

An Oral Selective NMDA Modulator in Chemotherapy-induced Peripheral Neuropathy (CIPN)

CIPN

30–40%

of chemo patients

Zero FDA-approved treatments

PHASE 1 COMPLETE

56 Volunteers

• 0 SAEs • 600mg

Why MIRA. Why Now.

Four reasons institutions should be paying attention

UNMET NEED



Zero FDA-Approved Treatments for CIPN

30–40% of all chemo patients develop CIPN. Gabapentin, pregabalin, duloxetine — all used off-label, **none approved**.



DIFFERENTIATED ASSET



No Psychotropic Risk. Not a Controlled Substance.

DEA confirmed non-scheduled. No euphoria, no hyperlocomotion. NMDA modulator at IC50 ~100µM — clean selectivity profile.



CLINICAL PROOF



Phase 1 Complete. Phase 2a Imminent.

56 healthy volunteers. 0 SAEs. Doses to 600mg. Hadassah Medical Center. Phase 2a protocol submission H1 2026.



NEAR-TERM CATALYST



AACR Presentation: April 17, 2026

Phase 1 data debut at AACR Annual Meeting, San Diego. Investor attention typically peaks at conference windows.



Chemotherapy-Induced Peripheral Neuropathy



The most common dose-limiting toxicity of cancer treatment

Affects sensation, motor function, and quality of life — often permanently

0

FDA-Approved Treatments

CIPN: The Forgotten Oncology Crisis

30–40%

of chemo patients affected¹

\$2B+

CIPN market²

100%

off-label current standard of care³

Standard of Care Fails Patients



Gabapentin and pregabalin provide partial relief at best. Duloxetine shows modest benefit in select patients. None are FDA-approved for CIPN. Oncologists have no validated, approved option — and dose reductions or treatment discontinuation remain the only recourse for severe cases.

The Clinical Gap



Ketamir-2 is positioned to be the first approved therapy — a regulatory white space with \$2B+ addressable market.⁴

1. Seretny M et al. Pain. 2014;155(12):2461–2470. PMID: 25261162

2. IntelMarket Research (2025)

3. Smith EM et al. J Clin Oncol. 2020;38(28):3325–3348.

4. GM Insights (2025)

A Regulatory White Space Worth \$8 Billion

Market Opportunity



\$8B+

Neuropathic Pain Market

CIPN Addressable



~\$2-3B

Est. peak sales, CIPN-approved therapy

~3 Million



new CIPN cases annually (US)

40%



discontinue or reduce chemotherapy due to Severe CIPN¹

0



FDA-approved treatments available today

Ketamir-2



First-mover advantage in a validated, completely open market

1. Hershman DL et al. J Clin Oncol. 2014

Ketamir-2: Rethinking NMDA Modulation with Selectivity



Rationale:

MECHANISM

Ketamir-2 is an oral, low-affinity NMDA receptor modulator acting at the PCP site (IC₅₀ ~100μM). Unlike ketamine, it achieves analgesic effect without psychotropic risk, euphoria, or off-target binding.

SELECTIVITY

No binding to AMPA, Kainate, Sigma, Glycine, or Glutamate receptors. Active metabolite Nor-Ketamir (IC₅₀ ~300μM) maintains identical selectivity. DEA confirmed non-controlled.

STATUS

Phase 1 complete. Phase 2a protocol submission H1 2026 **under active IND**.

NON-CONTROLLED



DEA Confirmed —
Not Scheduled

ORAL DAILY DOSING



Convenient administration
for oncology patients

CLEAN PROFILE



Zero euphoria,
zero hyperlocomotion,
no off-target CNS binding

Preclinical Evidence: Outperforming Gold Standard

PTX Model (Paclitaxel-Induced CIPN)

Ketamir-2 achieved complete pain reversal at 100–300 mg/kg in the paclitaxel taxol model — the most clinically relevant CIPN model. Gabapentin and pregabalin achieved only partial relief at maximum doses.

Chung Model (Spinal Nerve Ligation)

Superior efficacy vs. gabapentin and pregabalin. Demonstrated dose-dependent analgesia with clean tolerability at all doses tested.

Published: Frontiers in Pharmacology

Source: Frontiers in Pharmacology

Complete Pain Reversal

vs. Partial Relief
with Gabapentin

at 100–300 mg/kg

PTX Model · Published · Peer-
Reviewed



Outperformed

Gabapentin &
Pregabalin

In both primary
CIPN models



Phase 1: Safety Established Across 56 Volunteers

56

Healthy
Volunteers

0

Serious
Adverse Events

600mg

Maximum
Dose Tested

SAD+MAD

Cohorts
Complete



Hadassah Medical Center, Jerusalem — Rigorous Academic Oversight

3:1 randomization for single ascending dose (SAD) and multiple ascending dose (MAD) cohorts. Completed with no dose-limiting toxicities. The Phase 1 package supports Phase 2a protocol submission to FDA **under active IND**, targeted H1 2026.

Ketamir-2: Clinical Phase IIa study design



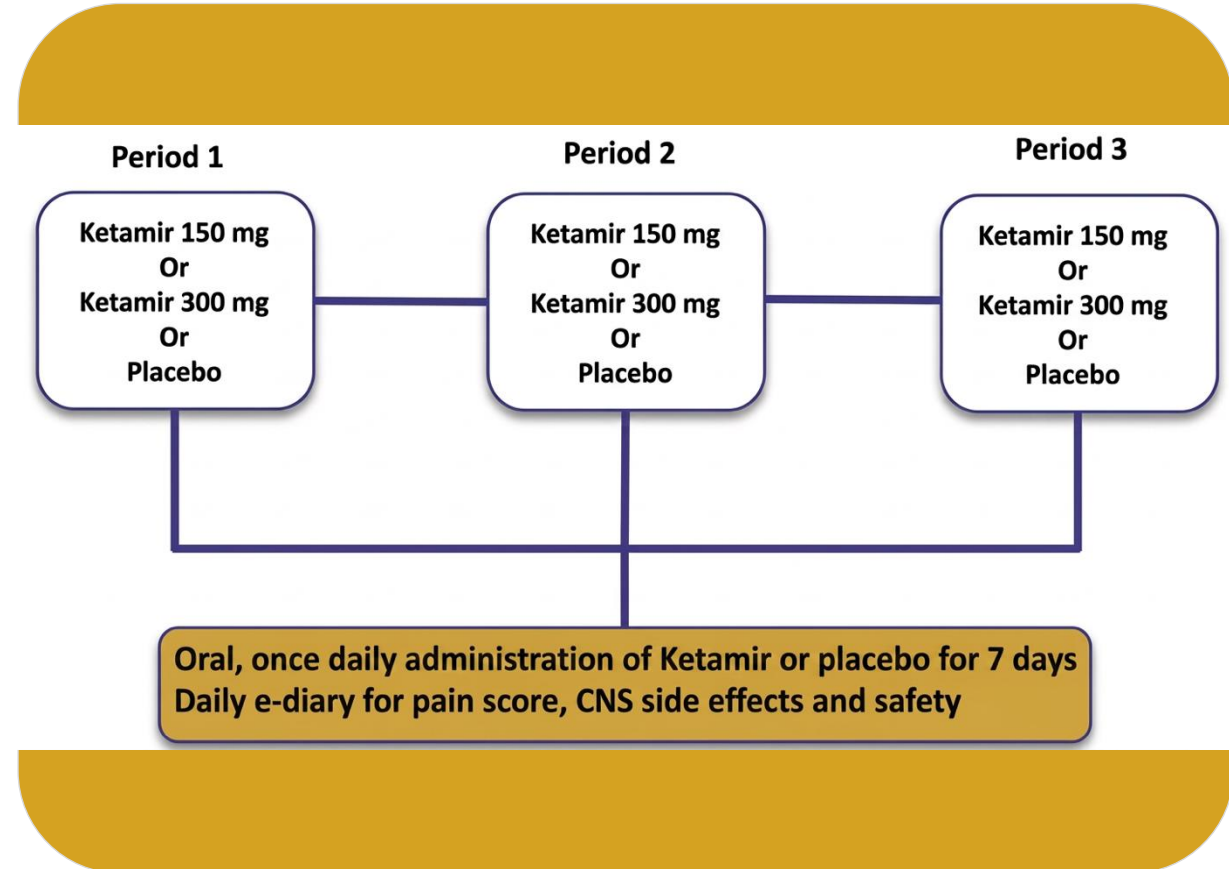
Current Design with Top Cancer Institution Support

Randomized, Double-Blind, Placebo-Controlled, Three-Period Crossover, Single-Centre Study to Evaluate the Safety, Tolerability, and Dose-Response Relationship of Oral Ketamir-2 on Neuropathic Pain in Patients with Moderate-to-Severe Persistent CIPN




A total of 24 participants will be randomized in a 3-way cross-over design to evaluate the analgesic properties of Ketamir for the treatment of CIPN.

The participants will be screened and randomized on Day 1 to one of the following three (3) sequences:

- Placebo to Ketamir 150 mg to Ketamir 300 mg
- Ketamir 150 mg to Ketamir 300 mg to Placebo
- Ketamir 300 mg to Placebo to Ketamir 150 mg



Pipeline

Lead Asset Ketamir-2 	Asset SKNY-1 	Asset MIRA-55 
Indication CIPN	Indication Obesity / Smoking Cessation	Indication Inflammatory Pain
Preclinical ✓	Preclinical Active	Preclinical Active
Phase 1 ✓	Rights MIRA	Rights MIRA
Phase 2 Q2 2026→		
Rights MIRA		

Pipeline spans pain neurology and metabolic medicine — all assets are unencumbered, wholly owned, and debt-free.



2026 Catalysts: Multiple Value Inflection Points



IND Active

Phase 2a Prep

IND cleared and active. Phase 2a trial design finalized. Site selection finalized with top tier cancer centers.



AACR Annual Meeting

Phase 1 Data Debut

First public presentation of Phase 1 clinical data. San Diego, April 17–22, 2026. Institutional visibility event.



Phase 2a

Enrollment Begins

Site activation and patient enrollment begin. First readout expected **Q1 2027**.









Phase 2a Protocol

1H 2026

Full protocol package to be submitted to FDA under active IND. ~30 patient randomized CIPN trial.



Why Ketamir-2 Wins Where Others Fail

Attribute	Ketamir-2	Gabapentin	Duloxetine	Ketamine
 FDA Approved for CIPN	Targeted	Off-label	Off-label	Not approved
 Mechanism	Selective NMDA Antagonist	Alpha-2-delta	SNRI	NMDA Antagonist
 Controlled Substance	No	No	No	Yes (Schedule III)
 Psychotropic Risk	None	Low	Moderate	High
 Oral Administration	Yes	Yes	Yes	No (IV/nasal)
 CIPN Preclinical Data	Published	Limited	Limited	Limited

KETAMIR-2 IP PROTECTION

Protected IP, North American Exclusivity



Global patent protection is pending for Ketamir-2 and its therapeutic uses

- (WO 2024/191676 A1 — "Antidepressant Compounds, Pharmaceutical Compositions, and Methods of Treating Depression and Other Disorders")

MIRA holds an exclusive license to Ketamir-2 patent rights across the United States, Canada, and Mexico, with corresponding national stage applications filed in September 2025

SKNY-1 and MIRA-55 IP Filed with Strong Protection



Capital-Efficient Path to Phase 2a

Balance Sheet



Debt-Free



\$0 Debt



Annual Burn



~\$5–6M



Disciplined operating structure



Why This Matters



MIRA operates with institutional-grade capital discipline. At current burn, the company can execute Phase 2a CIPN with modest additional capital — a targeted raise, not a major dilutive event.



- Phase 2a CIPN: Estimated 30 patient trial, \$4–6M all-in

- NASDAQ-listed with direct institutional access

Led by Experienced Management



**Erez
Aminov**



**Chief Executive Officer &
Executive Chairman**

Strategic architect of MIRA's pipeline. Drives capital markets and development strategy.



**Alan
Weichselbaum,
CPA, MBA**



Chief Financial Officer

30+ years capital markets experience. Oversees NASDAQ compliance, IR, and financial operations.



**Dr.
Itzchak
Angel,
PhD**



Chief Scientific Advisor

40+ years drug discovery. Former Head of Pharmacology, Sanofi. Architect of Ketamir-2 program and MIRA's entire pipeline.



**Alex
Weisman,
PhD**



Scientific Advisor

30+ years drug development expertise supporting clinical translation and regulatory strategy with CMC expertise spanning decades

MIRA Pharmaceuticals, Inc.

NASDAQ: MIRA

*Phase 1 Complete.
Targeting the First FDA-Approved CIPN Therapy.*

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