

From Unmet Need to Reality

Roluperidone is potentially the first treatment for negative symptoms of schizophrenia

Corporate deck I Fall 2026



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De-risked path to first approved therapy for negative symptoms of schizophrenia



Unmet need

Negative symptoms drive profound, lifelong disability and remain untreated, with no FDA-approved therapies and clinical practice focused primarily on positive symptoms



Only therapy of its kind

Roluperidone is only late-stage drug in development targeting primary negative symptoms of schizophrenia



Clinical evidence

Roluperidone monotherapy had a meaningful improvement in negative symptoms while supporting stable positive symptoms with a low relapse rate in two registrational trials (C03 & C07 studies)



De-risked execution

Confirmatory Phase 3 trial design (C19 study) established following extensive FDA engagement; topline 12-week efficacy data expected in 2H 2027



Financial strength

\$200 million financing in October 2025 led by Vivo Capital with other top-tier investors;* provides funding through C19 study data, NDA resubmission and preparation for commercialization

Large US patient population — roluperidone addresses a significant unmet need

~3.1M

US adults

Estimated Schizophrenia prevalence (US)

1.17% age-adjusted prevalence
(Krasa et al., JAMA Psychiatry 2026)

~1.6M

US adults

Treated patients

~50% of prevalent cases receive
treatment (IQVIA NDTI 2017)

~954k

US adults

Negative symptoms (≥60%)

60% of treated patients have clinically
relevant Negative Symptoms (Correll &
Schooler, 2020)

~650k

US adults

Stable (roluperidone target)

68.8% stable; ~41% of treated
(Starzer et al., World Psychiatry 2023)

Current market¹

~\$4.2B

US schizophrenia drugs market

2025 (North America ~63% of global)
Growing at ~6–7% CAGR

~\$8.7B

Global schizophrenia market

2025 — projected \$14–22B by 2035
depending on novel therapy approvals

\$0

Negative symptoms —
no approved treatments in US

No FDA-approved therapy for primary
negative symptoms — first-mover opportunity

Market opportunity²

>\$2B

Roluperidone peak net sales
potential

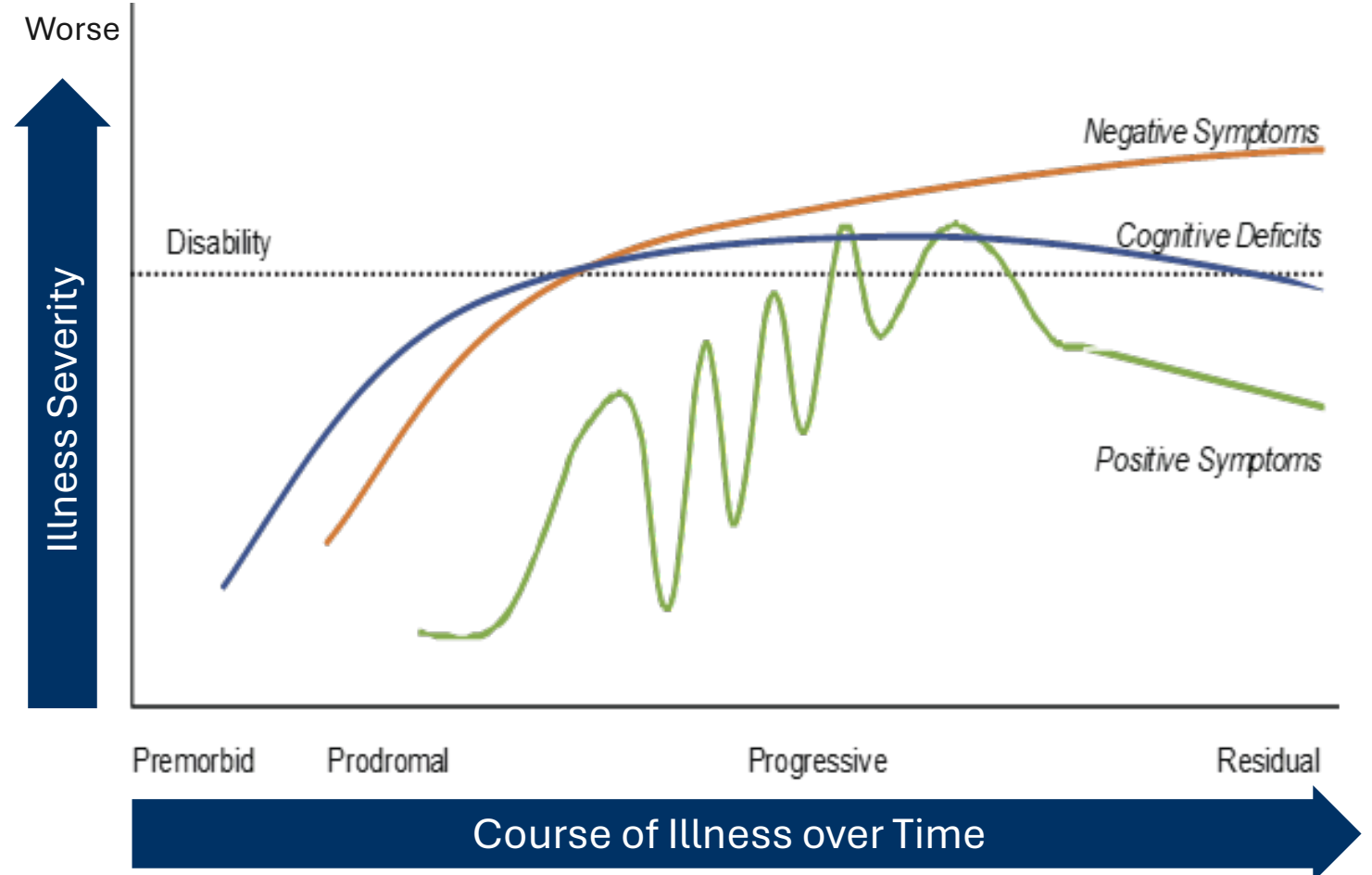
Annual net sales potential
(Minerva Neurosciences estimate)

**Negative symptoms of schizophrenia drive
lifelong disability and remain untreated**

Current treatment options improve positive symptoms, but negative symptoms remain untreated and drive long-term disability

Schizophrenia has three symptom domains

- 1) **Positive Symptoms** - delusions, hallucinations, disorganized behavior
- 2) **Negative Symptoms** - diminution or absence of normal behaviors related to motivation and interest
- 3) **Cognitive Deficits**



Functional disability more closely correlates with negative symptoms rather than positive symptoms over time

*“While positive symptoms are often the most recognized features of schizophrenia due to their external observation of distorted normal function, **negative symptoms** are the lack of normal functions that **differentially affect schizophrenia treatment and prognosis.**”*

80%–90% of people with schizophrenia are **unemployed**

vs. ~4–5% in the general population

Negative symptoms; not positive symptoms drive unemployment in schizophrenia

Consistent finding across >25 studies; yet no approved treatment targets negative symptoms

Chan A et al. Schizophrenia Research. 2026;288:95-103

Targeting avolition improves entire constellation of negative symptoms & functional outcomes

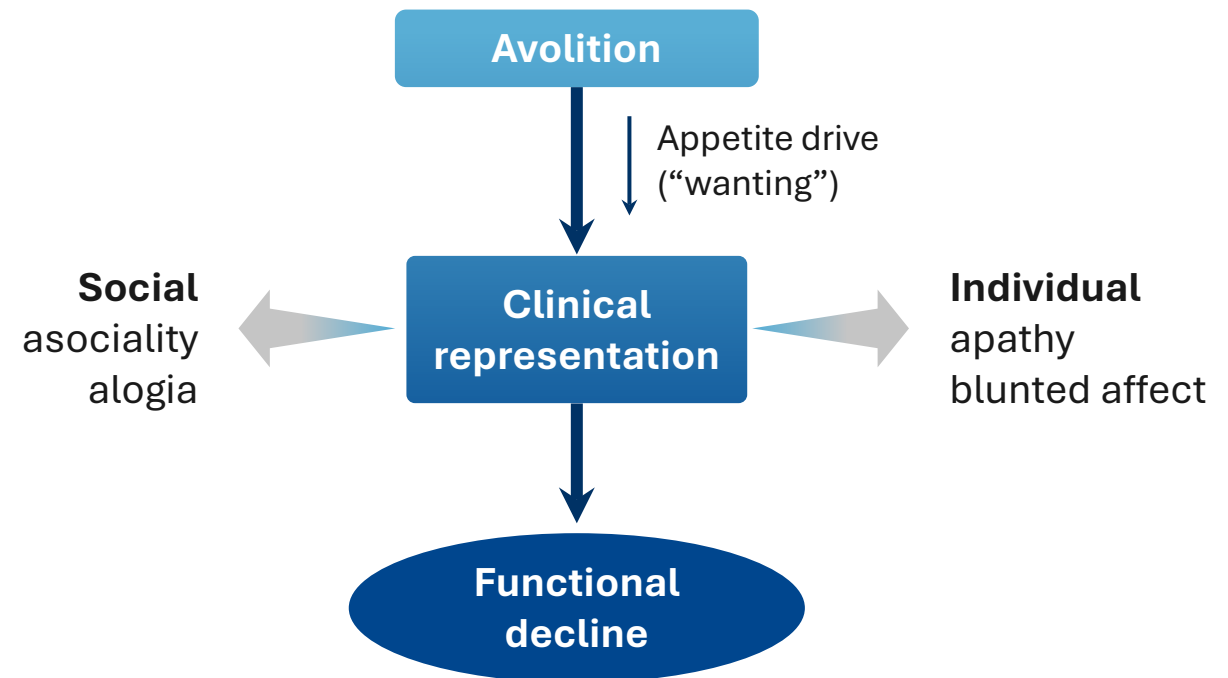
Avolition (lack of motivation)

Disrupts goal-directed behavior and reward processing

Significantly impacts other the other Negative Symptom domains:

- **anhedonia** (pleasure loss)
- **asociality** (social withdrawal)
- blunted **affect** (reduced emotional expression)
- **alogia** (poverty of speech)

Avolition is a determinant of poor functional outcome



Roluperidone for negative symptoms of schizophrenia

Clinical data that matters

C03 & C07 Studies: similar designs and significant results – guiding C19 confirmatory trial

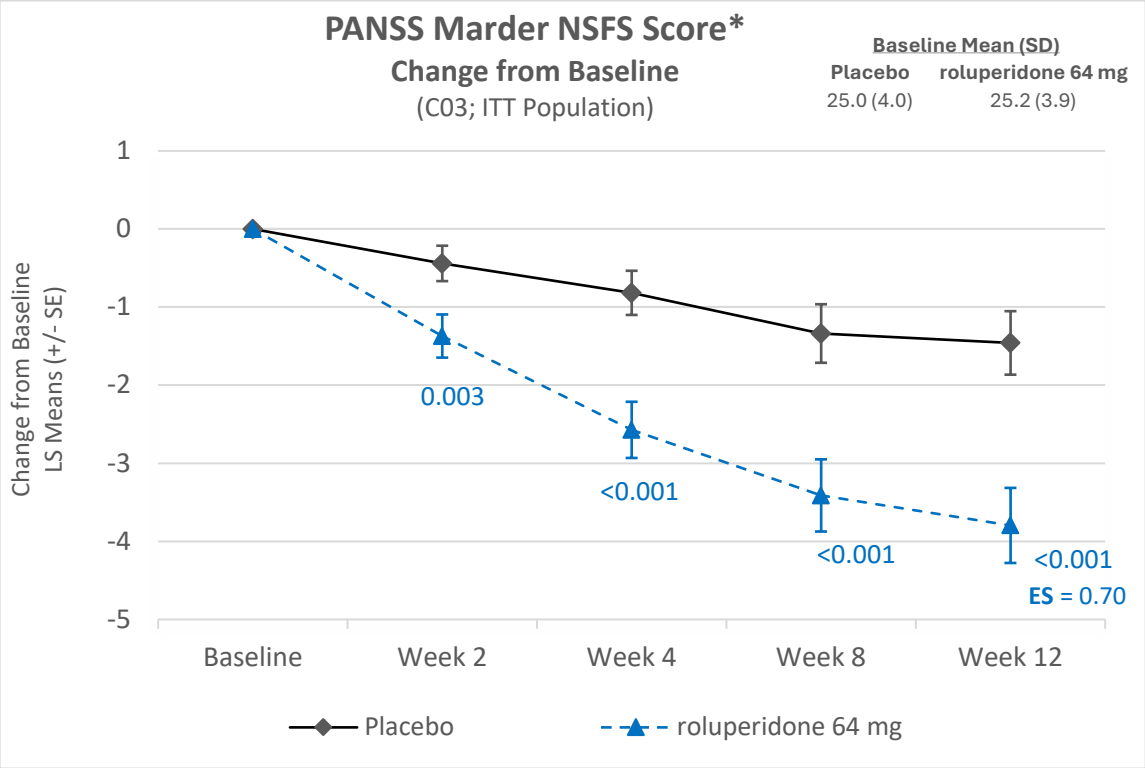
		C03 (MIN101C03) · Phase 2b	C07 (MIN101C07) · Phase 3
Design	Design and number of patients	244 patients randomized 1:1:1 (monotherapy) Placebo · 32 mg · 64 mg PO, QD	515 patients randomized 1:1:1 (monotherapy) Placebo · 32 mg · 64 mg PO, QD
	Duration	12-wk efficacy (DB) → 24-wk safety (OLE)	12-wk efficacy (DB) → 40-wk safety (OLE)
Results	PANSS Marder NSFS* Change from baseline to Week 12	$p \leq 0.001$ ✓ Statistically significant (64 mg) Significant improvement in negative symptoms	$p \leq 0.043$ ✓ Nominally significant (64 mg) Nominally statistically significant improvement in negative symptoms** †
	PSP Total Score (Personal & Social Performance — functional endpoint)	$p \leq 0.002$ ✓ Statistically significant (64 mg) Improvement in patient functioning as measured by PSP Total Score	$p \leq 0.016$ ✓ Statistically significant (64 mg) Improvement in patient functioning as measured by PSP Total Score†
	Positive Symptoms	Stable throughout Positive symptoms stable over 12-week double-blind + 24-week open-label extension	Stable throughout Positive symptoms stable over 12-week double-blind + 36-week open-label extension
	Relapse Rate (positive symptoms)	14% After 12-week DB + 24-week OL; comparable to antipsychotic-treated comparator (CATIE 15%)	9% After 12-week DB + 40-week OL; markedly lower than antipsychotic-treated comparator (CATIE 18%)

*PANSS Marder NSFS was not primary endpoint of C03 study but is shown here because it is the primary endpoint agreed with FDA for the ongoing C19 confirmatory study (the primary endpoint of the C03 study was the PANSS Pentagonal-NFS, which also showed a statistically significant improvement (0.004 for 64 mg); **C07 study's primary endpoint met only on nominal basis ($p \leq 0.043$) due to statistical plan's use of Hochberg Type I correction; †mITT population (excludes 1 site for reasons of implausible data).

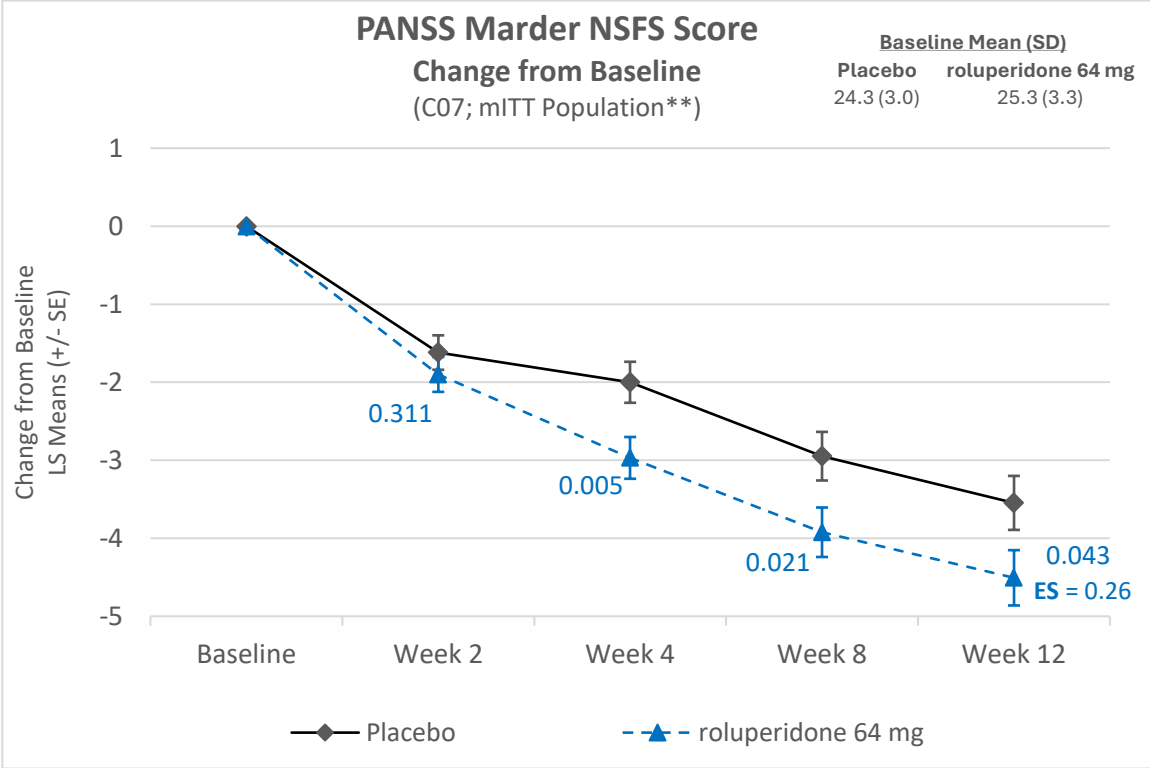
PO: oral dose. QD: once daily dose. DB: double-blind. OLE: open-label extension. NSFS: Marder Negative Symptoms Factor Score. PSP: Personal and Social Performance scale. Source: Minerva Neurosciences.

C03 & C07 Studies: Negative Symptom Factor Score

C03 Study

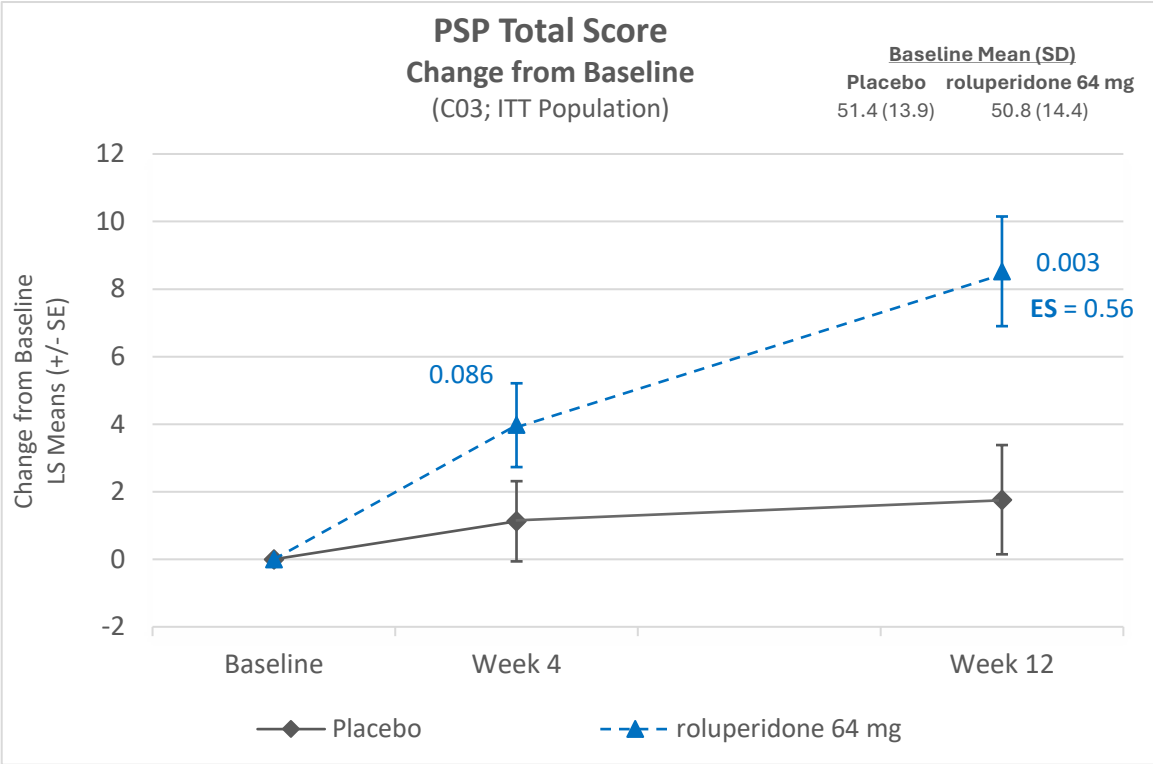


C07 Study

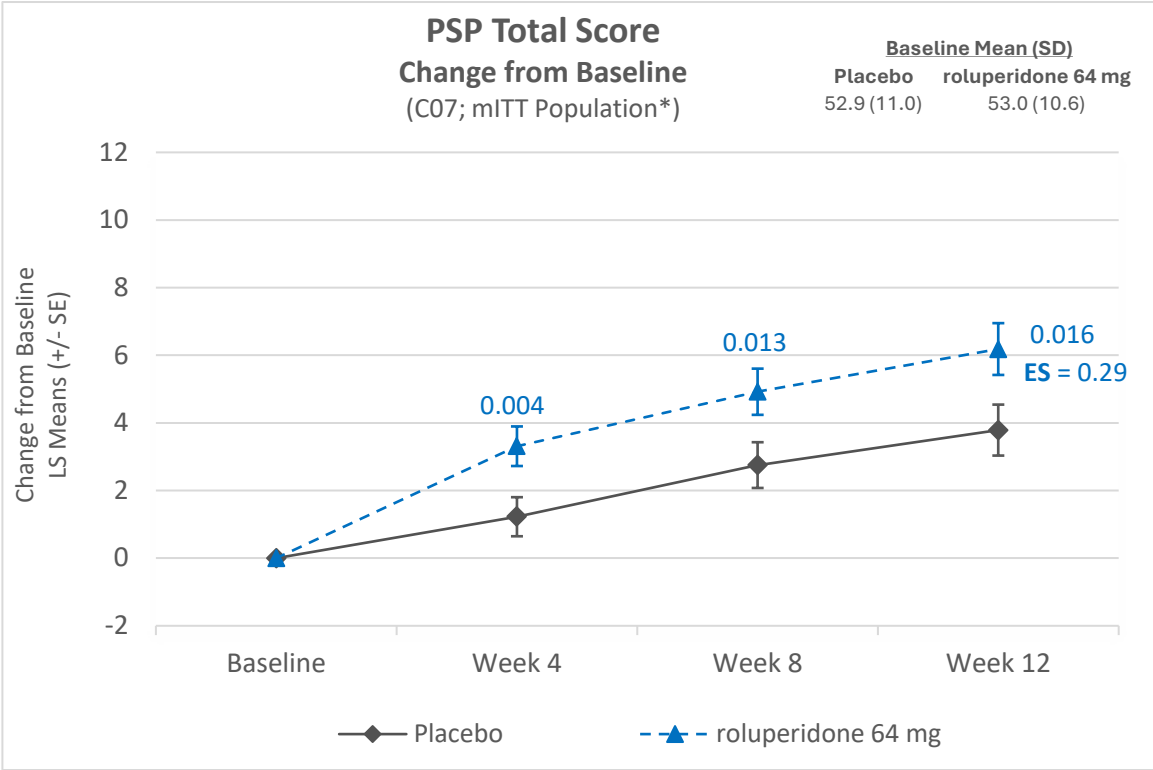


C03 & C07 Studies: Personal and Social Performance (PSP) Score

C03 Study



C07 Study



Conclusions from C03 and C07 Studies

Roluperidone demonstrated clear statistical significance on multiple efficacy endpoints:

- ✓ Improves primary negative symptoms (i.e., NSFS)
- ✓ Improves functioning (i.e., PSP)
- ✓ Improves avolition
- ✓ Stable positive symptoms, with a low relapse rate

Roluperidone avoids well-known troubling sides effects seen with atypical antipsychotics:

- ✓ Metabolic syndrome
- ✓ Sedation
- ✓ Motor symptoms (extra pyramidal symptoms (EPS))
- ✓ Prolactin elevation
- ✓ Nausea (for muscarinic antipsychotics)

Unique pharmacological profile that drives the differentiated clinical benefits in previous clinical trials

**De-risked, execution-focused
confirmatory C19 trial design**

FDA Alignment on C19, confirmatory trial design: **actively enrolling** [NCT07565428](#)

Alignment reached on design of a confirmatory Phase 3 study following extensive collaborative discussions with FDA throughout 2023-2024 and the findings of an FDA Public Meeting in August 2024:

Evaluating the Negative Symptoms of Schizophrenia in Clinical Trials¹

Excerpts from FDA Meeting Minutes

- **FDA acknowledges Minerva's position** that a population of people with schizophrenia can be identified **with high negative symptoms and a low risk of relapses** who can safely be withdrawn from antipsychotic treatment.
- The Division is willing to discuss an additional study that provides robust, controlled data about the efficacy and safety of long-term **monotherapy** with roluperidone in **subjects with negative symptoms of schizophrenia**.
- The Division agreed that it would consider a resubmission that included a double-blind, placebo- or active-controlled trial of roluperidone with a duration of at least 52 weeks.
- The Division does not object to a 12-week primary endpoint for negative symptom.
- To support a **monotherapy indication**, a comparison of relapse rates between patients on roluperidone monotherapy and similar patients maintained on antipsychotics would be important for regulatory decision making.
- [The approach] **would represent a new treatment paradigm**.

C19 trial design: *trial actively enrolling*

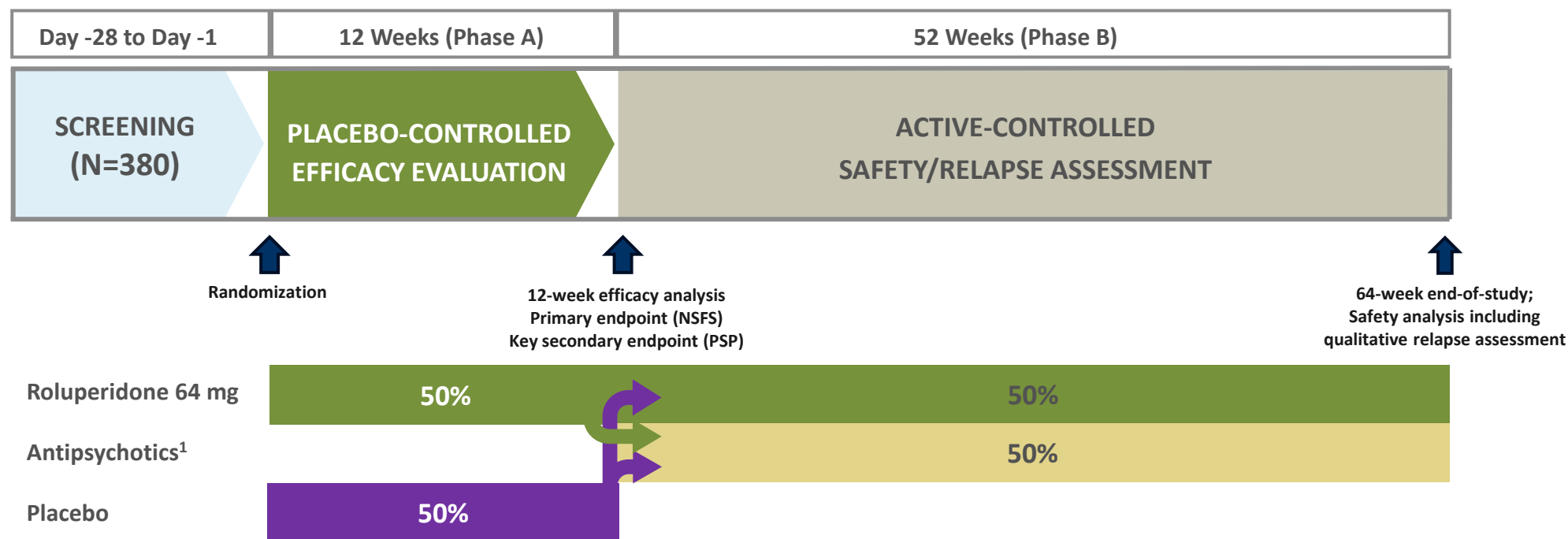
Screening (28 days) – to ensure patients meet eligibility criteria for stable symptoms prior to randomization

Efficacy Assessment (12 weeks):

Two parallel treatment arms randomized (1:1) to roluperidone or placebo using a double-blind study design

Safety/Relapse Assessment (52 weeks following first 12 weeks):

Two parallel treatment arms re-randomized (1:1) to roluperidone or one of three antipsychotics using a double-dummy study design



Execution-focused trial maximizes probability of a clean, interpretable C19 Study outcome

Trial Design Improvements

- **64 mg of roluperidone** in treatment arm, the dose which showed greater symptom improve in C03 and C07 trials
- Single active dose (64 mg) versus placebo **eliminates need for Type I error correction** applied in C03 and C07 trials
- Single active dose (64 mg) versus placebo **reduces treatment expectation bias**, which inflates placebo response
- Fewer patient assessment visits to **limit the “nursing effect,”** which inflates placebo response in CNS trials
- Rigorous, systematized **inclusion and exclusion criteria** to ensure enrollment of appropriate patients

Scale, Monitoring and Data Quality Controls

- ~380 patients across ~40 sites in the U.S. (25–30%) and four European countries
- **Focused site footprint** reduces variability and supports statistical integrity; and selection accounts for **prior site performance** in C03 and C07 trials
- **Standardized training** in PANSS ratings; and **oversight to support patient selection consensus** between investigators and sponsor
- Independent expert **oversight of rating quality** with real-time monitoring
- **Centralized data collection** using electronic tablets with built-in prompts to reduce rater error

Summary: the Minerva confluence

Right Pharmacology and MOA

Only drug to date to demonstrate a significant and clinically relevant specific improvement on *primary* negative symptoms of schizophrenia

Right Phase 3 Trial Design

Previous experience with two statistically significant (one nominally) trials + ongoing 'high touch' confirmatory Phase 3 trial improves probability of success

Right Moment

FDA alignment on Phase 3 trial + broad awareness of the unmet need in the psychiatry community + \$200m investment from top tier investors to support trial and commercialization

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