
**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): October 26, 2016

Minerva Neurosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36517
(Commission
File Number)

26-0784194
(I.R.S. Employer
Identification No.)

1601 Trapelo Road
Suite 284
Waltham, MA
(Address of principal executive offices)

02451
(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))
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Item 8.01 Other Events

On October 26, 2016, Minerva Neurosciences, Inc. (the “Company”) issued a press release announcing data from the 24-week open-label extension of its 12-week, randomized, double-blind, placebo-controlled Phase IIb clinical trial of MIN-101 as monotherapy in patients with negative symptoms of schizophrenia. A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and a copy of the Company’s presentation that includes supporting data for the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated October 26, 2016
99.2	Presentation of the Company dated October 26, 2016

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/ Mark S. Levine

Name: Mark S. Levine

Title: Senior Vice President, General Counsel and Secretary

Date: October 26, 2016

INDEX OF EXHIBITS

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Contact:

William B. Boni
VP, Investor Relations/
Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

FOR IMMEDIATE RELEASE

**MINERVA NEUROSCIENCES ANNOUNCES POSITIVE DATA FROM SIX-MONTH
EXTENSION OF PHASE IIB TRIAL OF MIN-101 MONOTHERAPY IN SCHIZOPHRENIA**

Data show continuous improvement in negative symptoms, stable positive symptoms and extended safety profile

Waltham, MA, October 26, 2016 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today announced data from the 24-week open-label extension of its 12-week, randomized, double-blind, placebo-controlled Phase IIB clinical trial of MIN-101 as monotherapy in patients with negative symptoms of schizophrenia. Data from the 12-week core phase of this trial were reported in May of this year.

Graphic representations of the data summarized below are available at <http://ir.minervaneurosciences.com/events.cfm> and contained in the Current Report on Form 8-K filed by Minerva on October 26, 2016.

“Data from the extension phase demonstrate a further and continuous improvement in negative symptoms in patients with schizophrenia, as measured by the negative symptom subscales of the Positive and Negative Syndrome Scale (PANSS),” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “The longer patients were on monotherapy with MIN-101, the greater improvement they were observed to experience in their negative symptoms during the entire extension period, without evidence of reaching a plateau. We believe that such continuous improvement in symptoms over a nine month period in this patient population is unprecedented.

“The data also provide an extended safety profile for MIN-101 consistent with that observed during the core double-blind phase of the trial,” said Dr. Luthringer. “MIN-101 was reported to be well tolerated at both doses over the entire 36-week duration of the study by schizophrenic patients. In addition, positive symptoms were observed to remain stable through the extension period as measured by the PANSS positive symptom subscale score. Improvements in overall schizophrenic psychopathology were also observed, as measured by the PANSS general psychopathology subscale and the total PANSS score.

“We believe these exciting data point the way toward pivotal testing of MIN-101 as a novel, differentiated treatment for the large worldwide population of patients with schizophrenia for whom negative symptoms contribute substantially to poor quality of life and functional outcomes,” said Dr. Luthringer.

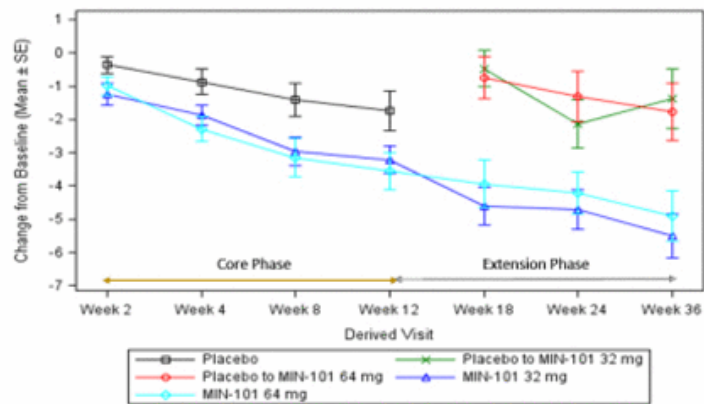
Results announced earlier this year from the double-blind, placebo-controlled 12-week core phase of the trial showed that it met its primary endpoint of statistically significant improvement in negative symptoms as measured by the PANSS pentagonal structure model (PSM), and showed statistically significant benefit in multiple secondary endpoints that included general psychopathology and cognition.

Patients who completed the core phase were provided the opportunity to enter into a 24-week, open-label extension phase. During the extension phase, all patients received either 32 milligrams (mg) or 64 mg of MIN-101. Patients who received placebo in the core phase were randomized to one of these two doses at the beginning of the extension phase. Data generated during the extension period were intended to provide longer term supportive evidence of efficacy and to complement the statistically significant results obtained during the core phase.

One hundred forty-two patients from the treatment and placebo groups in the core phase entered the extension phase, with 88 patients completing the extension. Seventy patients received 32 mg and 72 patients received 64 mg during the extension.

Negative symptoms, assessed based on the PANSS PSM, were observed to continue to improve during the extension phase, as shown by a reduction from the study start for the 32 and 64 mg-treated groups of 5.5 points and 4.9 points, respectively, and by a reduction of 5.4 points and 5.3 points, respectively, in the PANSS three factors negative symptoms subscale. Reductions over time of PANSS negative PSM scores are shown in the attached graph.

MIN-101C03: Negative Symptoms (Pentagonal Structure)



Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

Positive symptoms were observed to remain stable throughout the study, as measured by PANSS positive symptom scores. This finding is consistent with the hypothesis that MIN-101 has a direct and specific effect on negative symptoms.

General psychopathology was observed to improve during the extension phase for the 32 and 64 mg groups, as shown by reductions in the PANSS general psychopathology subscale score and total PANSS score.

MIN-101 was generally reported to be well tolerated through the entire 36-week period. QTcF, a measurement of cardiac function, was closely monitored throughout the study, and discontinuation criteria based on QTcF prolongation were incorporated in the protocol. As previously announced, two patients out of 162 who received MIN-101 in the core phase were discontinued based upon these criteria; both of these patients received the higher dose (64 mg). In the extension phase no additional patients were discontinued. The extension data also confirm that MIN-101 at the doses tested did not have an effect on extrapyramidal symptoms (EPS), prolactin or weight gain.

About MIN-101

MIN-101 is a drug candidate with equipotent affinities for sigma 2 and 5-hydroxytryptamine-2A (5-HT_{2A}) and lower affinity at α 1-adrenergic receptors. MIN-101 has no direct dopaminergic post-synaptic blocking effects, known to be involved in some side effects like extrapyramidal symptoms, sedation, prolactin increases and weight gain.

About Schizophrenia and Negative Symptoms

As described by the National Institute of Mental Health, schizophrenia is a chronic and severe disorder that affects how a person thinks, feels and acts¹. In 2015 approximately 3.2 million people suffered from schizophrenia in the U.S., Japan and the five major European markets. Schizophrenic patients suffer from positive, negative and cognitive symptoms. Negative symptoms are disruptions to normal emotions and behaviors that may signal social withdrawal. Patients may be socially inhibited, lack the ability to begin and sustain planned activities, or speak little even when forced to interact. Negative symptoms account for a substantial portion of the morbidity associated with schizophrenia². They persist chronically throughout an individual patient's lifetime and increase with severity over time.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, which recently completed a Phase IIb clinical trial for schizophrenia; MIN-117, which recently completed a Phase IIa clinical trial development for MDD; MIN-202 (JNJ-42847922), which recently completed Phase IIa and Phase Ib clinical trials for insomnia and MDD, respectively; and MIN-301, in pre-clinical development for Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

Forward-Looking Safe Harbor Statement

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 results of future clinical milestones with MIN-101; the clinical and therapeutic potential of MIN-101; our ability to successfully develop and commercialize MIN-101; 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

¹ <https://www.nimh.nih.gov/health/publications/schizophrenia-booklet-12-2015/index.shtml>

² Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, American Psychiatric Association.

including, without limitation, whether MIN-101 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 the results of future clinical trials of MIN-101, if any, will be consistent with the results of past clinical trials; whether MIN-101 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts with MIN-101 will be successful; our ability to achieve the results contemplated by our co-development agreements; 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 June 30, 2016, filed with the Securities and Exchange Commission on August 4, 2016. 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.



MIN-101C03 Update with Open Label, Extension Phase Data

October 26, 2016

Forward-Looking Statement Safe-Harbor

This presentation contains certain forward-looking statements about Minerva Neurosciences that are intended to be covered by the safe harbor for “forward-looking statements” provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as “expect(s),” “feel(s),” “believe(s),” “will,” “may,” “anticipate(s)” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to: the benefits, efficacy and safety of our new formulations; whether studies performed on analogs or backups of our compounds are a good predictor of the clinical efficacy of our compounds; the timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials; statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; our expectations regarding approval for our products by the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; estimates regarding the market potential for our products; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, but are not limited to: the benefits, efficacy and safety of our new formulations; whether analogs or backups of our compounds are a good predictor of the clinical efficacy of our compounds; the timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials; whether any of our therapeutic candidates will advance further in the clinical trials process and whether and when, if at all, they 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 candidates will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim reports filed with the Securities and Exchange Commission which are available on the SEC website at www.sec.gov. Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

MIN-101C03: Patient Disposition

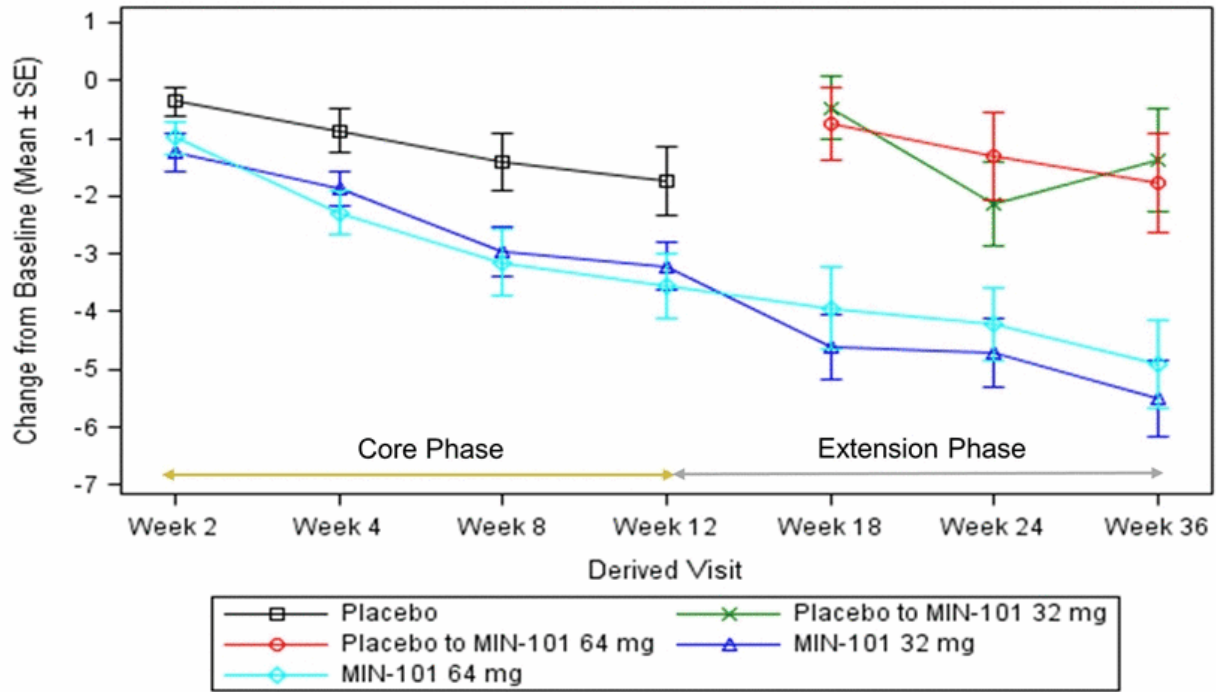
	Placebo ¹	Placebo to MIN-101 ²			MIN-101			Overall
		32 mg	64 mg	Total	32 mg	64 mg	Total	
Screened Population								N' = 342
Subjects Screened But Not Randomized								98 (28.7%)
Randomized Population		42	41	83	78	83	161	244
Safety Population	N" = 39	N" = 25	N" = 19	N" = 44	N" = 78	N" = 83	N" = 161	N" = 244
Intent-to-Treat (ITT) Population	35 (89.7%)	25 (100.0%)	19 (100.0%)	44 (100.0%)	76 (97.4%)	79 (95.2%)	155 (96.3%)	234 (95.9%)
Per Protocol (PP) Population	9 (23.1%)	25 (100.0%)	19 (100.0%)	44 (100.0%)	48 (61.5%)	52 (62.7%)	100 (62.1%)	153 (62.7%)
Subjects Completed Double-Blind Phase and Entered Open-Label Phase	0 (0.0%)	25 (100.0%)	19 (100.0%)	44 (100.0%)	45 (57.7%)	53 (63.9%)	98 (60.9%)	142 (58.2%)
Subjects Completed the Study	0 (0.0%)	15 (60.0%)	13 (68.4%)	28 (63.6%)	28 (35.9%)	32 (38.6%)	60 (37.3%)	88 (36.1%)

¹ Patients treated with placebo during double-blind phase but did not participate in open-label extension part of the study

² Patients treated with placebo during double-blind phase and crossed-over to MIN-101 in open-label extension part of the study

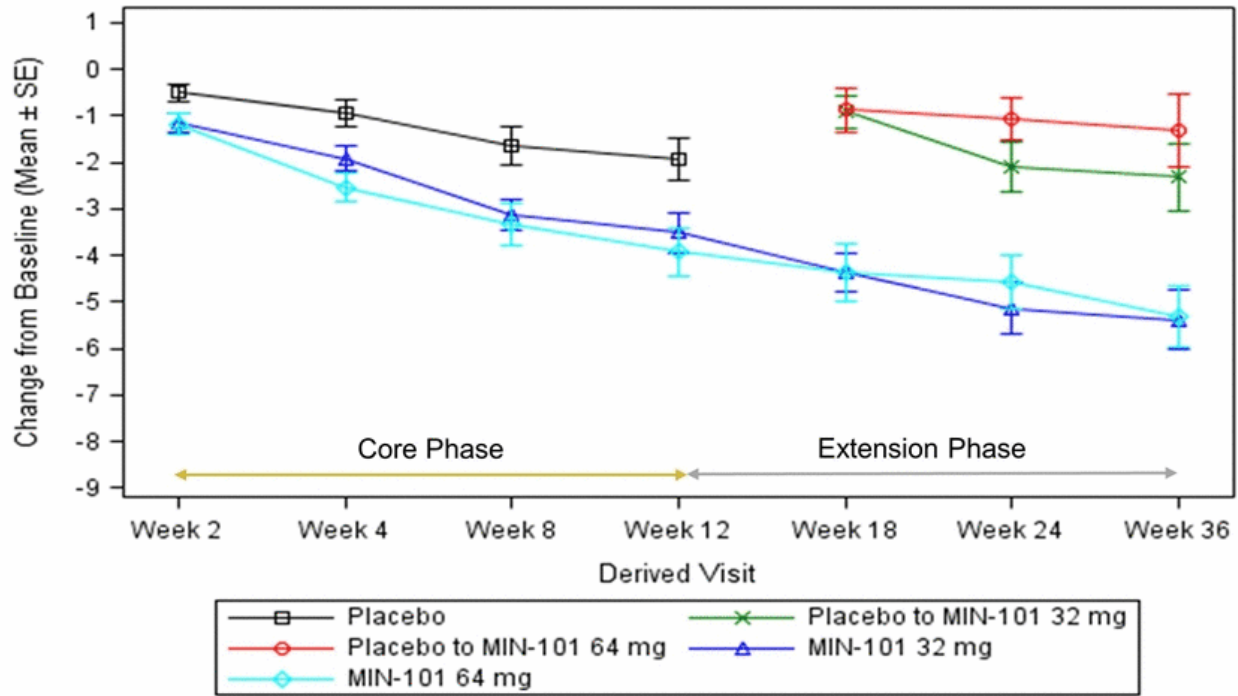
Baseline for Patients
who Crossed from
Placebo to MIN-101 is
Start of Open Label
(Week 12)

MIN-101C03: Negative Symptoms (Pentagonal Structure)



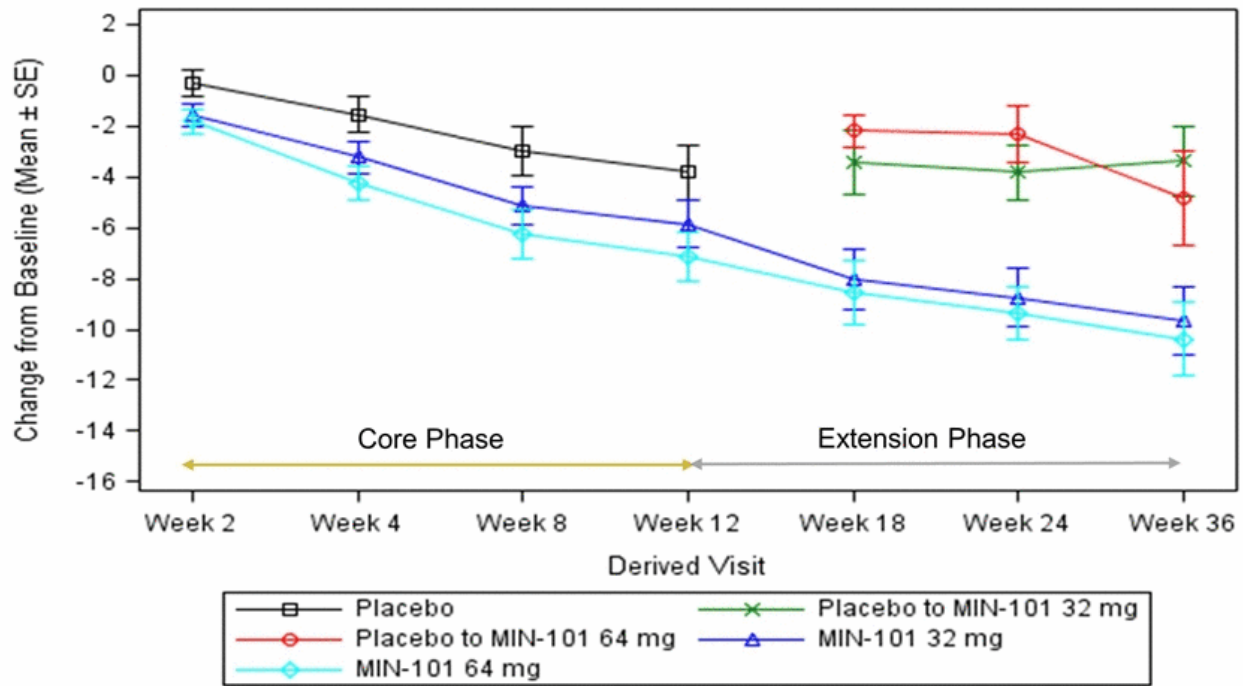
Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

MIN-101C03: Negative Symptoms (3-Factors)

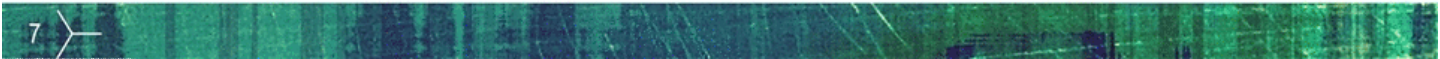


Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

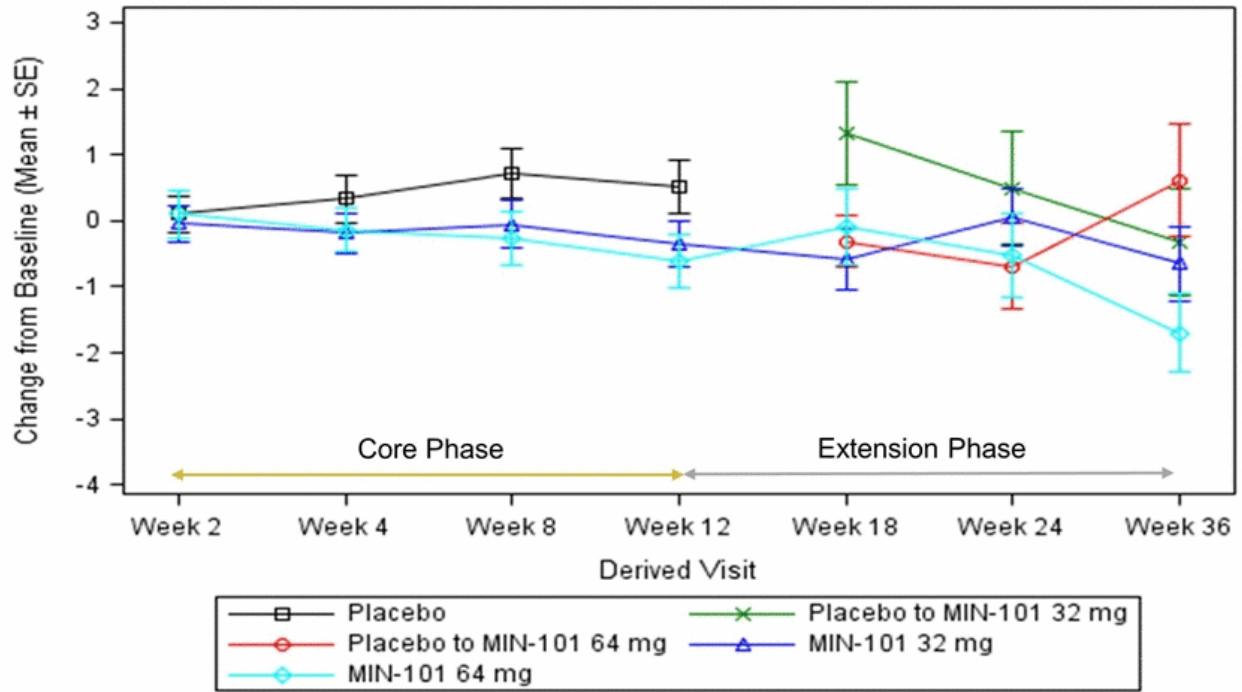
MIN-101C03: Brief Negative Symptom Score



Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

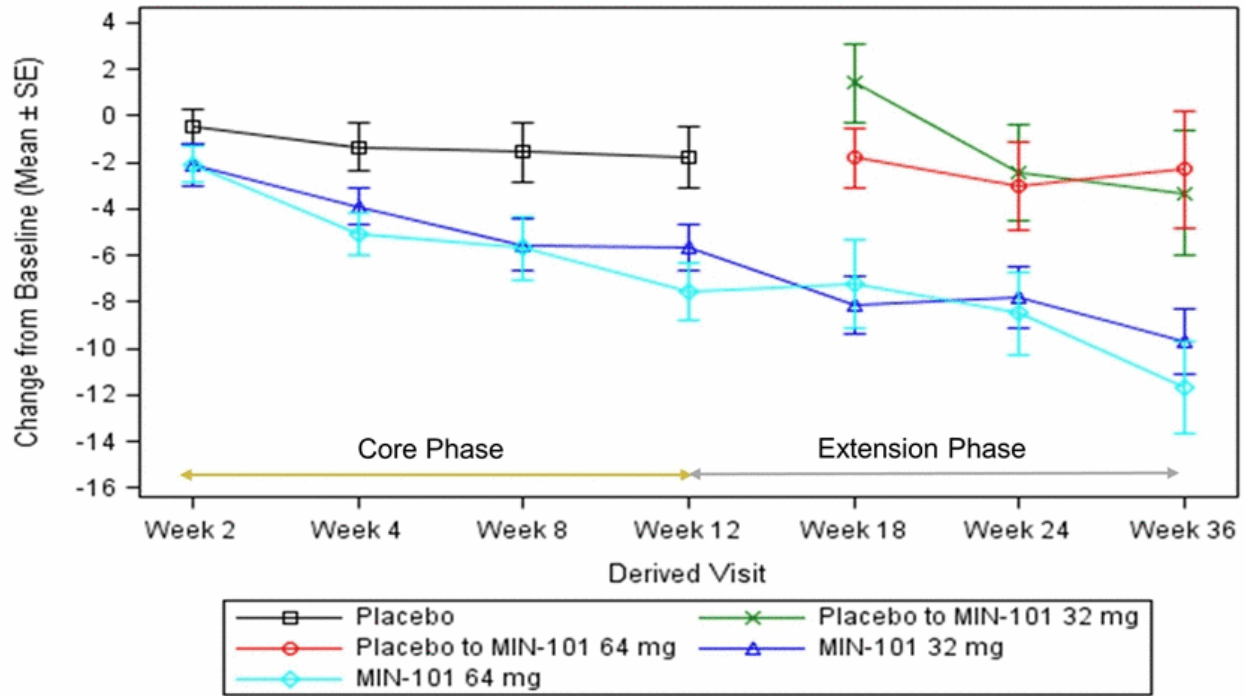


MIN-101C03: Positive Symptoms (3-Factors)



Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

MIN-101C03: Total PANSS



Baseline for Placebo-to-MIN-101 is From Start of Open Label (Week 12)

Safety Results Findings

MIN-101C03: Common Adverse Events (≥ 5% of Patients)

System Organ Class Preferred Term	Placebo ¹ (N = 83)	MIN-101 ²			Overall (N = 244)
		32 mg (N = 103)	64 mg (N = 102)	Total (N = 205)	
Subjects with Any Common TEAE	20 (24.1%)	24 (23.3%)	29 (28.4%)	53 (25.9%)	69 (28.3%)
Investigations	0 (0.0%)	0 (0.0%)	6 (5.9%)	6 (2.9%)	6 (2.5%)
Electrocardiogram QT prolonged	0 (0.0%)	0 (0.0%)	6 (5.9%)	6 (2.9%)	6 (2.5%)
Nervous system disorders	3 (3.6%)	9 (8.7%)	8 (7.8%)	17 (8.3%)	19 (7.8%)
Headache	3 (3.6%)	9 (8.7%)	8 (7.8%)	17 (8.3%)	19 (7.8%)
Psychiatric disorders	18 (21.7%)	17 (16.5%)	18 (17.6%)	35 (17.1%)	50 (20.5%)
Anxiety	5 (6.0%)	8 (7.8%)	7 (6.9%)	15 (7.3%)	19 (7.8%)
Insomnia	8 (9.6%)	7 (6.8%)	8 (7.8%)	15 (7.3%)	22 (9.0%)
Schizophrenia	9 (10.8%)	4 (3.9%)	7 (6.9%)	11 (5.4%)	19 (7.8%)

¹ Patients treated with placebo during double-blind phase for 3-Month

² All patients treated with MIN-101 including patients previously treated with placebo during double-blind phase and crossed-over to MIN-101 in open-label extension part of the study