
**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): December 3, 2014

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 December 3, 2014, Minerva Neurosciences, Inc. (the “Company”) announced the completion of its development and final selection of a once-daily dose formulation of MIN-101 for its schizophrenia program. The new formulation will be used in the Company’s planned Phase 2b clinical trial in schizophrenia, scheduled to begin recruiting in the first half of 2015.

A copy of the Company’s press release regarding the information referenced above is filed as Exhibit 99.1 to this Current Report on Form 8-K.

A copy of the Company’s updated corporate 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 issued by Minerva Neurosciences, Inc., dated December 3, 2014.
99.2	Presentation of Minerva Neurosciences, Inc.

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: Vice President, General Counsel and Secretary

Date: December 3, 2014

INDEX OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Minerva Neurosciences, Inc., dated December 3, 2014.
99.2	Presentation of Minerva Neurosciences, Inc.

**MINERVA NEUROSCIENCES ANNOUNCES COMPLETION OF DEVELOPMENT
AND FINAL SELECTION OF ONCE-DAILY DOSE FORMULATION OF MIN-101 FOR ITS
SCHIZOPHRENIA PROGRAM**

New formulation to be used in planned Phase 2b clinical trial has been developed to offer improved safety, tolerability and pharmacokinetic profile

WALTHAM, Mass., December 3, 2014 (GLOBE NEWSWIRE) – Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat neuropsychiatric diseases and disorders, today announced the completion of development and final selection of a once-daily dose formulation of MIN-101, an antagonist on 5-HT_{2A} and Sigma₂ receptors for the treatment of schizophrenia. The new formulation will be used in the Company’s planned Phase 2b clinical trial in schizophrenia, scheduled to begin recruiting in the first half of 2015.

“The development and final selection of this once-daily formulation of MIN-101 represents an important milestone in our plan to develop a formulation of MIN-101 to achieve optimal efficacy, safety, tolerability and pharmacokinetic profiles,” said Dr. Remy Luthringer, chief executive officer and president of Minerva. “We are especially encouraged by the pharmacokinetic parameters of this formulation and believe it has the ability to address significant areas of unmet need in the treatment of negative symptoms, cognitive impairments and sleep disorders.”

The administration trial objectives were to develop a formulation of MIN-101 to allow for chronic daily administration by maintaining daily exposure of the compound and keeping the maximum plasma concentration (C_{max}) and its two active metabolites (BFB-520 and BFB-999) below a level based on previous pharmacokinetic/pharmacodynamics analyses. The trial results show that the final formulation of MIN-101 lowers levels of BFB-520, which has been previously associated with prolongation of QT intervals at supra-therapeutic levels.

“We believe that this new once-daily formulation will be able to maintain plasma levels of MIN-101 over the course of one day while reducing BFB-520 levels and increasing levels of BFB-999 associated with sleep improvements due to its affinity to 5-HT_{2A} and histaminergic H₁ receptors,” added Dr. Luthringer.

About The Study

The new formulation was assessed in a single-center, open-label trial to evaluate the safety, tolerability and pharmacokinetic profiles of several formulations of MIN-101 in a single dose administration setting. Plasma levels of parent compound MIN-101 as well as of the two main metabolites (BFB-520 and BFB-999) were assessed in 12 young healthy volunteers, who received three different formulations of MIN-101. Six adverse reactions of mild to moderate intensity were reported in five subjects: sleepiness (2); headache (3); and blurred vision (1). QT_c measures stayed in the recommended values as given by ICH-E14 on Clinical Evaluation of QT/QT_c Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs.

About Schizophrenia

Patients suffering with schizophrenia can present with a range of symptoms, including: positive symptoms, such as delusions, hallucinations, thought disorders, and agitation; negative symptoms, such as mood flatness and lack of pleasure in daily life; cognitive symptoms, such as the decreased ability to understand information and make decisions, difficulty focusing, and decreased working memory function; and sleep disorders. Most currently approved therapies for schizophrenia show efficacy primarily in the management of positive symptoms. An estimated 4.2 million people suffered from schizophrenia in 2012 in the United States and the five major European Union markets. Of those, an estimated 48% experienced predominantly negative symptoms and 80% suffered from cognitive impairment. In addition, about 50% of patients with schizophrenia experience sleep disorders, which can further exacerbate both positive and negative symptoms.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat neuropsychiatric diseases. Minerva is developing a portfolio of first-in-class proprietary compounds, including lead compound MIN-101, which is in Phase 2 trials for schizophrenia, and additional candidates targeting major depressive disorder (MDD), insomnia and other CNS disorders. Minerva's common stock is listed on the NASDAQ Global Market where it trades 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 benefits, efficacy and safety of the new once-a-day formulation of MIN-101; timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials regarding MIN-101; clinical and therapeutic potential of MIN-101 and our ability to successfully develop and commercialize MIN-101; and management's ability to successfully achieve its goals. These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-101 or any of our other therapeutic products 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 MIN-101 and our other therapeutic products will be successfully marketed if approved; whether any of our other therapeutic product discovery and development efforts 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 September 30, 2014, filed with the Securities and Exchange Commission on November 6, 2014. Copies of reports filed with the SEC are posted on our website. 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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Source: Minerva Neurosciences, Inc.

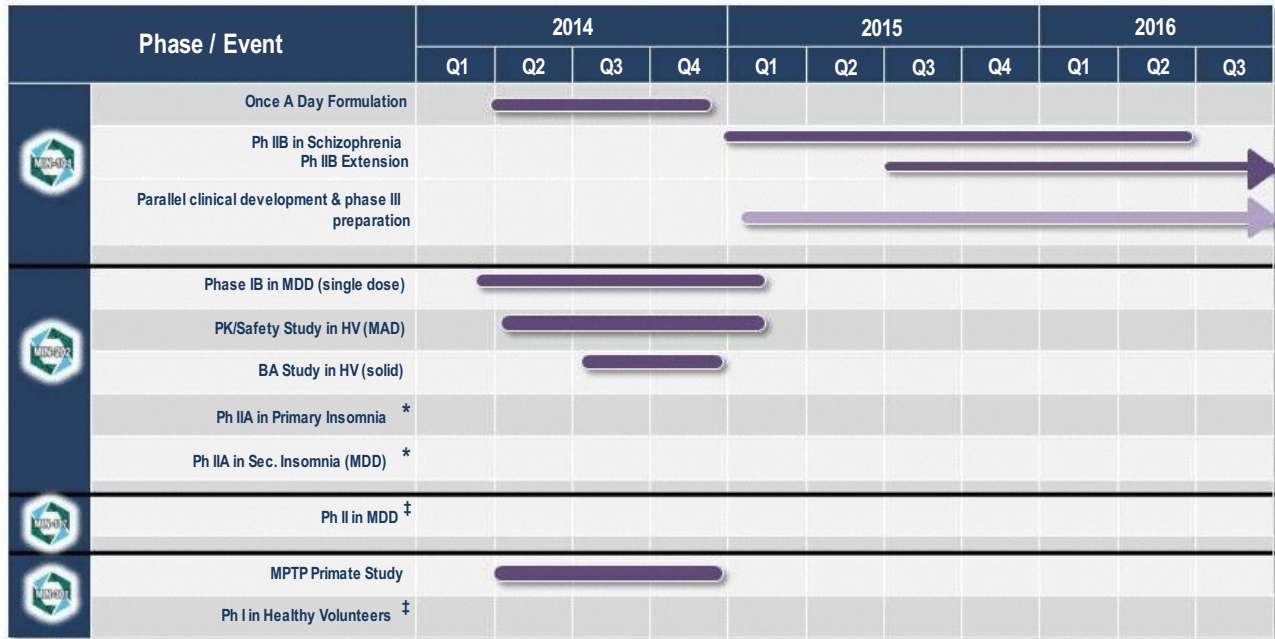


Minerva Neurosciences, Inc.
1601 Trapelo Road, Suite 284, Waltham, MA
02451

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 the new once-a-day formulation of MIN-101; 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 the new once-a-day formulation of MIN-101; 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.



End of bar = expected availability of topline results

[Bar with arrow] Subject to additional financing

* TBC – subject to Ph1 results

‡ Planning in progress; subject to additional financing

MIN-101

R&D update

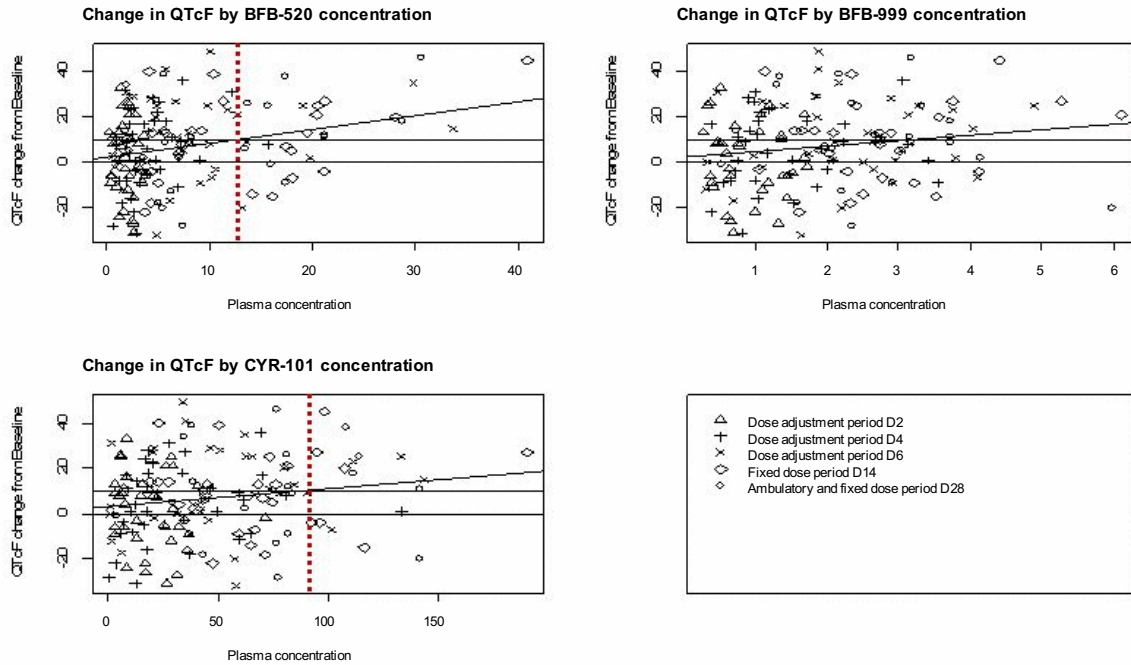
- Once a day formulation results
- Phase IIB study design

MIN-101C02

Study Title:

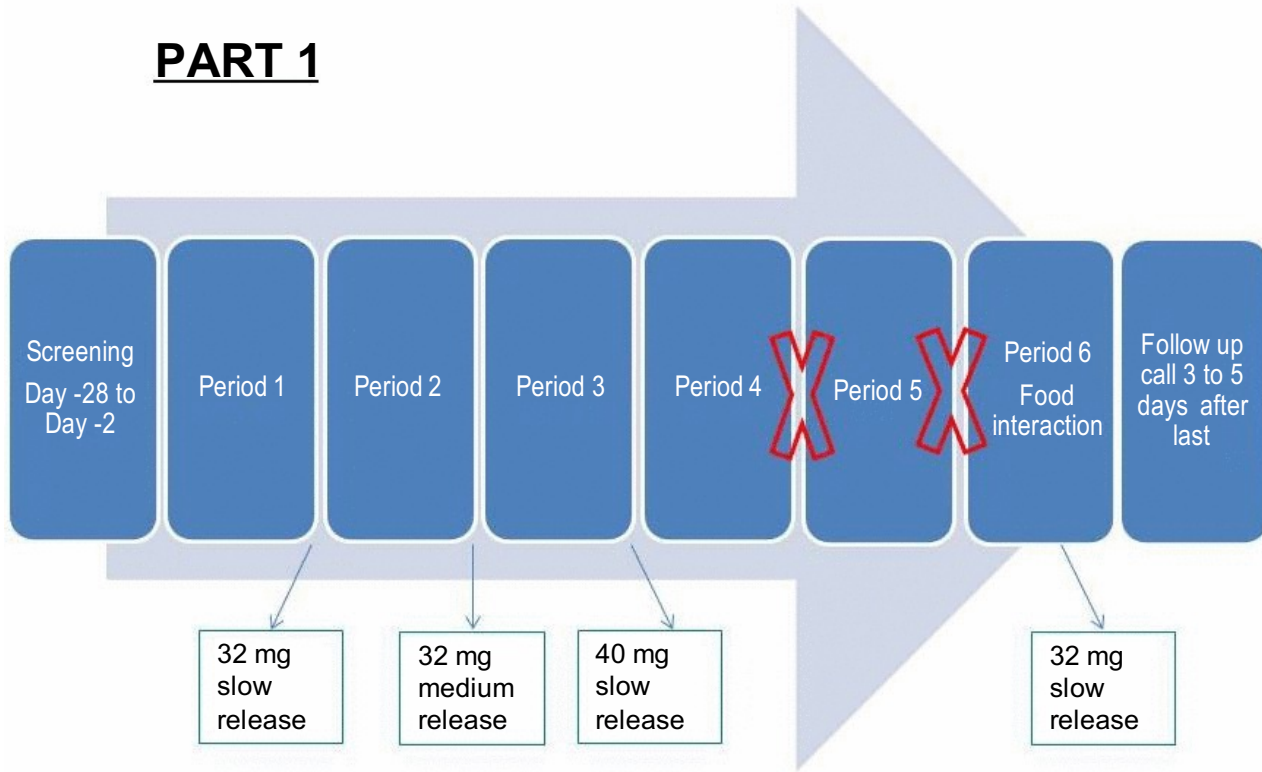
A Two-Part Study Designed to Evaluate the Pharmacokinetic Profile of MIN-101 and its Main Metabolites Following Single and Multiple Dose Modified Release Prototype Formulation Administration in Healthy CYP2D6 Extensive Metaboliser Male and Female Subjects, and to Evaluate the Relationship Between the Pharmacokinetic Profile of MIN-101 and its Main Metabolites and Cardiovascular Parameters

Exposure levels not to exceed....

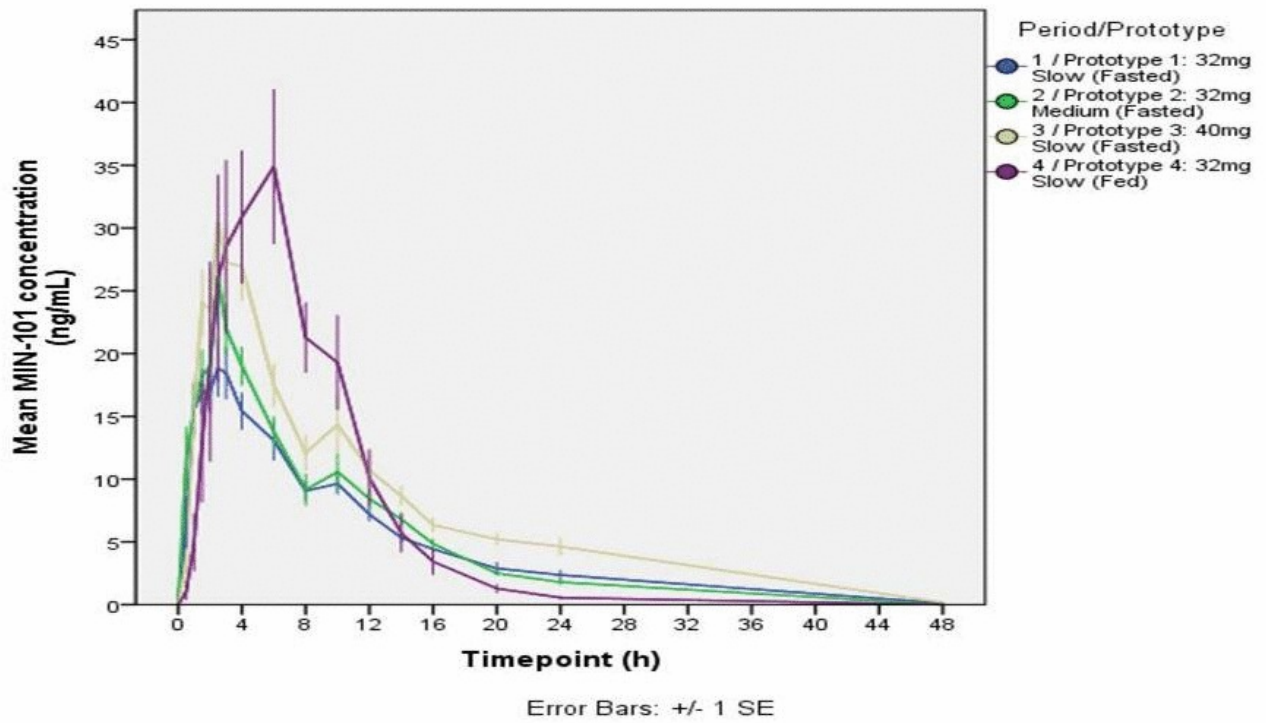


2 subjects with outlying values removed

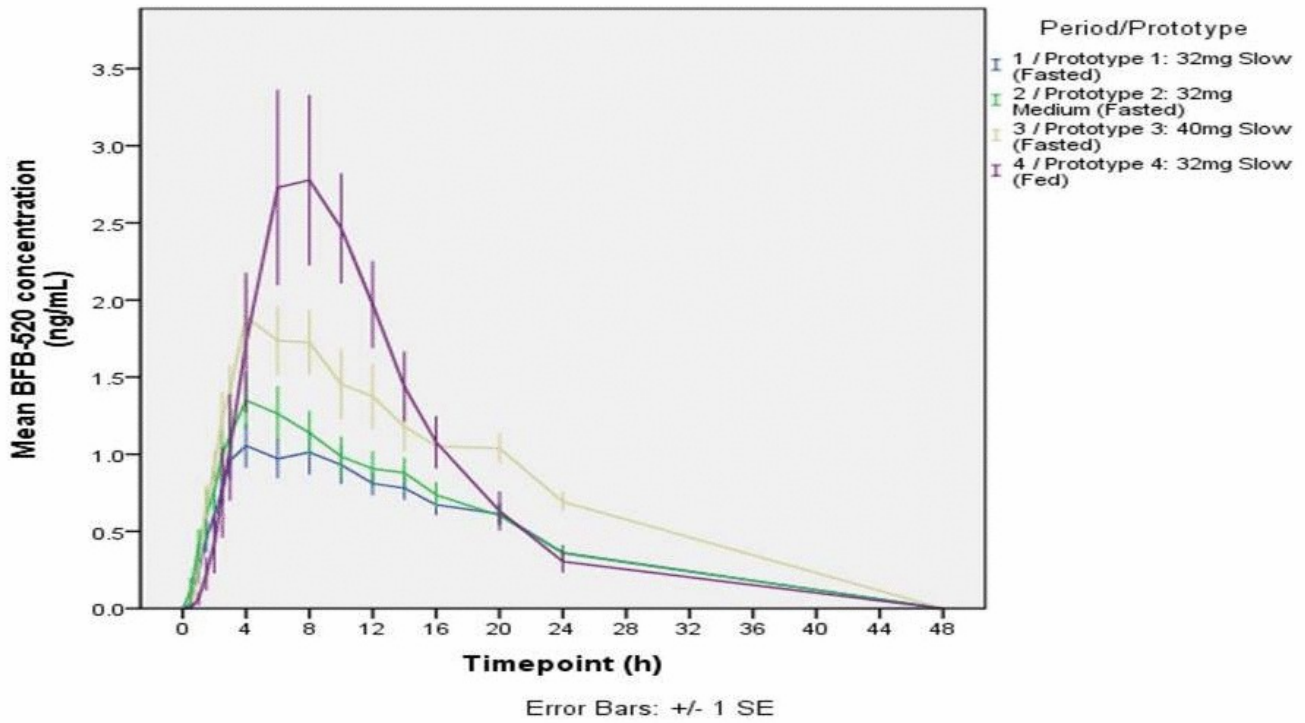
PART 1



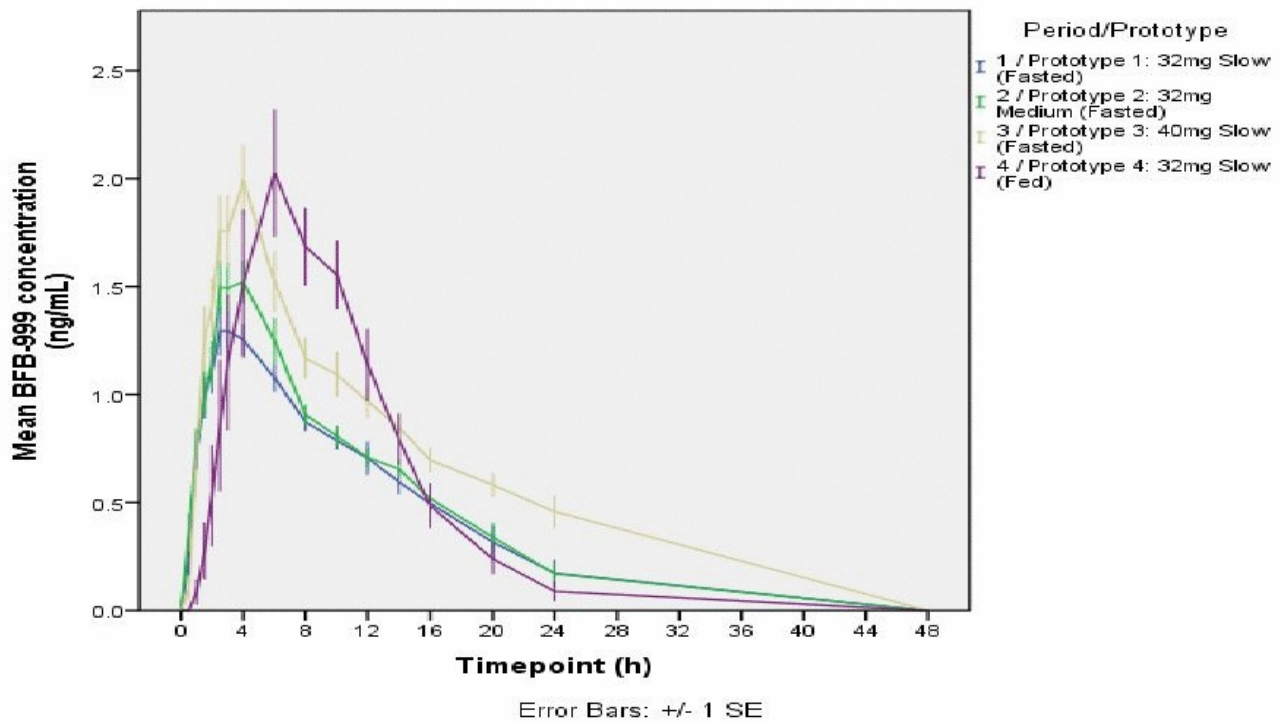
Plasma Concentration-Time Profiles: MIN-101 Linear Scale



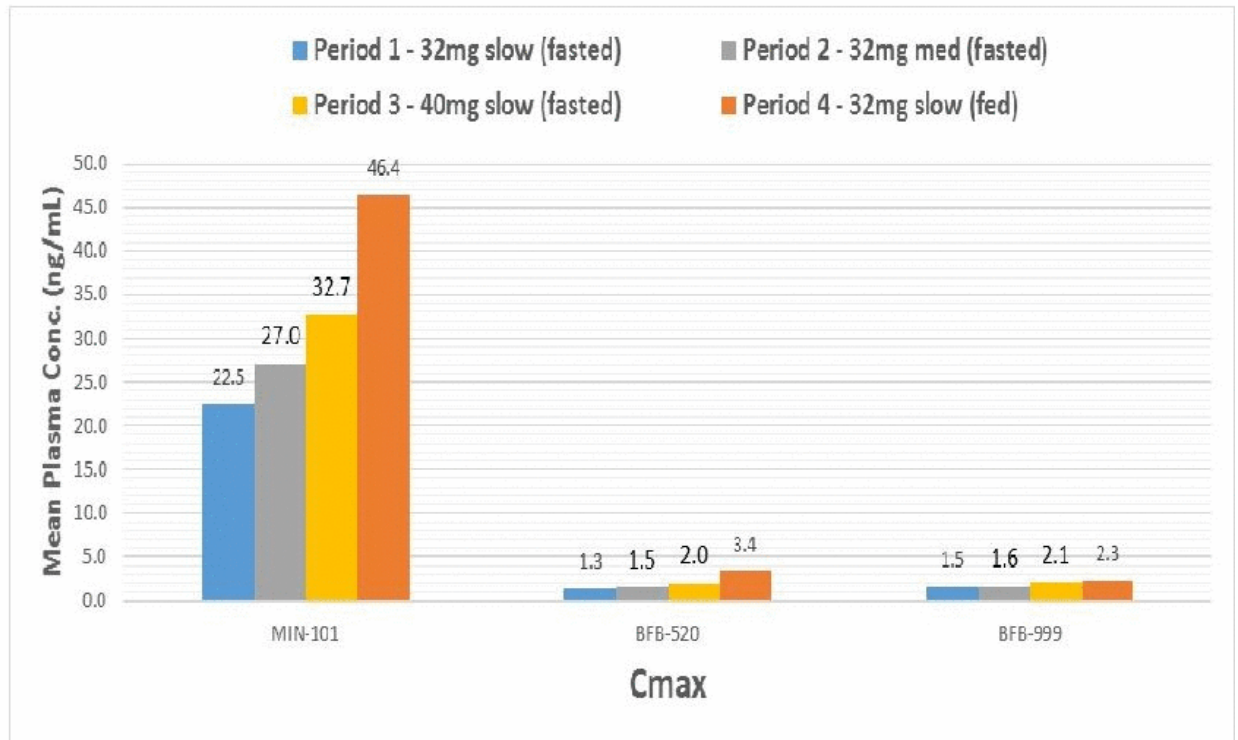
Plasma Concentration-Time Profiles: BFB-520 Linear Scale



Plasma Concentration-Time Profiles: BFB-999 Linear Scale



C_{max} by Period



Summary of Select PK Parameters -Period 1 (32 mg Slow Release, Fasted)

MIN-101	Tmax (h)	Cmax (ng/mL)	Tlag (h)	t1/2 (h)	AUClast (h*ng/mL)
N	10	10	10	9	10
Mean	NA	22.52	NA	6.257	211.9
Median	2.25	23.74	0	5.353	220.4
CV%	NA	28.3	NA	38.1	18.6

BFB-520	Tmax (h)	Cmax (ng/mL)	Tlag (h)	t1/2 (h)	AUClast (h*ng/mL)
N	10	10	10	4	10
Mean	NA	1.321	NA	6.540	18.60
Median	4	1.294	0.5	6.458	18.04
CV%	NA	27.7	NA	21.1	24.7

BFB-999	Tmax (h)	Cmax (ng/mL)	Tlag (h)	t1/2 (h)	AUClast (h*ng/mL)
N	10	10	10	5	10
Mean	NA	1.510	NA	6.202	16.02
Median	3	1.436	0.25	5.486	15.22
CV%	NA	19.5	NA	27.3	22.3

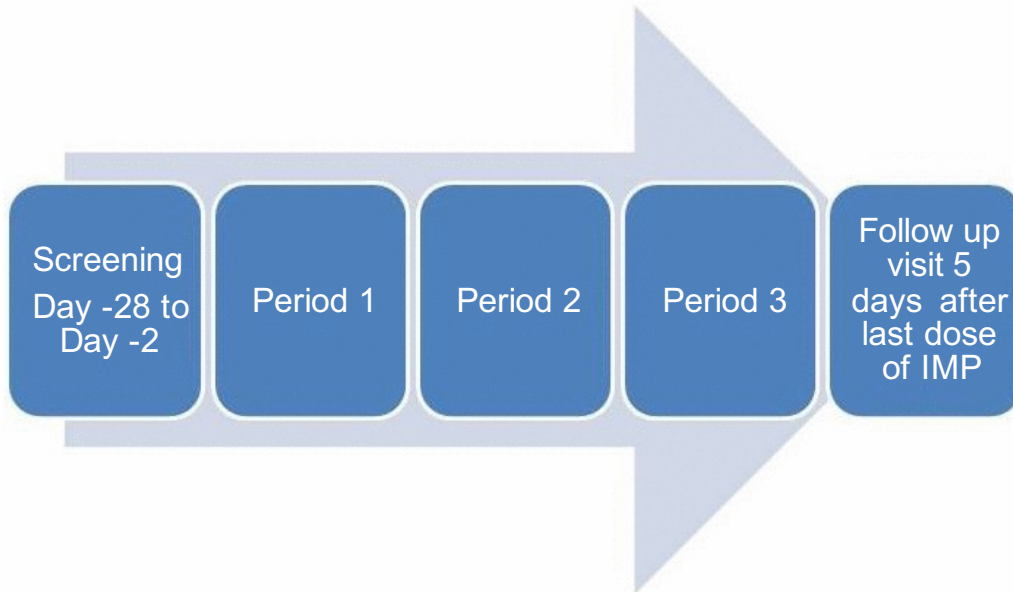
- Short lag time suggestive of fast bioavailability
- Exposure variability is generally low
- Low to non-quantifiable values for most by Hour 24
- PK is generally dose proportional for MIN-101 & BFB-999, and less so for BFB-520
- Inversion of BFB-520 & BFB-999 occurred with generally suppressed levels of BFB-520, and a higher BFB-999 to BFB-520 ratio
- MR formulation findings suggest shorter time in small intestine is helpful in suppressing BFB-520 levels
- Half-life for MIN-101 and 2 metabolite in 3-8 hour range, longer for 40 mg slow release most likely due to flip-flop (absorption & elimination balanced during terminal phase)
- Simulation results indicate steady state within 10-14 days, and no accumulation for all 3 analytes

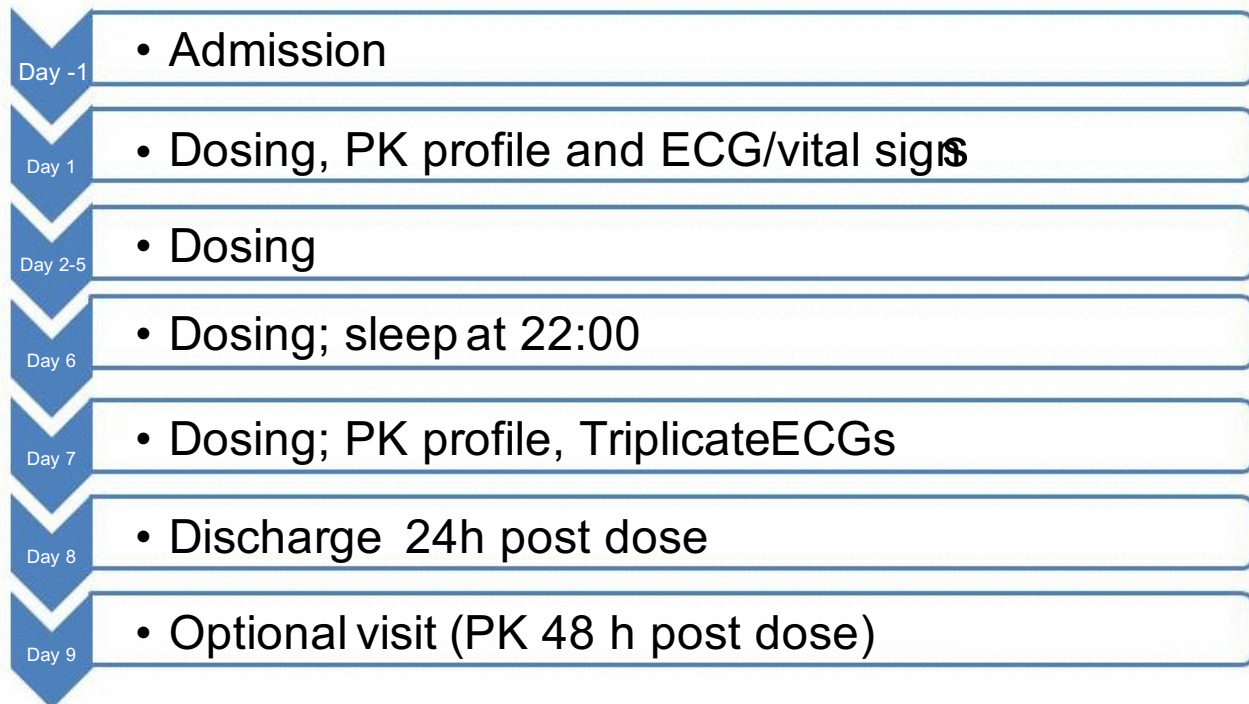
- Positive food effect evident -Higher exposure
- MR formulation behaved similar to IR formulation with rapid release and absorption, mostly prior to reaching colon
 - This explains further increase in BFB-520 levels
- Due to rapid absorption MIN-101 Cmax increase was ~ 2x, BFB-520 Cmax increase was ~ 3x, and BFB-999 Cmax increase was ~ 0.5x
- Half-life was shortened substantially: Fed to Fasted ratios were
 - 0.5 for MIN-101
 - 0.8 for BFB-520
 - 0.6 for BFB-999
- Consequently, accumulation is not expected
- AUC increase was minimal (compared to Cmax): 1.3 to 1.8 multiples with highest increase to BFB-520

32 mg slow release in fasted condition
will be the formulation used in the C03 upcoming patient
study in patients suffering from schizophrenia

Study Part 2:

16 and 32 mg will be explored



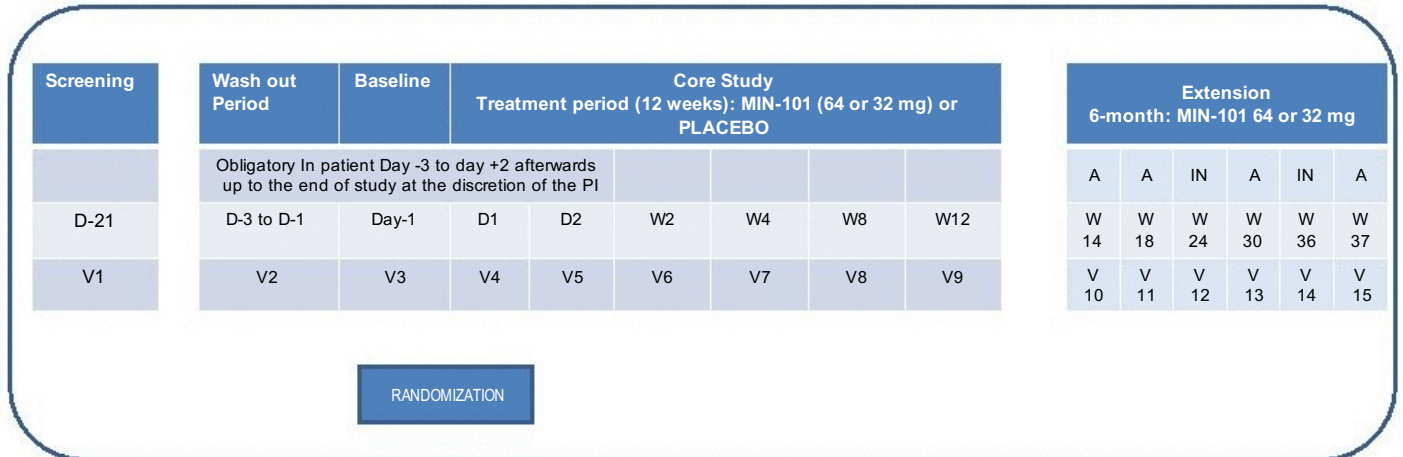


MIN-101C03

Study Title:

A Phase IIB, Multi-centre, Randomized, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate the Efficacy, Tolerability and Safety of MIN-101 in Patients with Negative Symptoms of Schizophrenia Followed by a 24-week, Open-label extension.

Global Study Design



Primary

To evaluate the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenia as measured by the **change from Baseline in the Positive and Negative Syndrome Scale (PANSS) negative subscale score of the pentagonal model over 12 weeks of treatment.**

Main Secondary

- To evaluate the efficacy of MIN-101 compared to placebo in improving other symptoms of schizophrenia as measured by the change from baseline in the **PANSS total score, and sub-scores** of the **pentagonal model AND 3 factors** analysis over 12 weeks of double blind treatment.
- To evaluate the efficacy of MIN-101 compared to placebo in improving negative symptoms of schizophrenia as measured by the change from Baseline in the **Brief Negative Symptoms Scale (BNSS)** total score over 12 weeks of double blind treatment.
- To assess the effects versus placebo of MIN-101 on cognitive function as measured by the **Brief Assessment of Cognition in Schizophrenia (BACS)** battery over 12 weeks of double blind treatment.
- To assess the persistence of efficacy, and the safety and tolerability of MIN-101 during the 24-week, of open-label extension phase.

Exploratory objectives

- To evaluate the effects versus placebo of MIN-101 on **depressive symptoms** as measured by the Calgary Depression Scale for Schizophrenia (CDSS) over 12 weeks of double blind treatment.
- To evaluate the effects versus placebo of MIN-101 on **social functioning** by means of the Personal and Social Performance (PSP) over 12 weeks of double blind treatment.
- To assess the effects versus placebo of MIN-101 on **sleep architecture and continuity** as measured with the help of the V-Watch methodology over 12 weeks of double blind treatment.

Main Inclusion Criteria

- Male or female patient, 18 to 60 years of age, inclusive.
- Patient meets the diagnostic criteria for schizophrenia as defined in the Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-V)
- Patient being stable in terms of positive symptoms over the last three months according to his treating psychiatrist
- Patient presenting with negative symptoms over the last three months according to his treating psychiatrist
- Patient with PANSS negative sub-score of at least 20.
- Patient with PANSS item score of <4 on: P4 Excitement, hyperactivity P7 Hostility P6 Suspiciousness G8 Uncooperativeness G14 Poor impulse control
- No change in psychotropic medication during the last month
- Patient must be extensive metabolizers for P450 CYP2D6, as determined by genotyping test before the first drug dose is administered.

Main Exclusion Criteria

- Current bipolar disorder, panic disorder, obsessive compulsive disorder, or evidence of mental retardation.
- Patient's condition is due to direct physiological effects of a substance (e.g., a drug of abuse, or medication) or a general medical condition.
- Significant risk of suicide or attempted suicide, or of danger to self or others.
- Patient who cannot be discontinued from psychotropics other than those allowed.
- Patient who received clozapine within 6 months of the Screening visit.
- Patient receiving treatment with depot antipsychotic medication can be enrolled in the study 4 weeks after the last injection.
- Patient with a history of significant other major or unstable neurological, neurosurgical (e.g., head trauma), metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, metabolic, gastrointestinal, or urological disorder.
- Patient with a clinically significant electrocardiogram (ECG) abnormality that could be a safety issue in the study, including QT interval value corrected for heart rate using the Fridericia's formula (QTcF) > 430 msec for males and > 450 msec for females.

- Main Efficacy Assessments
 - Positive and Negative Symptoms Scale (**PANSS**)
 - Brief Negative Symptoms Scale (**BNSS**): semi structured interview, designed to measure the current level of severity of negative symptoms in schizophrenia and schizoaffective disorder (Kirkpatrick et al.)
 - Anhedonia
 - Distress
 - Asociality
 - Avolition
 - Blunted affect
 - Alogia
 - Brief Assessment of Cognition in Schizophrenia (**BACS**)
 - Personal and Social Performance (**PSP**): assess social functioning; clinician rated
 - socially useful activities,
 - personal and social relationships,
 - self-care
 - disturbing and aggressive behavior
 - **Sleep architecture and continuity**

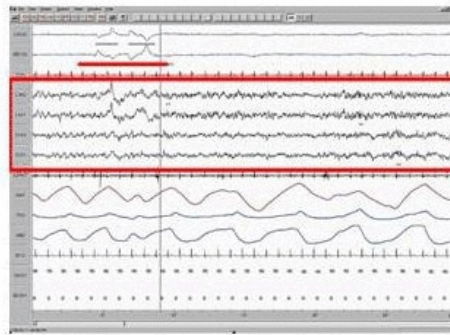
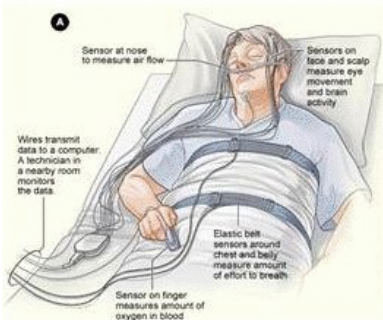
WHY?

- Sleep and circadian rhythm disruptions are reported in 30% to 80% of patients with schizophrenia.
- Patients with insomnia report
 - lower quality of life
 - greater symptom severity
 - worse adherence/compliance to treatment
- Sleep disturbances have also been associated with enhanced psychosis
- Sleep is important for memory consolidation, thus disturbances in sleep architecture, or circadian de-synchronization could also contribute to the cognitive impairment observed in schizophrenia.
- MIN-101 showed effects on sleep architecture in the previous Phase 2a study that could possibly be linked to the improvements observed on negative symptoms and cognition, thus they will be further investigated in the present study.
 - In a subgroup of patients (20) who underwent sleep recordings (PSG), sleep was evaluated at Baseline and Day 14. MIN-101 had an effect on
 - Slow Wave Sleep (SWS) distribution: it shifted SWS from the end to the beginning of the night: MIN-101 significantly increased SWS in the first third of the night and decreased it in the last third of the night.
 - Sleep initiation parameters (sleep onset latency, latency to persistent sleep).
 - Subjective sleep quality as measured by PSQI improved and this improvement was greater with MIN-101 than with placebo although not statistically significant.

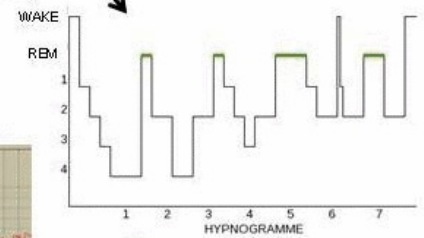
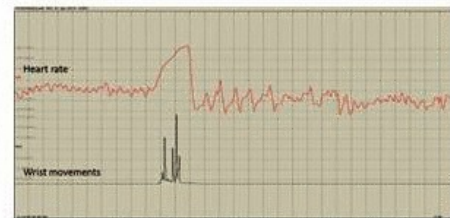
Monitoring sleep in MIN-101C03 using V-Watch, a sleep biomarker & companion diagnostic tool

VWatch methodology overview-2

PSG

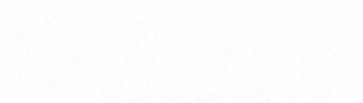


VWATCH



The Submissions Status is: (1)

- Romania (22 sites): **End November / Beginning December**
- Russia (11 sites): **December**
- Latvia (4 sites): **December**
- Estonia (3 sites): **End December/ Beginning January**
- Bulgaria (3 sites): **January**
- Ukraine (12 sites): **January**



Thank you