COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

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Investora 2023

September 14, 2023

Newron
Pharmaceuticals

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COMPANY HIGHLIGHTS

Unique portfolio of innovative CNS product candidates

- **Xadago®** for Parkinson's disease – Global approvals validate Newron's development capabilities from research to market
- **Evenamide** – New concept in treating inadequate/non-response in schizophrenia
- Ongoing search for strategically relevant assets

Management team with extensive experience and proven track record in drug development and commercialization

Significant near-term value drivers for leading candidate

Fully funded beyond key value inflection points

- Cash balance € 17.1 million (June 30, 2023)
- Royalty income, R&D tax credit: approx. €16m (2 yrs.)
- Cash reach 2024

EVENAMIDE IN – A PROMISE TO CHANGE THE TREATMENT PARADIGM IN SCHIZOPHRENIA

- Large market
- Unique MoA and positioning
  - **First add-on drug**
    - Changes a non-responder into a responder
    - No need to change current therapy, minimizing risk of patient relapse
    - Ease-of-use for patients & physicians
  - **First/only TRS drug since/beyond clozapine**
    - 30-50% of total population
    - Opportunity to keep niche indication within TRS for commercialization

- Positive results from phase II Study 002 in non-TRS patients
- 1 of 2 pivotal studies (non-TRS) ongoing
- Pilot study in TRS patients ongoing, 6 weeks final, 6 and 12 months interim results available
- Chance for early market access
- Exclusivity: 2033 (COMP) and beyond (10 yrs exclusivity post approval in the EU)

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ENORMOUS MEDICAL NEED FOR 20 MILLION PATIENTS WORLDWIDE

VAST MARKET OPPORTUNITY
(anti-psychotics market >$23bn)

- 1% prevalence of disease
- Disease onset in 20s, need for life-long treatment
- **Cost to society** (direct cost US only): $63bn p.a.

Over 30 antipsychotics available, but all provide short-term and insufficient relief of some of the symptoms

Most patients with schizophrenia demonstrate reduced control of positive symptoms by typical and atypical antipsychotics after first few years of treatment

Schizophrenia

~30% of patients respond well to monotherapy

+

Patients meeting TRS definition | **~30% TRS**

~40% Inadequate Response

~70% of patients

Major shortcomings of current antipsychotics:

- No effective drugs to eliminate symptoms, reduce progression, limit disability, suicide or early mortality
- All available options target D2/5HT2, but not glutamate, shown lately to be the major abnormality in poor/non-responders

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EVENAMIDE – DIFFERENTIATION AND COMMERCIAL OPPORTUNITY IN SCHIZOPHRENIA

- **Large Market Opportunity**
- **NO direct competition as evenamide can be added to all antipsychotics**
- **Promise to change treatment management paradigm in schizophrenia**

First add-on antipsychotic to be approved for inadequately responding patients

- **Up to 70%** of Chronic schizophrenia, non-TRS population, (every ~18 months)
- Add-on therapy with **no dose-limiting side effects** a key advantage for patients and prescribers

First drug for treatment of Treatment Resistant Schizophrenia (TRS) since clozapine (1989)

- **More than 30%** of schizophrenia population (with upside to **50%**)
- in routine practice, the use of clozapine is limited by safety, tolerability, and monitoring requirements
- Strong HTA value story to support pricing and coverage

Only option as add-on to clozapine

- No antipsychotic has demonstrated benefit as augmenting therapy for clozapine (~30k C-TRS patients in each key territory)

EVENAMIDE'S UNIQUE MOA DEMONSTRATED

Selectively blocks native sodium channels, showing no off-target effect on >130 other CNS receptors, enzymes, transporters, etc.

Selectively blocks VGSCs in a voltage-and use-dependent manner

Inhibition of native sodium channels expressed in rat cortical neurons

K_{rest} (μM)

25

K_{inact} (μM)

0.4

Modulates sustained repetitive firing without inducing impairment of the normal neuronal excitability

High frequency firing

Control

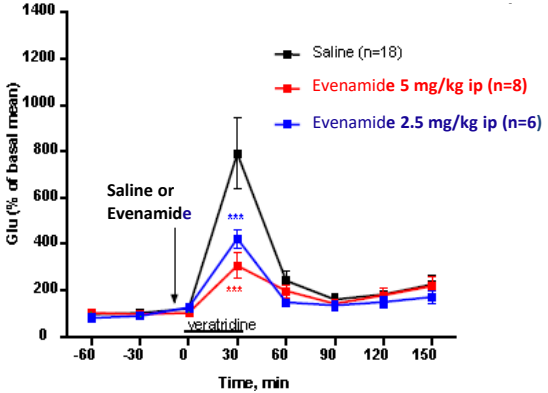
Evenamide 1μM

Low frequency firing

Control

Evenamide 1μM

Inhibits Glutamate Release



MONOTHERAPY AND ADD-ON EFFECT OF EVENAMIDE DEMONSTRATED IN ANIMAL MODELS RELEVANT TO SCHIZOPHRENIA

		MONOTHERAPY	ADD-ON
Information Processing Deficit	Pre-pulse inhibition (PPI) disrupted by dopamine activation (amphetamine -rat)	✓	✓
	Pre-pulse inhibition (PPI) disrupted by NMDA antagonists (MK-801, PCP, -rat)	✓	
	Pre-pulse inhibition (PPI) disrupted by natural stimuli (sleep deprivation -rat)	✓	
	Pre-pulse inhibition spontaneous deficit (C57 mice)	✓*	✓
	Pre-pulse inhibition (PPI) disrupted by Ketamine in rat	✓	✓
Negative Symptoms	PCP-induced deficit in Social Interaction in the rat	✓	✓
Psychosis and Mania	Amphetamine induced hyperactivity in mice	✓	✓
	Amphetamine plus Chlordiazepoxide induced hyperactivity in mice	✓	✓
Cognitive Impairment	Novel object recognition in the rat: short term scopolamine impairment	✓	
	Novel object recognition in the rat: long term 24 hr natural forgetting	✓	
Impulse Control and Mood Symptoms	Resident–Intruder test in mice (Impulsivity)	✓	
	Tail suspension test in mice (Depression)	✓	
	Marble burying test in mice (Obsessive Compulsive Disorders)	✓	

*Trend
Blank cells = not evaluated

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DISPOSITION OF SUBJECTS EXPOSED TO EVENAMIDE AND MOST FREQUENT (≥3%) TREATMENT EMERGENT ADVERSE EVENTS

- > 480 subjects have been treated with evenamide to date in 10 clinical trials (7 completed, 3 ongoing); 103 healthy volunteers (dose range 1-60 mg), > 380 patients with schizophrenia (dose range 7.5 to 30 mg)
- Discontinuations: 40; Withdrawal of consent, lost to follow up etc - 34; Adverse Events [Seizure, Atrial fibrillation, Flu-like symptoms, Somnolence, Death (2)] - 6
- Most frequent (≥3%) treatment emergent adverse events: Headache, Dizziness, Somnolence
- To date, no evidence of extrapyramidal side effects, metabolic syndrome, sexual dysfunction, significant CNS events, or laboratory abnormalities
- > 135 patients have been treated for at least 6 months; > 90 patients for 1 year
- TQT study in HVs indicated that evenamide is devoid of risks of QTc prolongation (evenamide maximal increase was <6 msec; placebo 7.6 msec) or arrhythmias
- > 550 EEGs and >3200 seizure checklists on patients on evenamide have been performed to date, no new or worsening abnormality detected
- All safety data are periodically reviewed by an Independent Safety Monitoring Board (ISMB)
- The emerging, favorable safety profile of evenamide indicates it could be added to any current APs in patients with schizophrenia without any risk of drug-drug interaction or additional toxicity

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EVENAMIDE: EFFICACY DEMONSTRATED IN PATIENTS WITH SCHIZOPHRENIA (NON-TRS, STUDY 002)

- 4-week, placebo-controlled, add-on study of evenamide (15-25mg BID/day) in 89 patients on stable doses of aripiprazole or risperidone showing signs of worsening when compared to standard of care, at every assessment during the study (starting from Day 8)
  - **Significant improvement of**
    - PANSS positive, both mean change AND responder rate
    - CGI-C
  - **Superior benefit on**
    - PANSS total
    - LOF total
    - CGI-S
- Evenamide's glutamatergic MoA seems to improve symptoms of psychosis in patients not responding to first- or second-generation antipsychotics

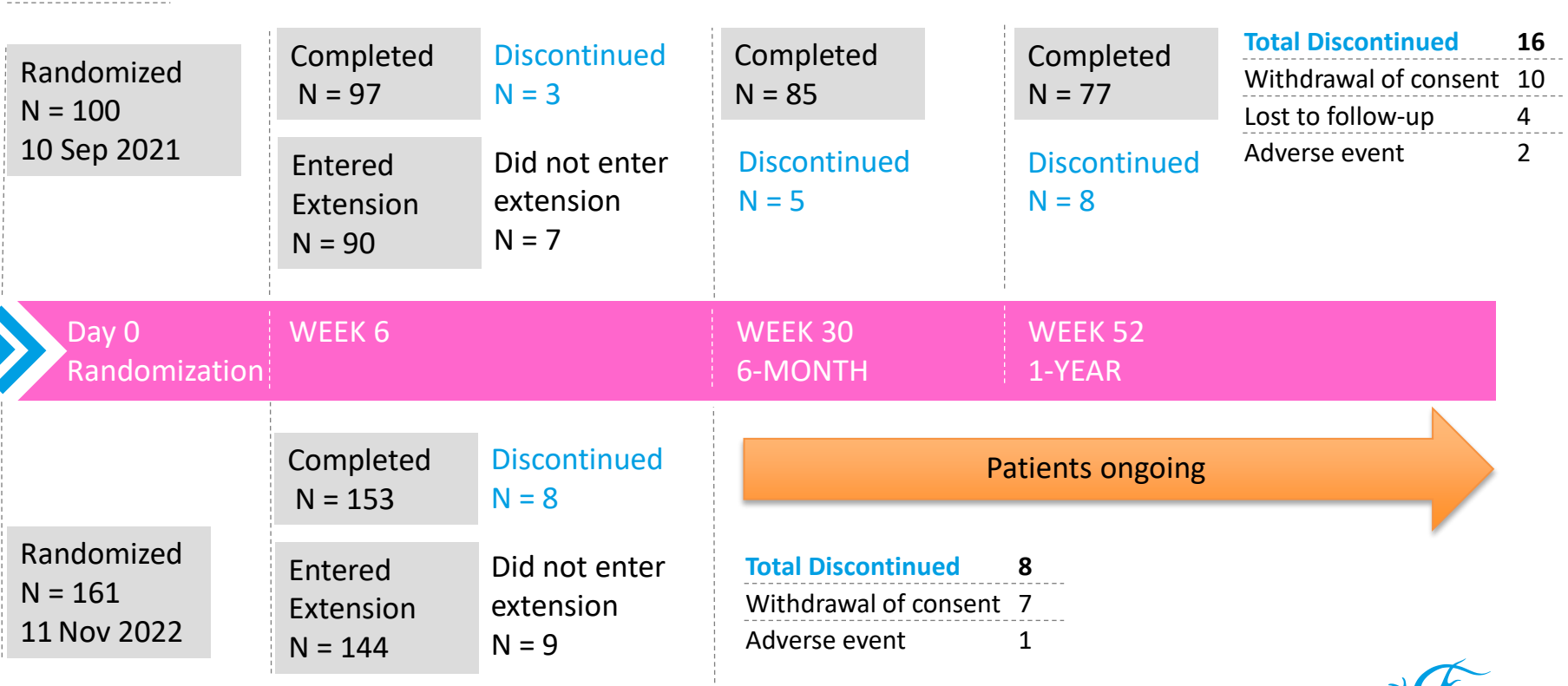
ONGOING PHASE II EXPLORATORY SAFETY AND EFFICACY STUDY IN TRS PATIENTS

PHASE II

Safety and Efficacy

- **Six-week, open-label,** randomized, **rater-blinded**, parallel group study, option to enter extension up to 12 months
- To evaluate tolerability and preliminary efficacy of adjunctive 7.5, 15, 30 mg BID
- TRS patients with PANSS scores ≥ 70 and ≤90; CGI-S 4 to 6, non-responders to their current antipsychotic medication
- **161 patients** randomized in 14 study centers in India, Sri Lanka, Italy
- Primary efficacy outcome measures mean change in PANSS total score
- Of 161 patients randomized,
  - 153 completed 6-weeks of treatment
  - 144 continued in extension study 015
  - > 135 completed 6-month treatment period
  - > 90 completed 12-month treatment period
- Promising interim analysis results of the first 100 TRS patients (Feb. 2023 – 1-Year)
- Topline results of study 014: 20 Mar 2023
- Results so far peer-reviewed and published in the *International Journal of Neuropsychopharmacology*
- **Final results of study 015: Q1 2024**

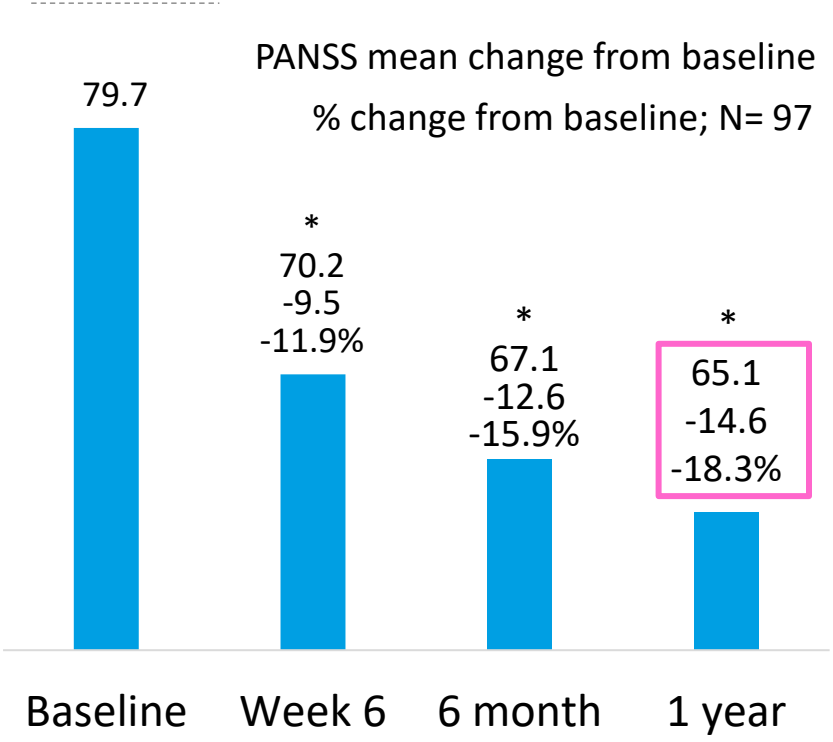
PATIENT DISPOSITION BY STUDY AND DURATION

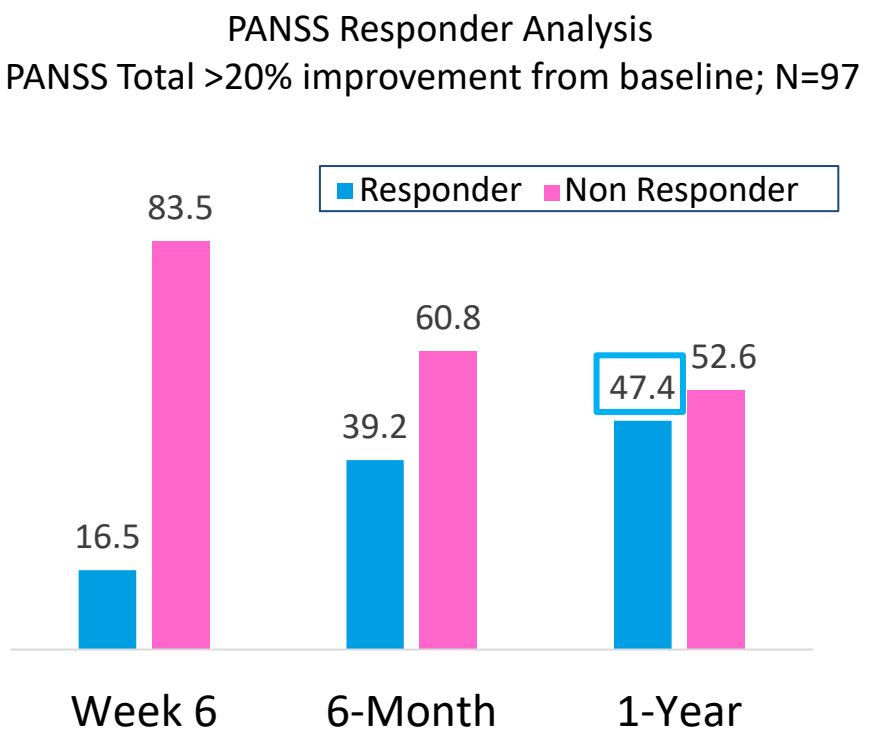


EFFICACY MEASURES RATED BY PSYCHIATRISTS CERTIFIED FOR THE STUDY

- Positive And Negative Syndrome Scale (PANSS)
- Clinical Global Impression *of Severity of Illness* (CGI-S)
- Clinical Global Impression *of Change from Baseline* (CGI-C)
- Level of Functioning (LOF - Strauss-Carpenter)

POSITIVE AND NEGATIVE SYNDROME SCALE - PANSS



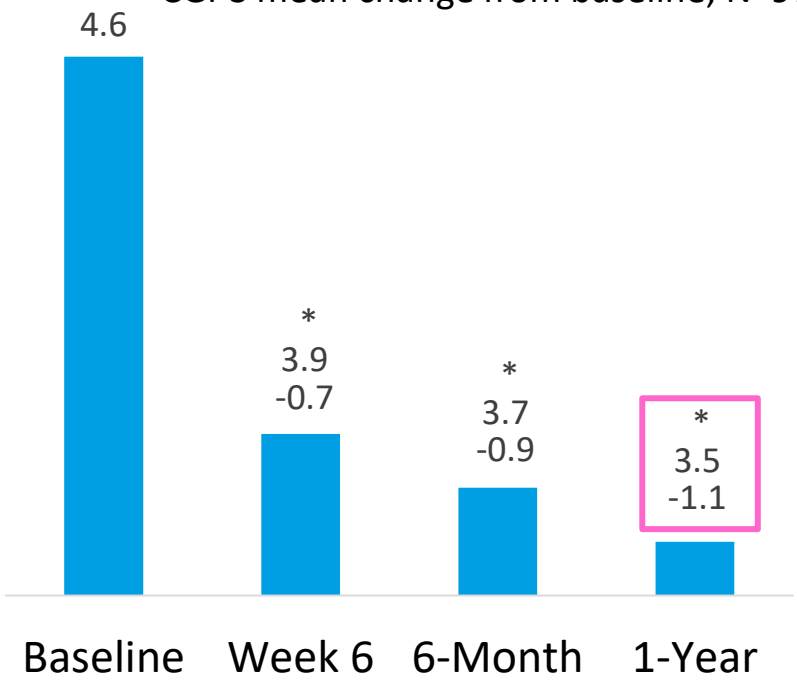


* p-value vs baseline < 0.001, paired t-test, LOCF;

Results from the full population (N=157) replicate benefits in the first 100 patients at week 6

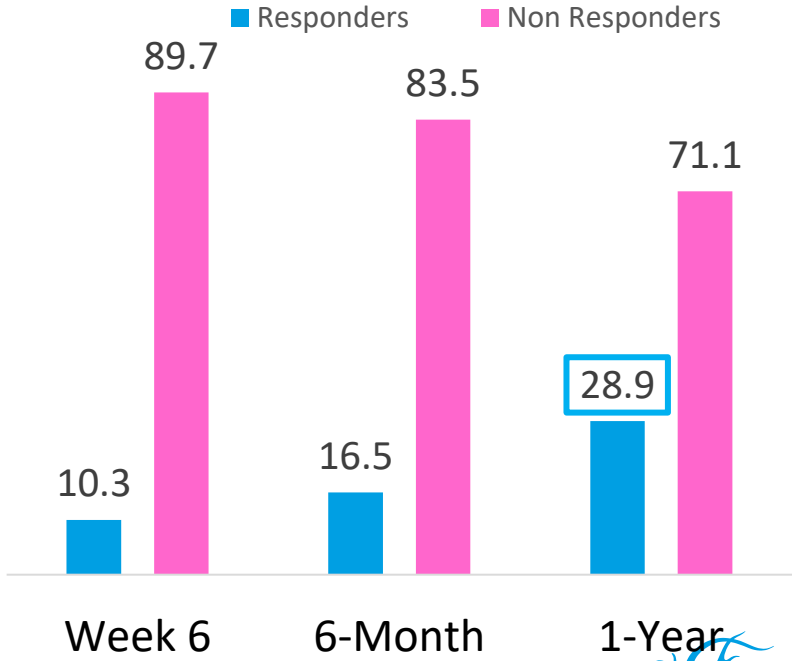
CLINICAL GLOBAL IMPRESSION OF SEVERITY OF ILLNESS (CGI-S)

CGI-S mean change from baseline; N=97



* p-value vs baseline < 0.001, paired t-test, LOCF;

CGI-S Responder Analysis
Improvement ≥ 2-category from baseline; N=97



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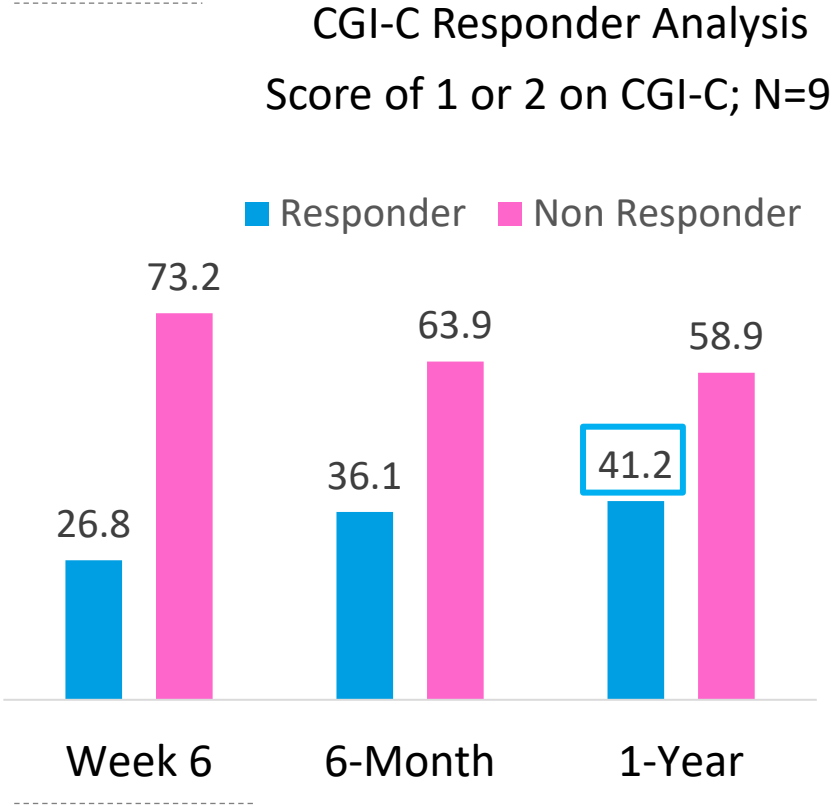
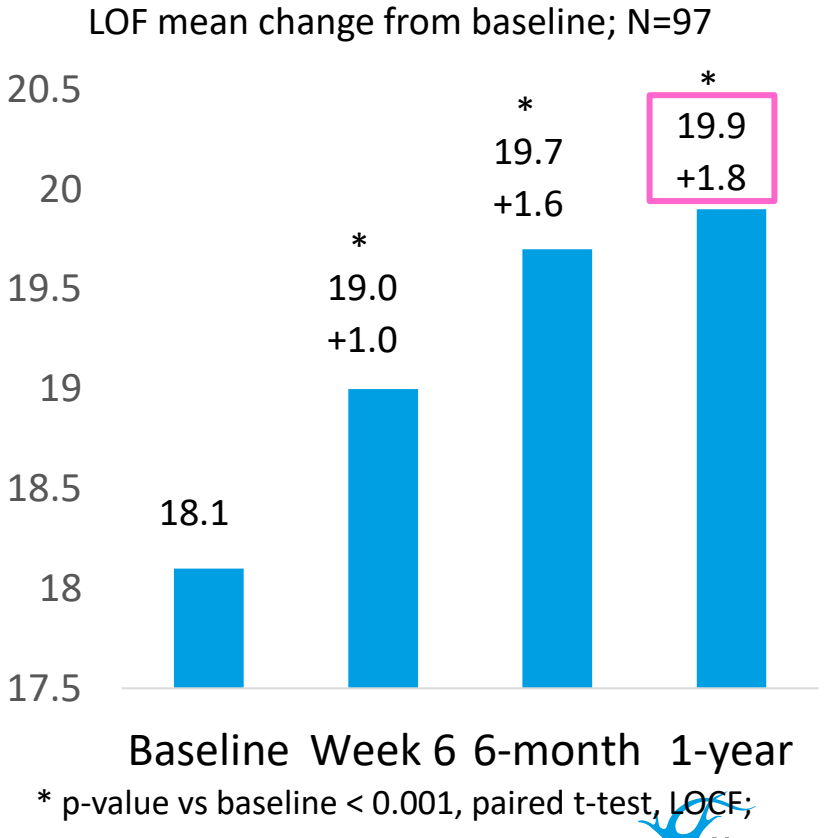
CGI OF CHANGE FROM BASELINE (CGI-C) AND LEVEL OF FUNCTIONING (LOF)





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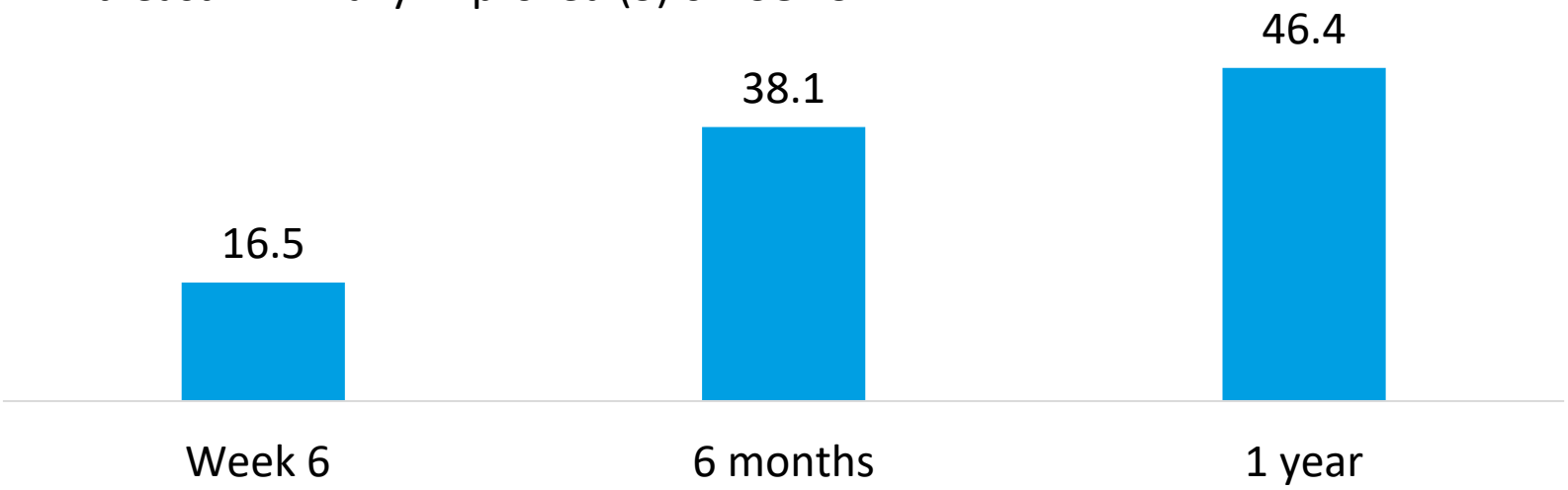
Results from the full population (N=157) replicate benefits in the first 100 patients at week 6

MULTI DOMAIN RESPONDERS

Proportion of patients with:

- At least 20% improvement from baseline on PANSS Total AND
- At least 1-category of improvement on CGI-S AND
- At least minimally improved (3) on CGI-C



NEWRON HAS INITIATED THE FIRST OF TWO PIVOTAL STUDIES

PHASE IIB/III

Safety and efficacy study (study 008A, **non-TRS**), started Sept 6th, 2021

- **Four-week,** randomized, double-blind, placebo-controlled study
- To evaluate efficacy and safety (tolerability and EEG effects) of **adjunctive 30 mg BID**
- Outpatients suffering from chronic schizophrenia being treated with one of the leading antipsychotics
- **Total 260 patients** to be enrolled at study centers in Europe, Asia and Latin America
- **Results expected by end 2023/early 2024**

PHASE III

Safety and efficacy study in **TRS** patients to start in 2023 (study 003)

- **12-week**, randomized, double-blind, placebo-controlled, parallel group **(40-week double-blind extension for demonstration of long-term efficacy)**
- To evaluate efficacy, safety, and tolerability of adjunctive 15 or 30 mg BID
- **Outpatients with treatment-resistant schizophrenia (TRS)** not responding adequately to any antipsychotic treatment (including clozapine)
- **Minimum 450 patients** to be randomized in approximately 40 centers in Europe, Asia, North America, Central America, and South America
- Study completion in 18 months from start

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XADAGO IN PD
MARKETED COMPOUND

- ✓ First approved NCE in >10 yrs (U.S., EU)
- ✓ Globally licensed
- ✓ Double digit/single digit % royalties
  - – >€75 milestones/royalties collected

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SIGNIFICANT COMMERCIAL OPPORTUNITY IN XADAGO® (SAFINAMIDE)

US / Canada	EU	Latin America	Israel	Japan / Asia	Australia /New Zealand
					
Launched in US in 2017 Launched in Canada in 2019	Launched in Germany, UK, Italy, Spain and other EU territories (2015), Switzerland, UAE, Brazil and Colombia; application for regulatory approval filed for Mexico		Approved in 2020	Launched in 2019	Launched in Australia in 2019

- Parkinson's disease affects 7 to 10 million people worldwide
- Milestone and royalty revenues to Newron since 2012
- Long period of Xadago® market exclusivity (patent life: 2029 in EU, 2031 in the US); ANDAs filed QII/2021

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