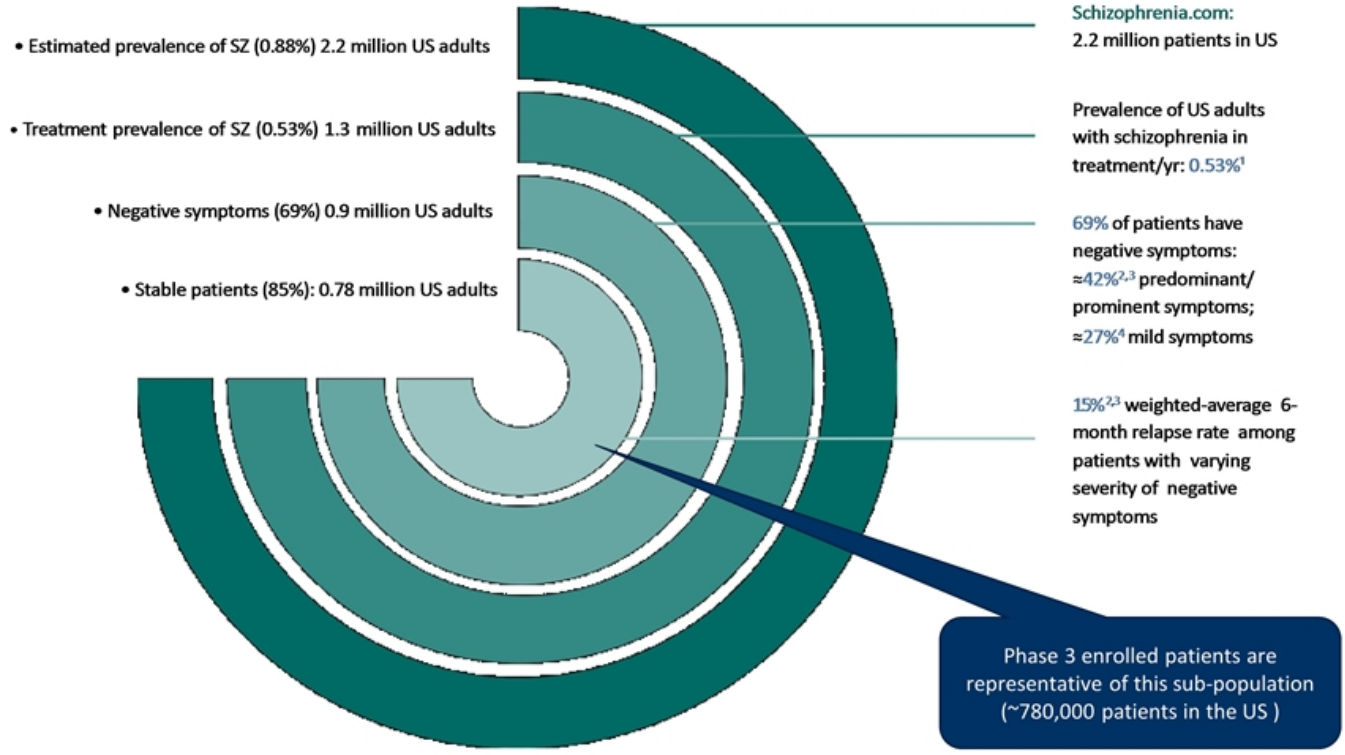
Large Patient Population and Currently No Approved Treatments in the US



SZ=schizophrenia.
1.Wu et al. Psychol Medicine. 2006; 2. Millier et al. J Market Acc Health Policy. 2017; 3.Haro et al. Schizophr Research. 2015; 4. Nordstroem et al. J Social Psychiatry. 2017

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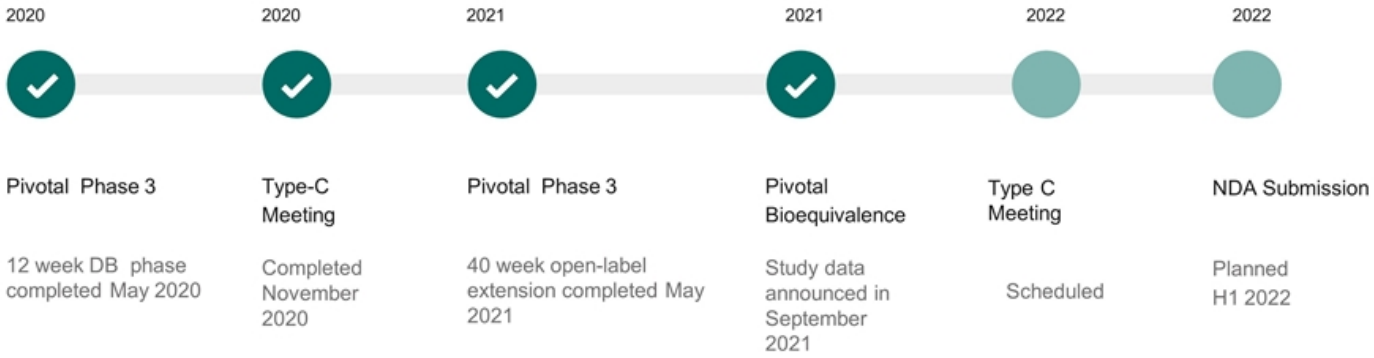
Upcoming Type-C Meeting with FDA to Discuss Roluperidone

Roluperidone's path:

Following successful completion of the pivotal Phase 2b study in 2016



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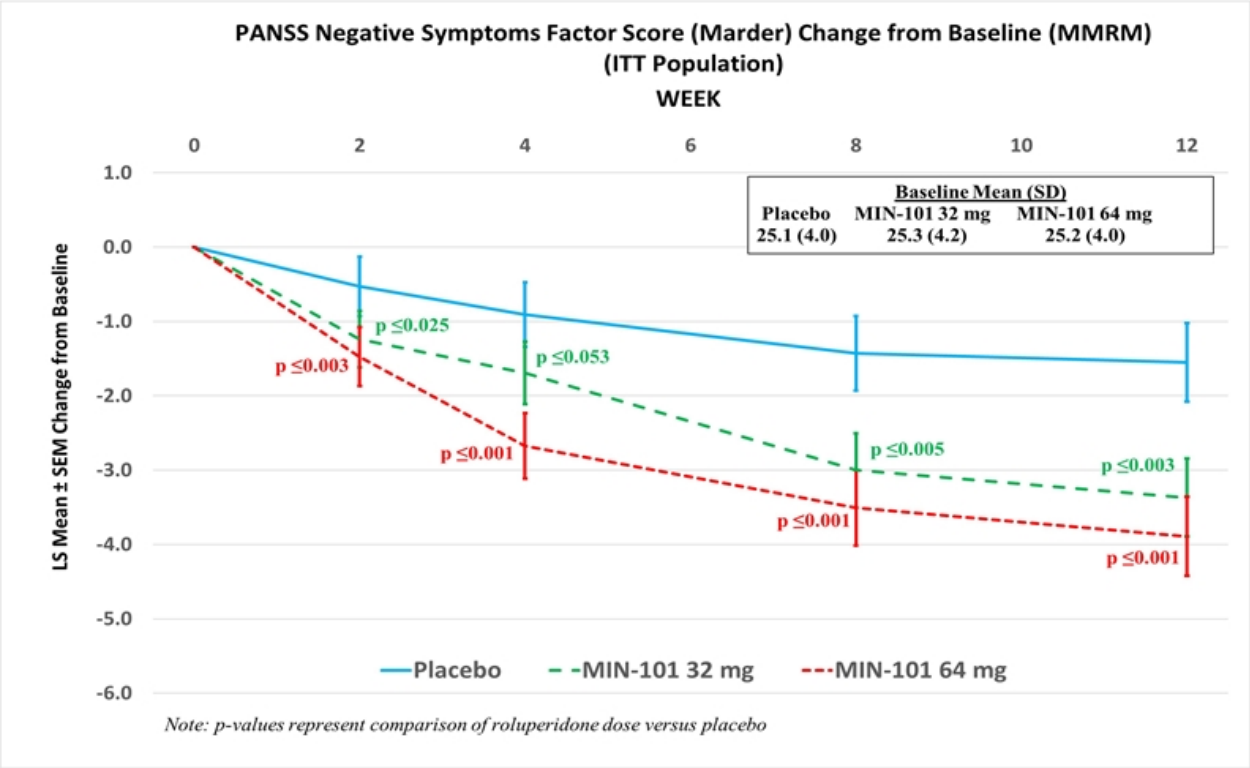
Phase 2b Recap

Phase 2b: Marder's Negative Symptom Factor Score – Post Hoc



Note: p-values represent comparison of roluperidone dose versus placebo

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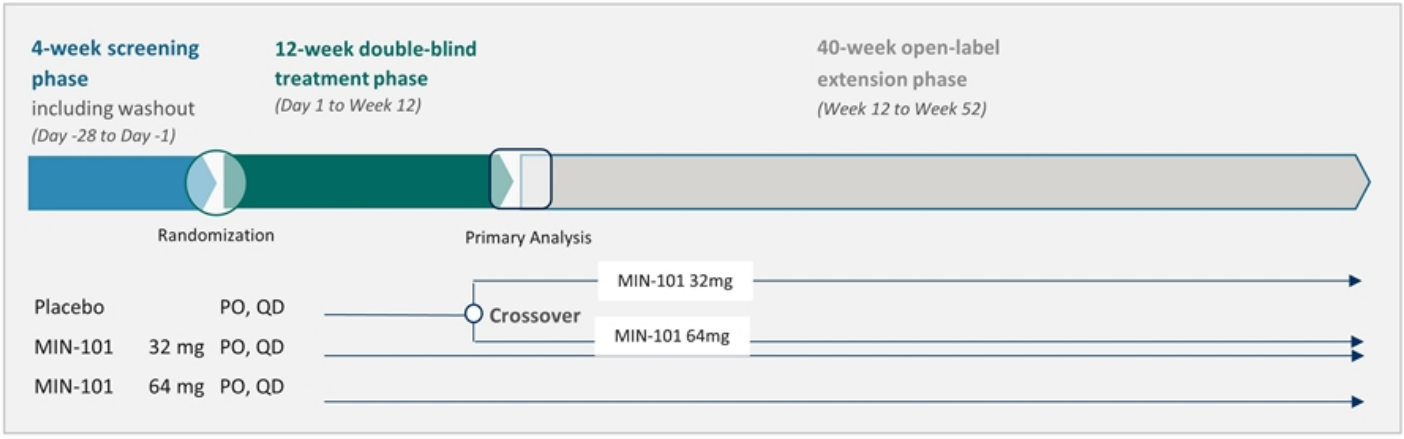
Phase 3: Recap

Phase 3 (MIN-101C07) Study Design Schematic 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
Target Number of Patients	501 patients randomized 1:1:1 (167 in each arm)
Sample Size Assumptions & Statistics	Delta versus placebo of 3 points, SD = 6.5, 90% power, and 40% drop-out rate ITT, MMRM, Truncated Hochberg to correct for multiplicity for primary & key secondary endpoints

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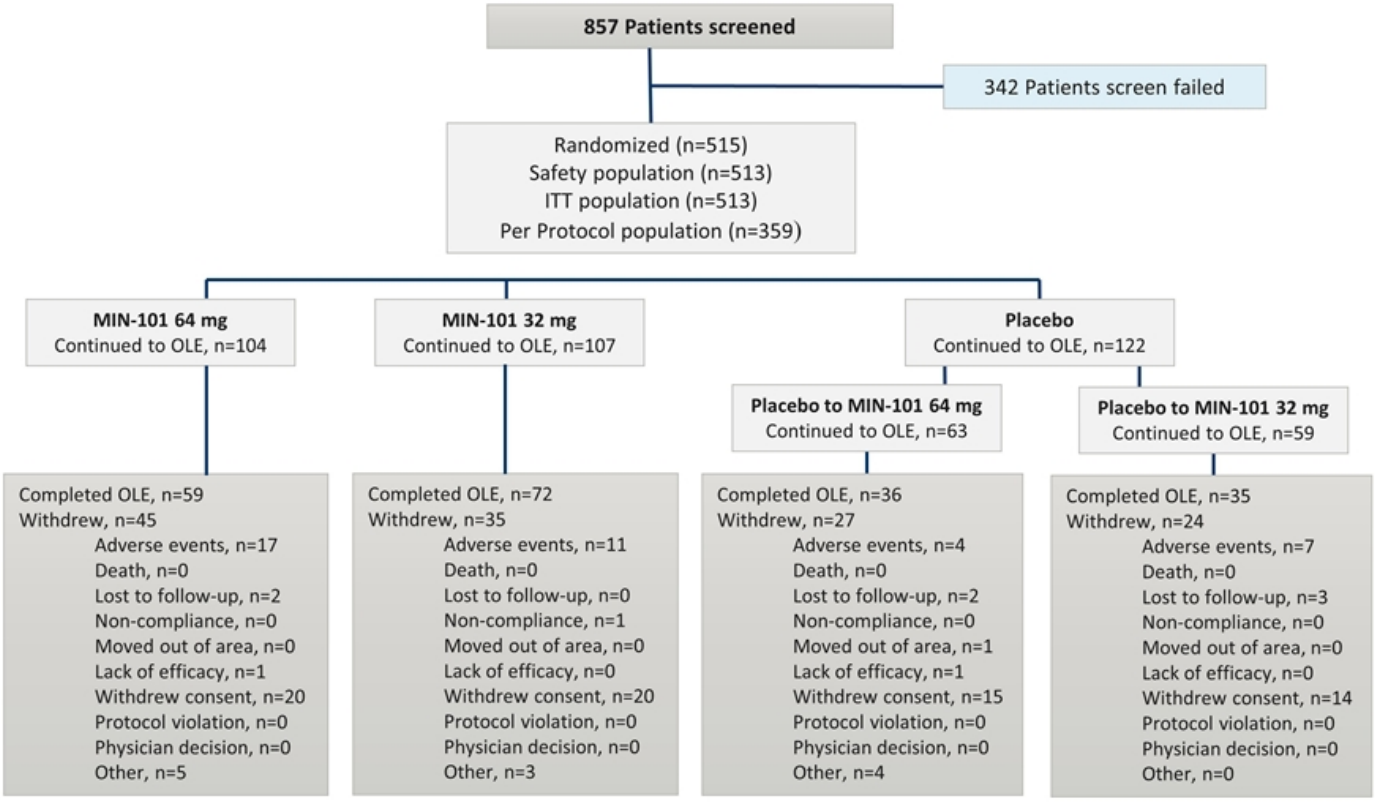
Phase 3 Disposition Flow Chart: Open-Label Extension



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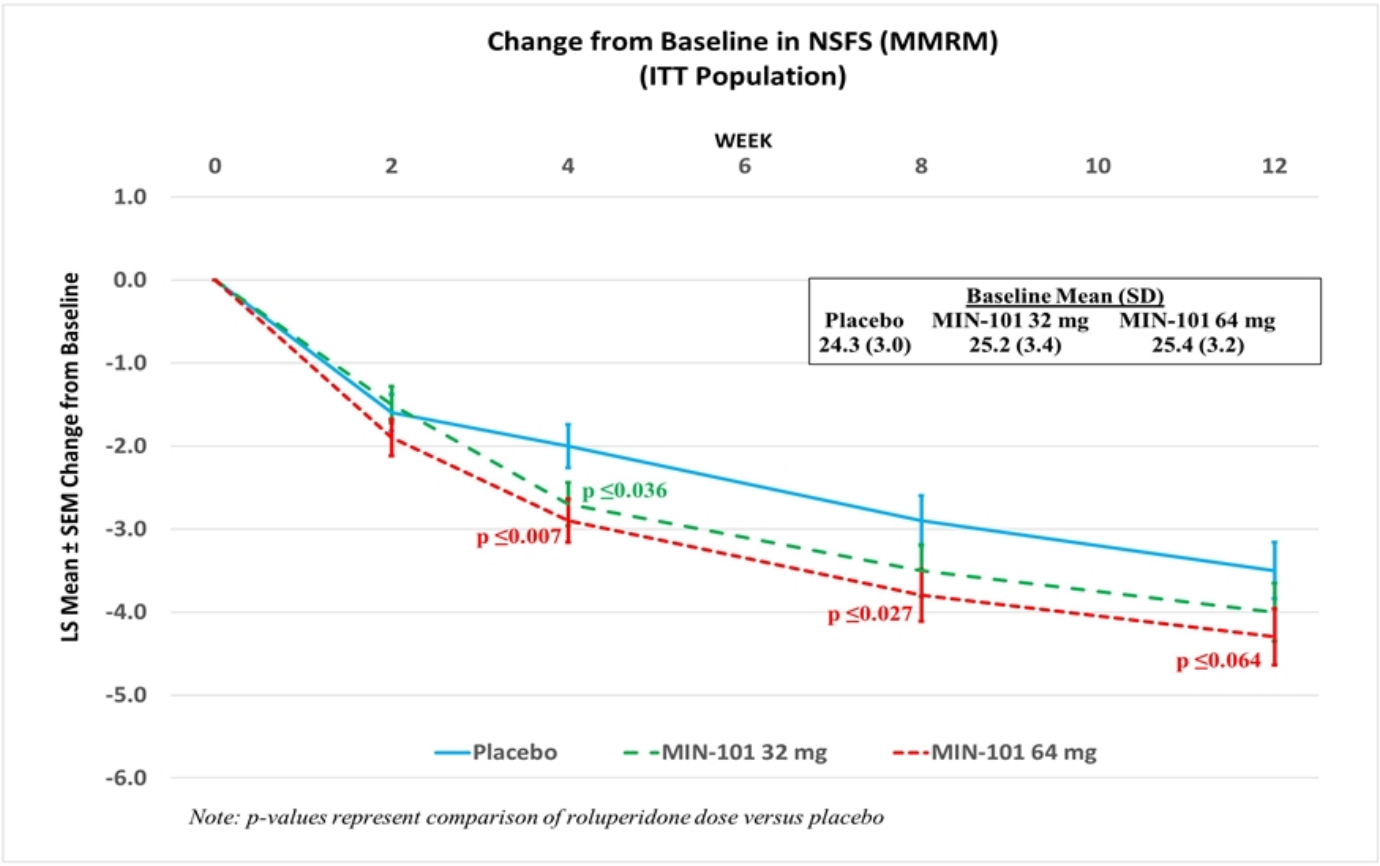
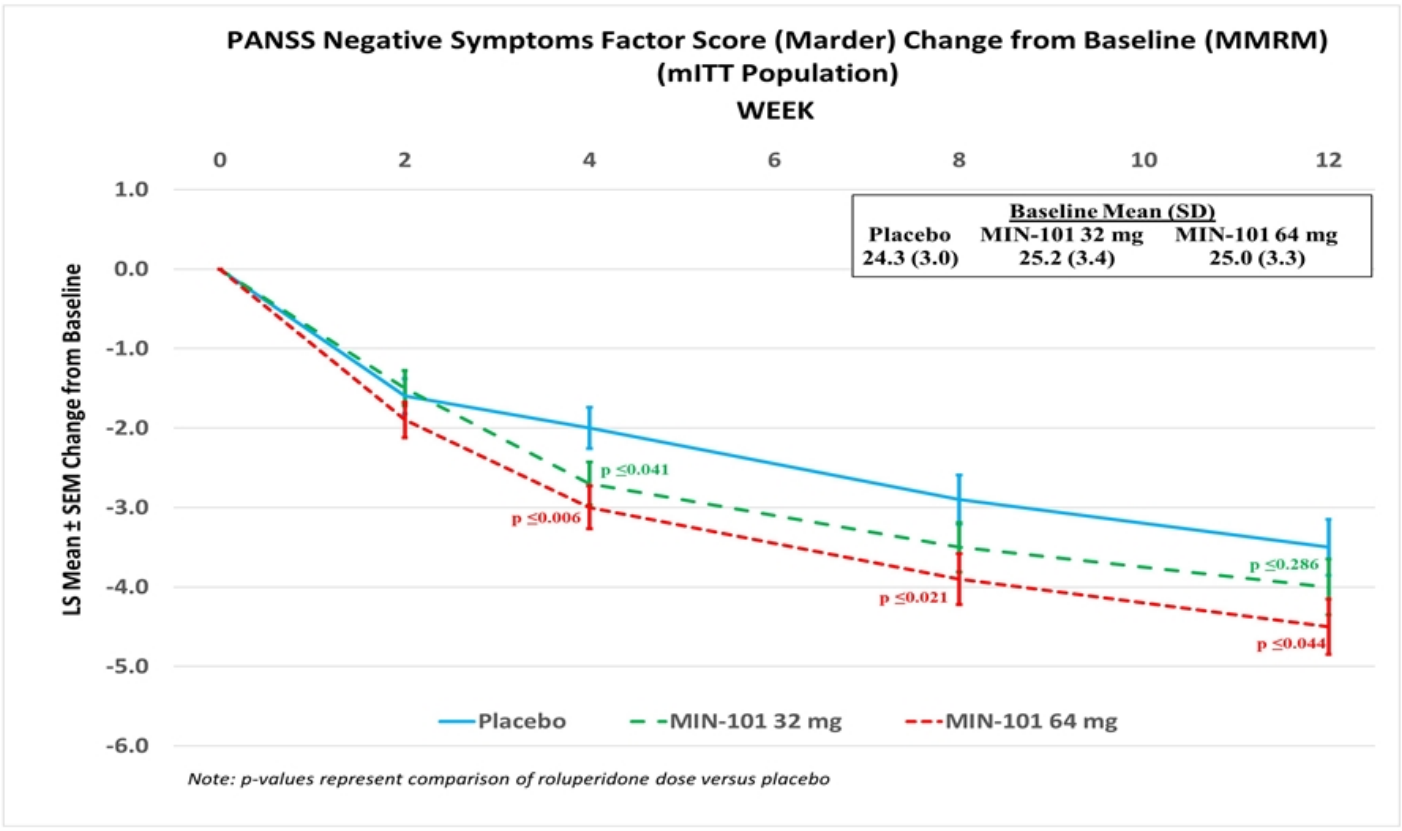
Phase 3 Double-Blind: NSFS (ITT population)



Note: p-values represent comparison of roluperidone dose versus placebo

Phase 3 Double-Blind: NSFS – (mITT population)



Note: p-values represent comparison of roluperidone dose versus placebo

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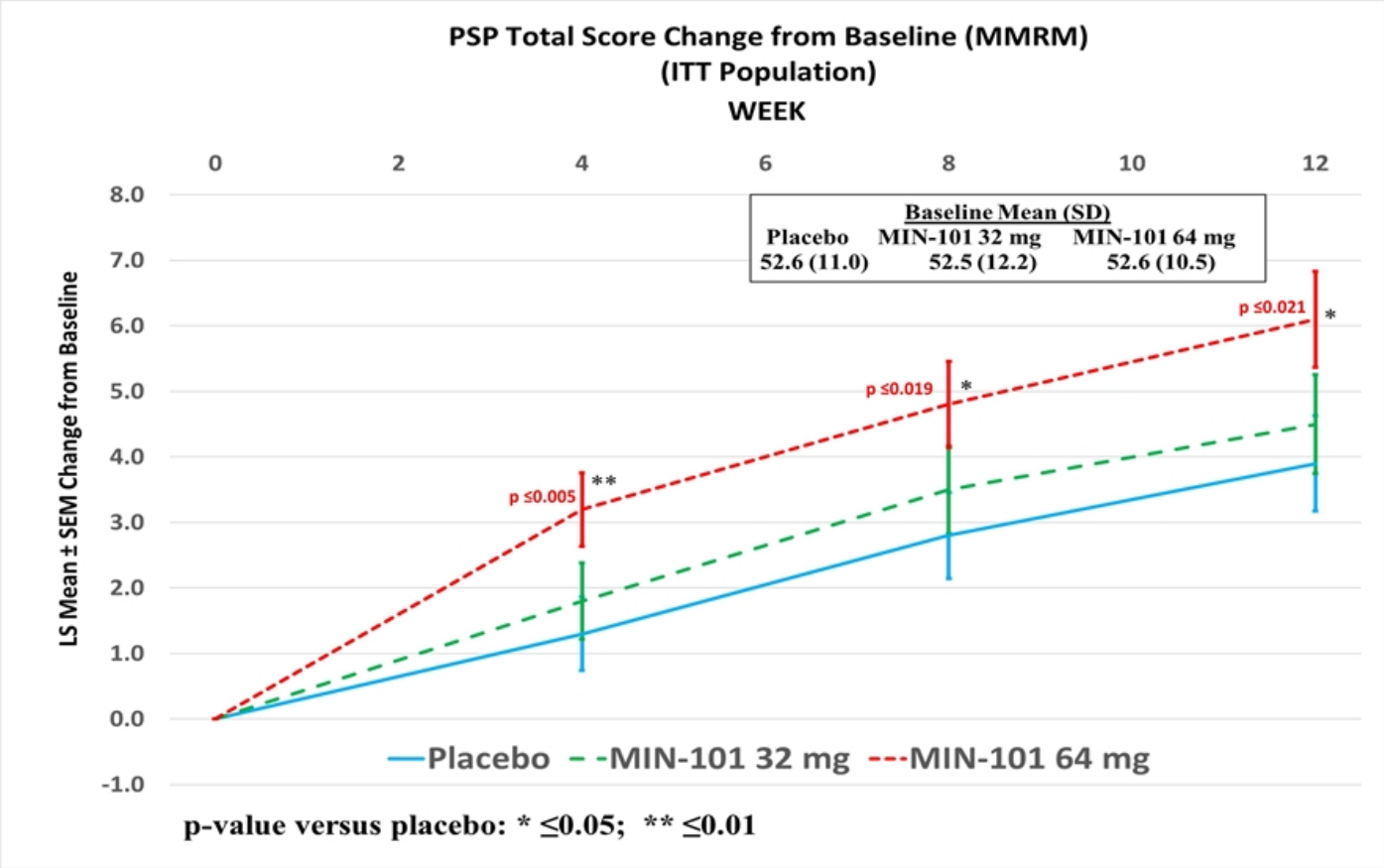
Phase 3: Personal and Social Performance Total Score – Key Secondary Endpoint (ITT population)



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Phase 3 Extension: Recap

Key Objectives of the open-Label Extension (OLE)

1. **Long term safety**

2. **Long term efficacy:**
   a. **Negative Symptoms**
      - Marder Negative Symptom Factor Score (NSFS) **(*Primary Endpoint*)**

   b. **Functioning**
      - Personal and Social Performance Total score (PSP) **(*Key Secondary Endpoint*)**

   c. **Overall Psychopathology**
      - Other dimensions of the disease, including CGI-S and other PANSS scale items

   d. **Relapse rate of Schizophrenia**

   e. **Cognition**

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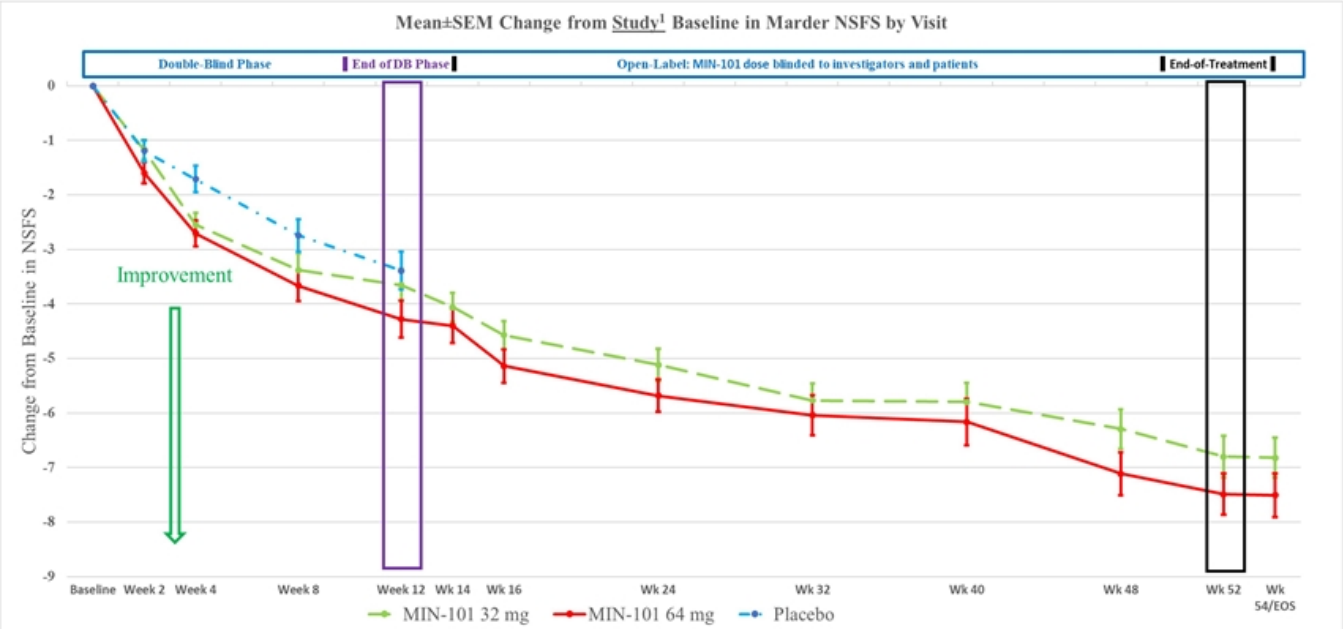
NSFS: Double-Blind & Open-Label Extension – Study Baseline

Figure depicting the observed data for the 3 treatment arms during double-blind phase and the 2 active treatment arms during the open-label extension phase



[1] *Study baseline is defined as the last valid evaluation done before the study drug administration on Day 1*

Change from Baseline				
	Double-Blind (12 Wks)		End-of-Treatment (WK 52)	
Treatment Arm	Mean	SD	Mean	SD
MIN-101 32 mg	-3.7	3.18	-6.3	4.00
MIN-101 64 mg	-4.3	3.80	-7.8	3.56
Placebo to MIN-101 32 mg	-3.4	3.91	-4.5	3.50
Placebo to Min-101 64 mg			-4.9	4.66

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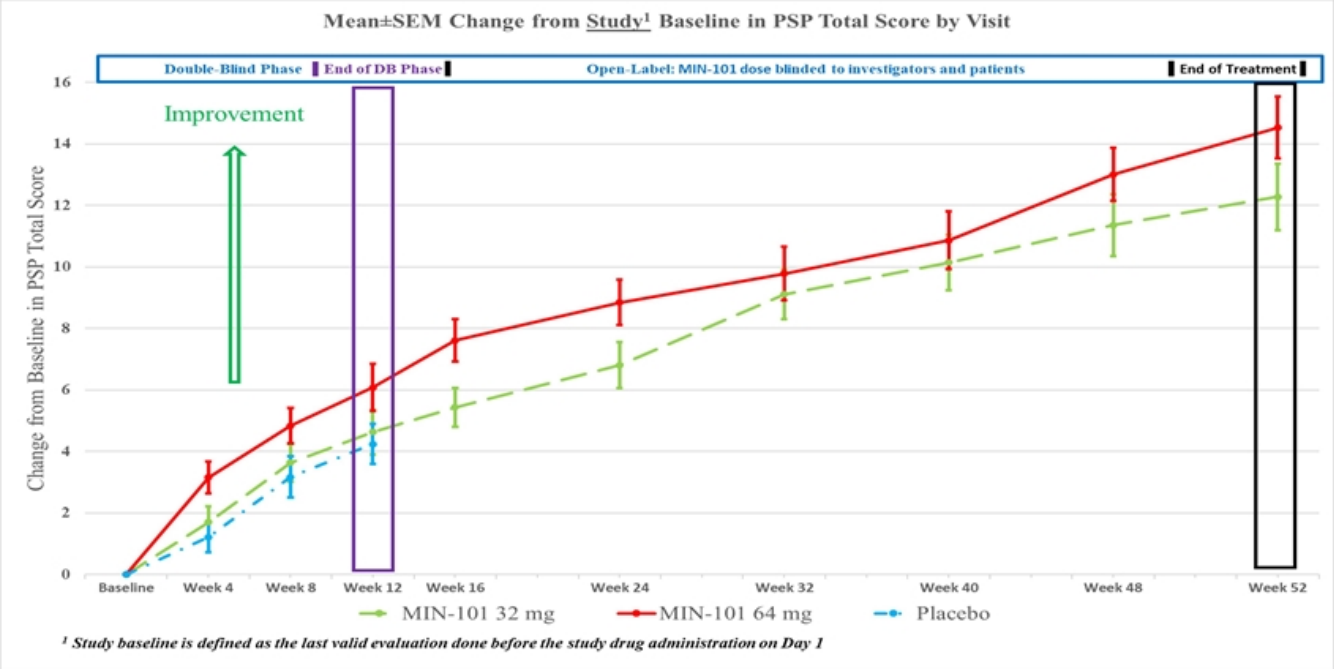
PSP Total Score: Double-Blind & Open-Label Extension – Study Baseline

Figure depicting the observed data for the 3 treatment arms during double-blind phase and the 2 active treatments arms during the open-label extension phase



Change from Baseline				
	Double-Blind (12 Wks)		End-of-Treatment (WK 52)	
Treatment Arm	Mean	SD	Mean	SD
MIN-101 32 mg	4.6	7.88	10.6	10.87
MIN-101 64 mg	6.1	8.37	14.1	9.19
Placebo to MIN-101 32 mg	4.2	7.34	11.7	9.48
Placebo to Min-101 64 mg			11.8	9.61

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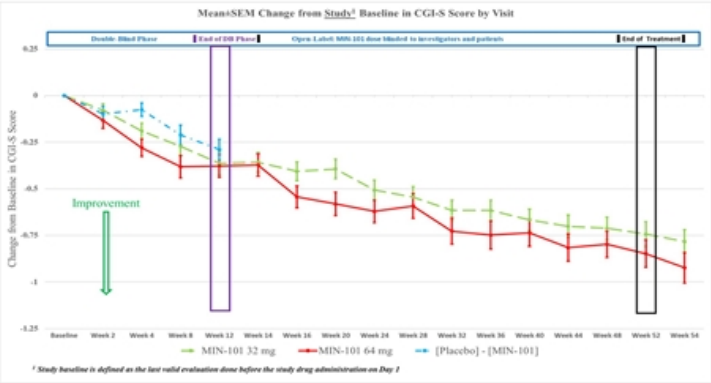
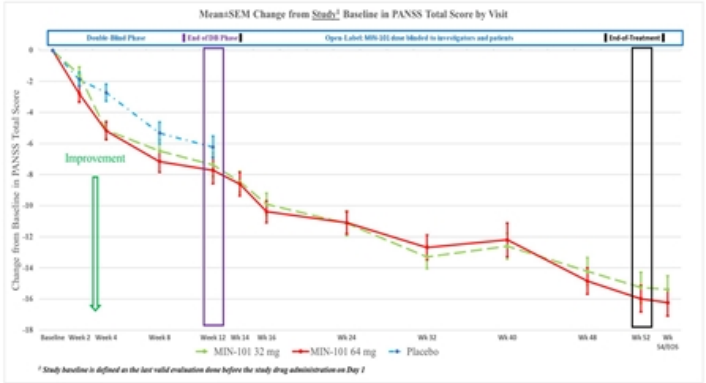
Other Key Efficacy Parameters: Double-Blind & Open-Label Extension – Study Baseline

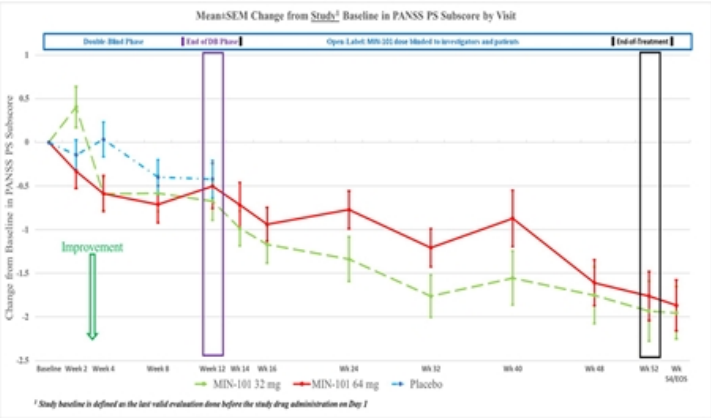
CGI-S



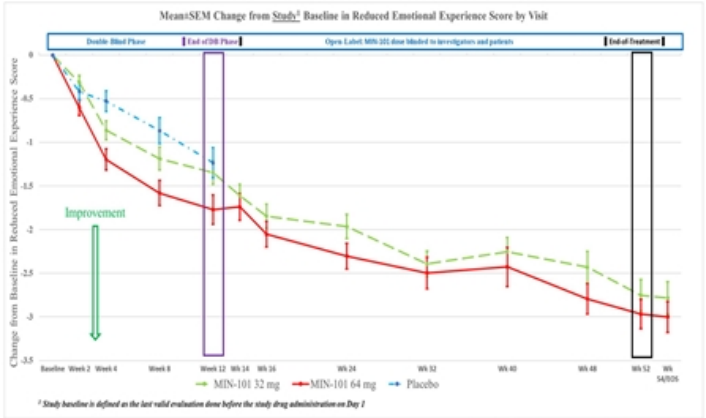
PANSS Total Score



PANSS Positive Symptoms Score



Reduced Emotional Experience Score



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Relapse* rate in the Double-Blind Phase and Open-Label Extension

Study Phase		Placebo (N=172)		MIN-101 32 mg (N=170)	MIN-101 64 mg (N=171)
Double-Blind	# of Patients	8 (4.7%)		18 (10.6%)	9 (5.3%)
	Mean±SEM Days to Relapse	79.8±0.91		68.5±1.35	80.2±1.13
Open-Label	Treatment	MIN-101 32 mg (N=59)	MIN-101 64 mg (N=63)	MIN-101 32 mg (N=107)	MIN-101 64 mg (N=104)
	# of Patients	6 (10.2%)	0 (0%)	9 (8.4%)	10 (9.6%)
	Mean±SEM Days to Relapse	253.6±6.98	-	232.4±4.86	186.7±3.67

Over the total study period (one year duration) the overall relapse rate was 11.7%

** Relapse is defined as worsening of schizophrenia symptoms that lead to permanent discontinuation from the study*

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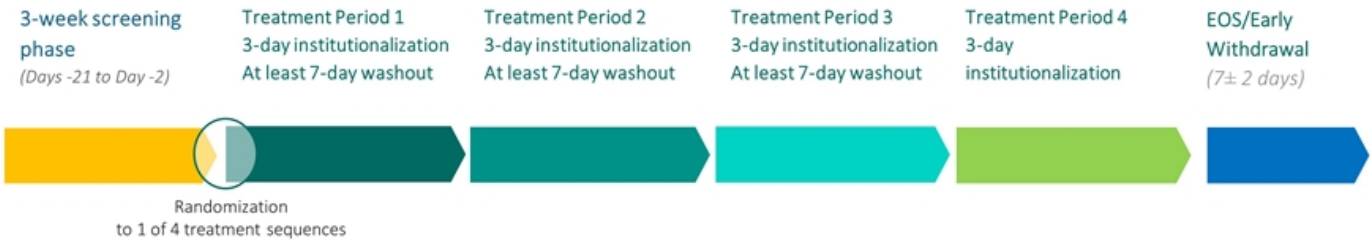
Pivotal BE study: Recap

Bioequivalence Study (MIN-101C15) Design Schema and Key Study Elements



Objectives	• Relative bioavailability of 64 mg single dose roluperidone Commercial (GR-01C) form relative to reference Phase 2b (MR-32) form in fasted state • Relative bioavailability of 64 mg single dose roluperidone Commercial (GR-01C) form relative to reference Phase 3 (GR-01B) form in fasted state • Relative bioavailability of 64 mg single dose roluperidone Phase 3 (GR-01B) form relative to reference Phase 2b (MR-32) form in fasted state • Relative bioavailability of 64 mg single dose roluperidone Commercial (GR-01C) form in fed state relative to fasted state
Primary Endpoints	The following key plasma PK parameters will be estimated using non-compartmental methods: C_{max}, T_{max}, AUC_{24}, AUC_{last}, AUC_{∞}, t_{lag}, $t_{1/2}$, CL, and V_d. The AUC parameters are the focus of the BA assessment, while both AUC and Cmax are the focus of the FE assessment
Other Endpoints	Safety & Tolerability
Main inclusion criteria	Healthy male or female subjects, CYP2D6 EM, Age 18-55
Number of subjects	48 subjects randomized to the 4 treatment sequences in a 1:1:1:1 ratio (12 per treatment sequence)
Sample Size Assumptions (preliminary)	Based on MIN-101 data and the standard BE boundaries of 0.80 to 1.25, and assuming AUC maximum intrasubject CV of 33%, ratio of log geometric mean of AUC of test to reference formulations of 1.03, correlation of 0.3, and power of 90%, a sample size of 36 subjects would be sufficient to establish bioequivalence between any 2 formulations or food conditions. This ratio will have a precision of 13.99 points and will fall within 89% and 120% of the true value with 90% confidence. Therefore, 48 subjects will be enrolled in the study to ensure that at least 36 subjects

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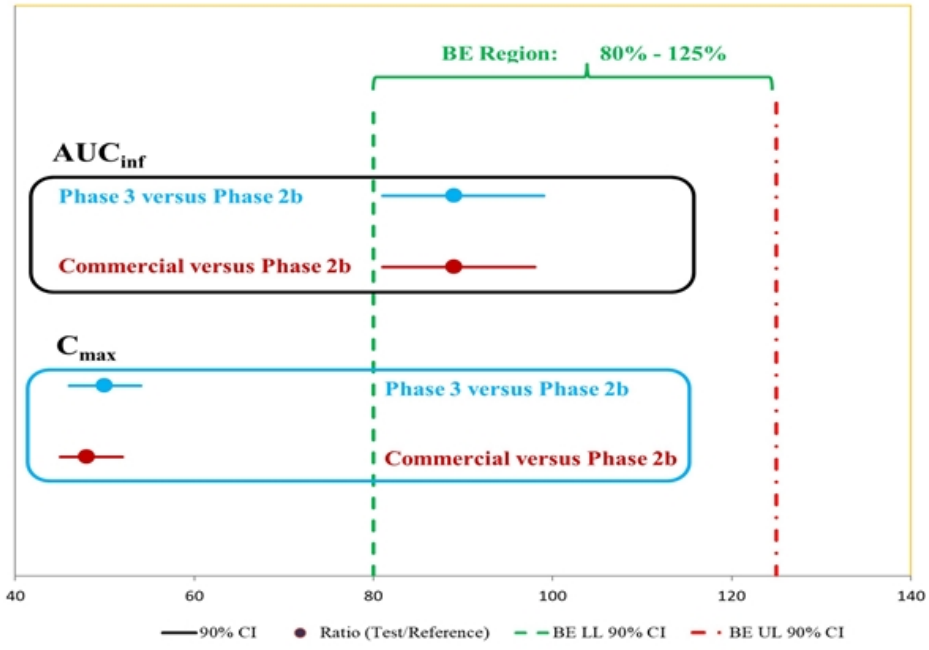
Bioequivalence Demonstrated for Key Parameters for Ph2b and Ph3 Formulations



MINERVA NEUROSCIENCES, INC.

Summary

Summary

Roluperidone **Negative Symptoms in Schizophrenia** **Regulatory Process**	▪ Phase 3 Double-Blind TLR data announced in May 2020 ▪ Phase 3 40 week OLE data announced in May 2021 ▪ Bioequivalence Study data announced in September 2021 ▪ Type C meeting scheduled ▪ NDA filing targeted H1 2022 (Subject to FDA feedback)
Seltorexant **MDD & Insomnia Symptoms**	▪ Phase 3 studies initiated by Janssen in 2020 ▪ Royalty rights sold to Royalty Pharma for $155m in Jan 2021 ($60m up-front) ▪ $95m future revenue dependent on clinical, regulatory & sales milestones
Cash	▪ $65.7m cash & cash equivalents at September 30th, 2021

MINERVA NEUROSCIENCES, INC.

Thank you

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