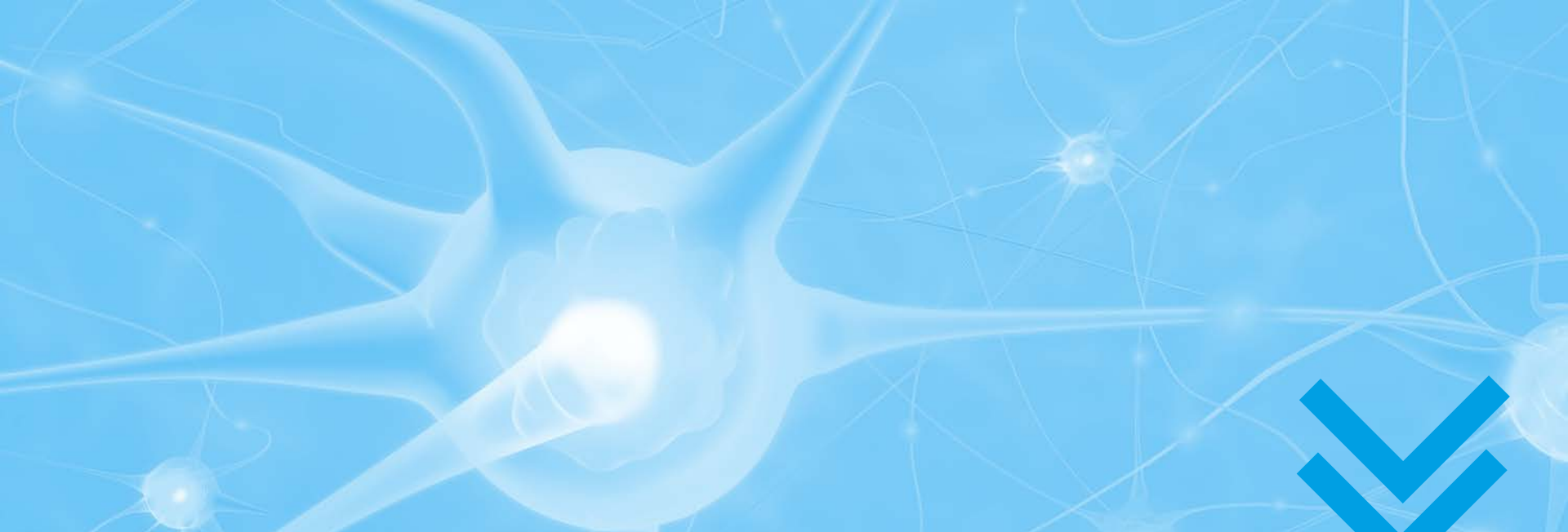




COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Corporate presentation
February 2024



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COMPANY HIGHLIGHTS



Differentiated 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



Significant near-term value drivers for leading candidate



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



Fully funded beyond key value inflection points

- Liquidity position € 17.1 million (June 30, 2023)
- Royalty income, R&D tax credit: approx. €8m/yr
- Cash reach mid-2024



EVENAMIDE – CHANGING THE TREATMENT PARADIGM IN SCHIZOPHRENIA

- Large market
- Differentiated 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 161 TRS patients completed, 6 weeks, 6 months and 12 months results available
- Chance for early market access
- Exclusivity: 2033 (COMP) and beyond (10 yrs exclusivity post approval in the EU)

HIGH MEDICAL NEED FOR 20 MILLION PATIENTS WORLDWIDE

LARGE 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

~40% Inadequate Response

~30% TRS

~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

EVENAMIDE'S DIFFERENTIATED 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

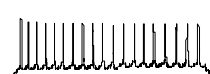


Evenamide 1 μM



Low frequency firing

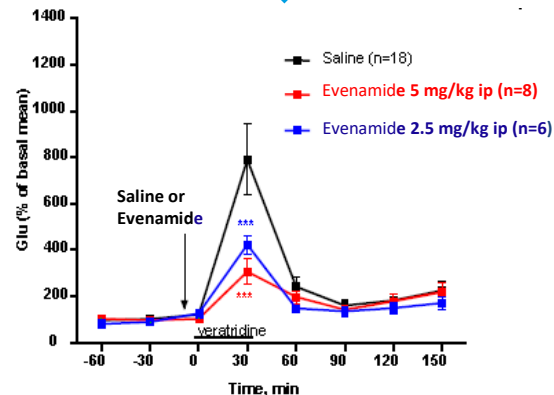
Control



Evenamide 1 μM



Inhibits Glutamate Release



EVENAMIDE – DIFFERENTIATION AND COMMERCIAL OPPORTUNITY IN SCHIZOPHRENIA

Large market opportunity

NO direct competition as evenamide can be added to all antipsychotics

Seeking to change treatment 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

FIRST POTENTIAL BREAKTHROUGH FOR TRS IN OVER 30 YEARS

Differentiated – structure, pharmacology, benign side effect profile, indication (Add-on to any antipsychotic for TRS patients), NO competitor identified

Evenamide treatment of 161 TRS patients **prevented ANY psychotic relapse** or hospitalization

Based on above results, and efficacy/safety profile **positive health technology assessment opinion** is deemed likely

Low incidence of treatment-emergent adverse events, or drop out due to intolerance

No QTc prolongation, cardiac abnormalities, no pattern of abnormal lab results, or side effects of antipsychotics (EPS, weight gain, sexual dysfunction, hormonal changes, CNS effects)

> 120 patients treated for 1 year; **> 500 unique subjects** and **> 400 patients with schizophrenia** treated with evenamide

All **tox studies** (except ERA and carcinogenicity – 1 species, 6 months) **accepted by health authorities**

Acceptance of registration dossier based on 1 sufficiently positive TRS study expected

OVERVIEW OF ONGOING STUDIES & RECENT RESULTS

TRS

Study 014/015: Open label, pilot, rater blinded study, fixed doses (7.5, 15, and 30 mg bid) in **TRS patients**, as add-on to any AP (except clozapine)

- **Study 014** (6 weeks) – **Completed**
- **Study 015** (extension to 1 year) – **Completed**



NON-TRS

Study 008A: potentially pivotal, phase II/III, 4-week, randomized, double-blind, placebo-controlled study of evenamide 30 mg BID vs placebo in 290 **patients who are inadequate responders to SGAs**, enrollment completed



EFFICACY RESULTS INDICATE

- **Statistically significant improvement from baseline** (within group analysis, paired t-test) on PANSS, CGI-S and LOF at Weeks 6, 30 and 52
- **Clinically “important” improvement** (responder analyses) in 41.8% on PANSS ($\geq 20\%$ improvement from baseline), 24.1% on CGI-S (2-category improvement from baseline), 37.6% on CGI-C (rated as at least “much improved”)
- **Increasing efficacy signal over time** for all efficacy measures
- Additional analyses demonstrate **unique pattern of efficacy**:
 - **Conversion of TRS patients to “responders” (abt. 50%)**
 - **Meeting “remission” criteria (abt. 25%)**

PILOT STUDY 014/015: DESIGN AND KEY CHARACTERISTICS

Study design:

A pilot, randomized, open-label, rater-blinded, parallel-group, 6 weeks, multi-center study followed by an extension up to **1 year of treatment with evenamide**

Objectives:

Evaluate the safety, tolerability and preliminary efficacy of three add-on fixed doses of evenamide (7.5, 15 and 30 mg bid) in patients with treatment resistant schizophrenia (TRS) not responding adequately to their stable, therapeutically active dose of a single antipsychotic medication, treatment for **up to 1-year in the extension study (Study 015)**

Efficacy measures: :

PANSS, CGI-S, CGI-C, LOF rated by psychiatrists certified for the study

The efficacy rater was blinded to the dose of evenamide and to any safety findings



Study Population:

- **Treatment-Resistance** with documented non-response to at least 2 antipsychotics from two different chemical classes including at least one atypical antipsychotic, for at least 6 weeks of treatment each
- **PANSS total 70-90; PANSS positive total score ≥ 20 , CGI-S of moderately to severely ill (4-6);**
- **Antipsychotic monotherapy** (except clozapine) for 4 weeks prior to screening, with current symptoms present for at least one month
- **NO** Patients at high risk of suicide/ other psychiatric disorders/ severe or unstable disease

Countries:

India | Italy | Sri Lanka

STUDY 014/015 – PATIENT DISPOSITION BY STUDY AND DURATION

Randomized N = 161	Completed N = 153	Discontinued N = 8	Completed N = 132	Completed N = 121	Total Discontinued	31
	Entered Extension N = 144	Did not enter extension N = 9	Discontinued N = 12	Discontinued N = 11	Withdrawal of consent	23
					Lost to follow-up	5
					Adverse event	2
					Death	1
Day 0 Randomi- zation	WEEK 6		WEEK 30 6-MONTH	WEEK 52 1-YEAR		
STUDY 014 6 weeks	STUDY 015 Additional 46 weeks of treatment					



STUDY 015 – SUMMARY OF SAFETY RESULTS

» **Less than 30% of the patients experienced at least one treatment emergent adverse event (TEAE)**

» Two (2) Serious Adverse Events (SAEs) were reported:

- Death (1) after approximately six months of treatment: Improvement from baseline $\geq 20\%$ in symptoms of psychosis (PANSS), no other prior adverse events reported, autopsy findings suggestive of atherosclerosis
- One (1) dilutional hyponatremia followed by an acute symptomatic seizure (more than 20 days out of IP) occurred beyond 1 year of treatment

» No pattern of extrapyramidal side effects, endocrine or metabolic syndrome, sexual dysfunction, significant CNS events, or laboratory abnormalities

» No patient relapsed during one year of treatment with evenamide

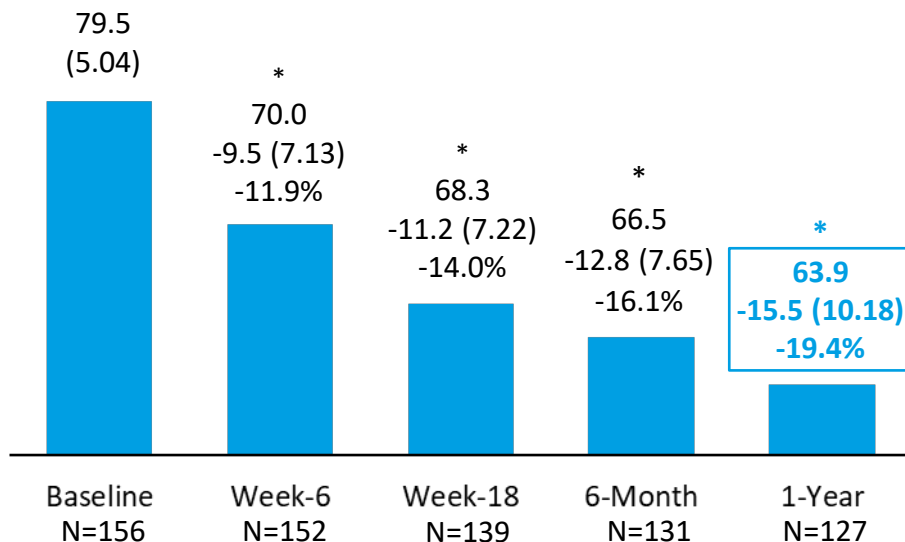
» Independent Safety Monitoring Board (ISMB):
chair R. Krishnan (Rush), R. Buchannan (Baltimore),
R. Trohman (Rush) – responsible for periodic reviews of
safety data

» 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

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

MEAN CHANGE FROM BASELINE (SD) – mITT; PRIMARY ESTIMAND TREATMENT POLICY

% change from baseline



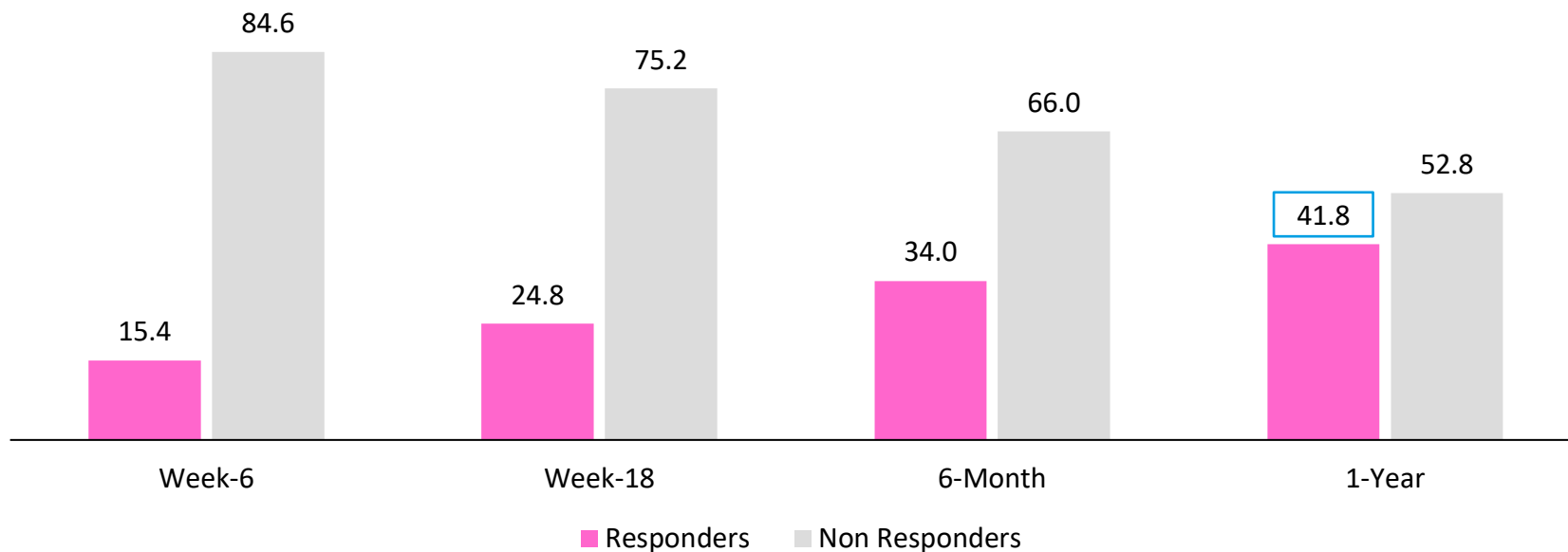
mITT population, N = 156	
Method	1-Year Mean change (SD)
Primary Estimand	-15.5 (10.18)
Sensitivity Analysis (LOCF)	-15.3 (10.09)

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

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS (%) – mITT; PRIMARY ESTIMAND TREATMENT POLICY

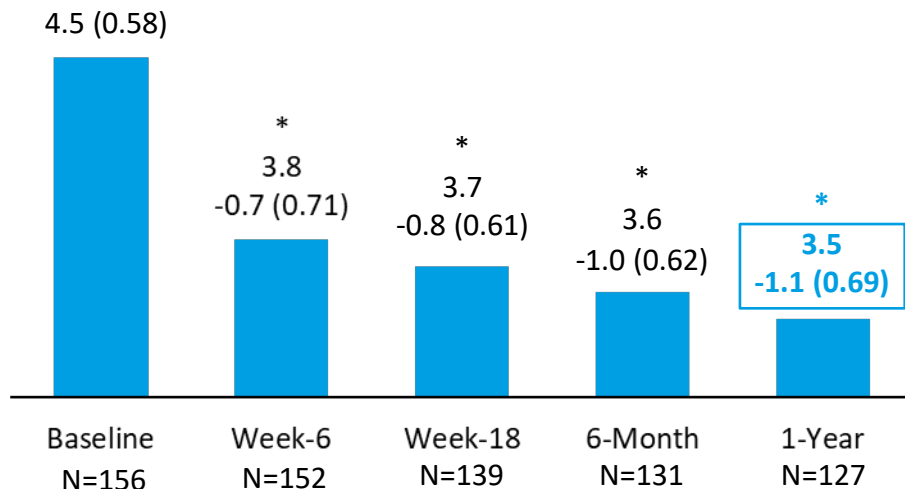
PANSS Total $\geq 20\%$ improvement from baseline



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

CGI-S MEAN CHANGE FROM BASELINE (SD)

% change from baseline



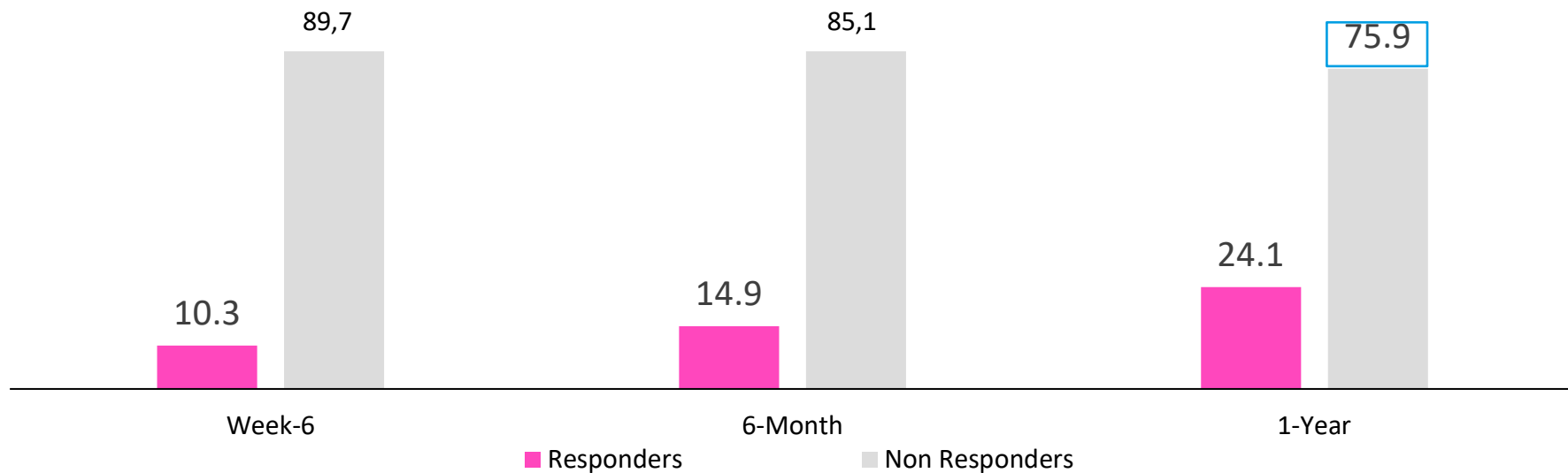
* p-value vs baseline < 0.001, paired t-test, OC

mITT population, N = 156	
Method	1-Year Mean change (SD)
Primary Estimand	-1.1 (0.69)
Sensitivity Analysis (LOCF)	-1.1 (0.71)

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

CGI-S RESPONDER ANALYSIS (%)

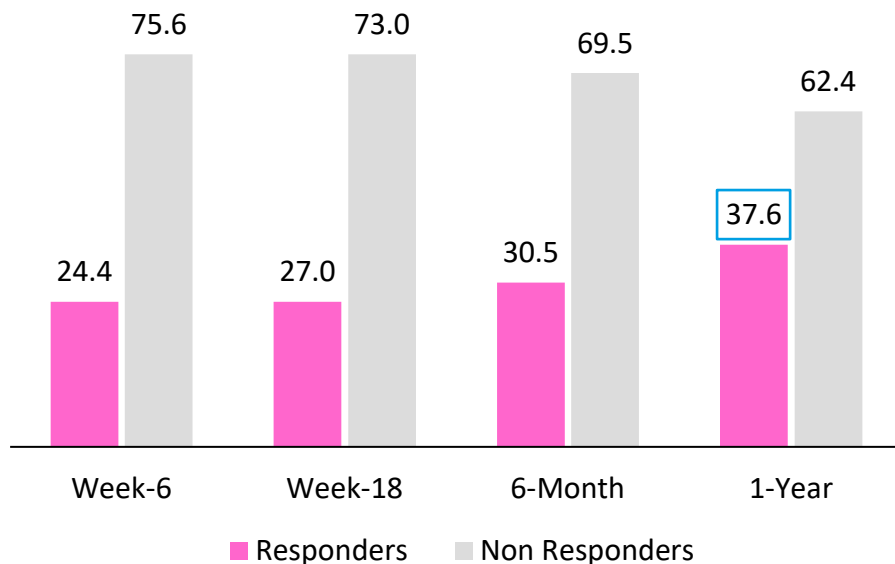
Improvement $\geq$ 2-category from baseline



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

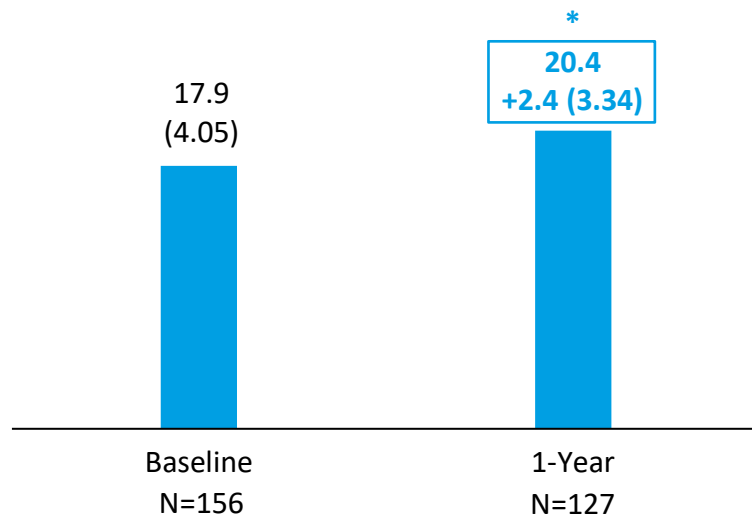
CGI-C RESPONDER ANALYSIS (%)

At least "Much Improved"



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

LOF MEAN CHANGE FROM BASELINE (SD)



PATIENTS NO LONGER MEETING SEVERITY CRITERIA FOR TRS

1/2



REQUIREMENTS FOR PATIENTS' ENROLMENT IN STUDY 014/015:

- Diagnosis of schizophrenia (DSM-V)
- Considered treatment-resistant based on duration of schizophrenia (onset within the past 10 years), and documented failure of treatment on 2 different antipsychotics (at least one SGA) and treated for an adequate period of time

SELECTION CRITERIA FOR SEVERITY OF SYMPTOMS:

- CGI-S of moderately ill to severely ill (score 4-6)
- PANSS total score ≥ 70
- Score of 4 or more on at least 2 of the PANSS core symptoms of psychosis: P2 (Conceptual Disorganization), P3 (Hallucinatory Behavior), P6 (Suspiciousness/Persecution) and G9 (Unusual Thought Content)
- Total score ≥ 20 on the combined total of the PANSS symptom items: P1 (Delusions), P2 (Conceptual Disorganization), P3 (Hallucinatory Behavior), P4 (Excitement), P6 (Suspiciousness/Persecution), P7 (Hostility), and G9 (Unusual thought content)

PATIENTS NO LONGER MEETING SEVERITY CRITERIA FOR TRS (mITT; LOCF/OC)

2/2

SEVERITY CRITERIA	VISIT	WEEK 6		6-MONTH		1-YEAR	
	STAT N	LOCF 156	OC 152	LOCF 156	OC 131	LOCF 156	OC 120
1. PANSS <70	n (%)	72 (46.1)	72 (47.3)	93 (59.6)	84 (64.1)	99 (63.5)	84 (70.0)
2. Core items* <20	n (%)	60 (38.4)	60 (39.4)	83 (53.2)	76 (58.0)	93 (59.6)	80 (66.7)
3. CGI-S < 4	n (%)	52 (33.3)	52 (34.2)	73 (46.7)	66 (50.4)	89 (57.1)	76 (63.3)
4. Score of > 4 in max 1 core symptom of psychosis#	n (%)	75 (48.1)	75 (49.3)	96 (61.5)	87 (66.4)	104 (66.7)	87 (72.5)
All combined	n (%)	40 (25.6)	40 (26.3)	57 (36.5)	51 (38.9)	76 (48.7)	66 (55.0)

*P1 (delusions), P2 (conceptual disorganization), P3 (hallucinatory behavior), P4 (excitement), P6 (suspiciousness), P7 (hostility), G9 (unusual thought content); #P2, P3, P6, G9

***Data on file at Newron Pharmaceuticals





REMISSION IN PATIENTS WITH SCHIZOPHRENIA



Remission is defined as a level of **symptomology that does not interfere with an individual's behaviour** and is also below that required for a diagnosis of schizophrenia*



Symptom improvements should last for a minimum of six months in order for remission to be reached



Individuals who achieve remission from schizophrenia have better **subjective well-being and better functional outcomes** indicating **long-term wellness**



Remission sets a standard for **minimal severity of symptoms** and signs and the **duration** these symptoms and signs need to remain at this minimal level

* Yeomans et.al., Cambridge University Press, Jan. 2, 2018

CRITERIA FOR REMISSION IN PATIENTS WITH SCHIZOPHRENIA

ORIGINAL REQUIREMENTS

Lieberman et al., 1993

- Score ≤ 3 on SADS-C+PD* items: suspiciousness, severity of delusions, hallucinations, **impaired understandability, bizarre behavior**
- CGI-S of maximum “mildly ill” (i.e. score ≤ 3)
- CGI-C at least “much improved” (i.e. score ≤ 2)
- Maintenance for ≥ 8 weeks

Andreasen et al., 2005

- Score ≤ 3 «mild» on PANSS items: P1= delusions - P2= conceptual disorganization - P3= hallucinatory behaviour - N1=Blunted affect - N4=Passive/apathetic social withdrawal - N6=Lack of spontaneity and flow of conversation - G5= Mannerism and posturing - G9=Unusual thought content
- Maintenance of this level of response for ≥ 6 months



PROPOSED ADAPTATIONS

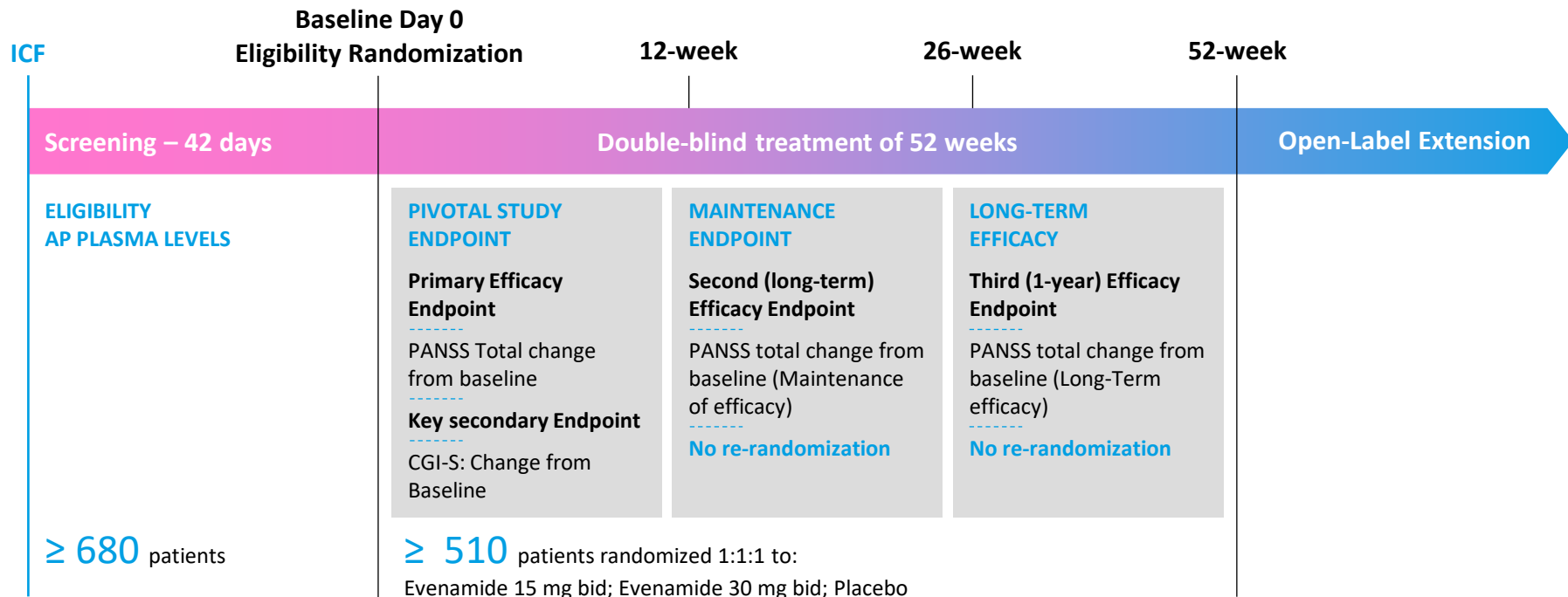
- SADS **Impaired understandability** → replaced with PANSS **P2** conceptual disorganization
- SADS **Bizarre behavior** → replaced with PANSS **G5** Mannerism and posturing

*Schedule for Affective Disorders and Schizophrenia - Change Version with Psychosis and Disorganization items

STUDY 014/015 – PROPORTION OF PATIENTS WHO MEET PROPOSED REMISSION CRITERIA FROM LITERATURE

Method	Criteria	Maintenance requirement	N=156 n (%) of patients meeting remission criteria
Lieberman et al, 1993	P1, P2, P3, P6, G5 ≤ 3 CGI-S «mildly ill»; CGI-C «much improved»	8 weeks	43 (27.6%)
Andreasen et al, 2005	P1, P2, P3, N1, N4, N6, G5, G9 ≤ 3	24 weeks	39 (25.0%)

PHASE III TRS STUDY – DESIGN





XADAGO IN PARKINSON'S DISEASE MARKETED COMPOUND



First approved NCE in >10 yrs (U.S., EU)



Globally licensed



Double digit/single digit % royalties
>€80 milestones/royalties collected

SIGNIFICANT COMMERCIAL OPPORTUNITY IN XADAGO® (SAFINAMIDE)

US / Canada



Launched in US in 2017
Launched in Canada in 2019

EU



Launched in Germany, UK, Italy, Spain and other EU territories (2015), Switzerland, UAE, Brazil and Colombia; application for regulatory approval filed for Mexico

Latin America



Israel



Approved in 2020

Japan / Asia



Launched in 2019

Australia / New Zealand



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 Q1/2021

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