

## **Corporate Presentation**

January 2022

#### 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 guarter ended September 30, 2021, filed with the Securities and Exchange Commission on November 8<sup>th</sup>, 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.

5<sup>th</sup> January 2022



- 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.







# Roluperidone

Treatment of negative symptoms in patients diagnosed with schizophrenia

Treatment targeting negative symptoms (social withdrawal, lack of motivation, reduction in spontaneous speech)

Improved tolerability of drug treatment

Improved options for patients with refractory positive symptoms

Treatments targeting the cognitive deficits in schizophrenia

Treatments addressing noncompliance

Greater understanding of schizophrenia etiology



Mean ranking of each unmet need (1–10)\*

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





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



### **Roluperidone's path:**

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







## Phase 2b Recap







# Phase 3: Recap

### Phase 3 (MIN-101C07) Study Design Schematic and Key Study Elements

<b>4-week screening</b> <b>phase</b> including washout ( <i>Day -28 to Day -1</i> )	<b>12-week double-blind</b> <b>treatment phase</b> (Day 1 to Week 12)	<b>40-week open-label</b> <b>extension phase</b> (Week 12 to Week 52)
Randomizat	ion Primary Analysis	
Placebo PO, MIN-101 32 mg PO, MIN-101 64 mg PO,	QD QD QD Crossover QD Change from Baseline to Week 1 Score (NSFS; Marder score)	MIN-101 32mg MIN-101 64mg
ey Secondary Endpoint ther Endpoints	Change from Baseline to Week 1 Change from Baseline to Week 1 • Clinical Global Impres • Clinical Global Impres • PANSS Total Scores, s • Cognition • Safety & Tolerability	2 in the Personal and Social Performance scale total score (PSP) 2 in: sion of Severity (CGI-S) sion of Improvement (CGI-I) sub-scores, and Marder's Factor Scores

Target Number of Patients501 patients randomized 1:1:1 (167 in each arm)

Sample Size Assumptions &<br/>StatisticsDelta versus placebo of 3 points, SD = 6.5, 90% power, and 40% drop-out rate<br/>ITT, MMRM, Truncated Hochberg to correct for multiplicity for primary & key secondary<br/>endpoints





















# Phase 3 Extension: Recap

### 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



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



<sup>1</sup> Study baseline is defined as the last valid evaluation done before the study drug administration on Day 1

Change from Baseline				
	Double-Blind End-of-Treatment (12 Wks) (WK 52)			
Treatment Arm	Mean	<u>SD</u>	Mean	<u>SD</u>
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	2.4	3.91	-4.5	3.50
Placebo to Min-101 64 mg	-5.4		-4.9	4.66



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 End (12 Wks)		End-of-Ti (WK	-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	



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

CGI-S



#### **PANSS Positive Symptoms Score**





#### **Reduced Emotional Experience Score**





Study Phase		Plac (N≕	rebo 172)	MIN-101 32 mg (N=170)	MIN-101 64 mg (N=171)
	# of Patients	8 (4	.7%)	18 (10.6%)	9 (5.3%)
Double-Blind	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





# Pivotal BE study: Recap

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

<b>3-week screening</b> <b>phase</b> (Days -21 to Day -2)	Treatment Period 1 3-day institutionalization At least 7-day washout	Treatment Period 2 3-day institutionalization At least 7-day washout	Treatment Period 3 3-day institutionalization At least 7-day washout	Treatment Period 4 3-day institutionalization	EOS/Early Withdrawal (7± 2 days)
Randomi to 1 of 4 treatme	ization ent sequences				
Objectives	<ul> <li>Relative bioavailabilit (MR-32) form in faste</li> <li>Relative bioavailabilit (GR-01B) form in fast</li> <li>Relative bioavailabilit 32) form in fasted sta</li> <li>Relative bioavailabilit state</li> </ul>	y of 64 mg single dose rolu ed state y of 64 mg single dose rolu ed state y of 64 mg single dose rolu te y of 64 mg single dose rolu	iperidone Commercial (GF iperidone Commercial (GF iperidone Phase 3 (GR-01 iperidone Commercial (GF	R-01C) form relative to refe R-01C) form relative to refe B) form relative to reference R-01C) form in fed state rel	erence Phase 2b erence Phase 3 ce Phase 2b (MR- lative to fasted
Primary Endpoints	The following key plasma PK parameters will be estimated using non-compartmental methods: $C_{max}$ , $T_{max}$ , $AUC_{24}$ , $AUC_{last}$ , $AUC_{\infty}$ , $t_{lag}$ , $t_{1/2}$ , 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 o 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				











### Summary

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





