COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Corporate presentation
October 2025

Newron
Pharmaceuticals

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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**
  - Only known* (add-on)- compound with scientific evidence of efficacy in treating poorly responding/treatment resistant schizophrenia patients, since and beyond clozapine
  - Partnered with EA/Eisai for Japan/Asia

Management team with extensive experience and proven track record in drug development and commercialization (Novartis, Roche, Organon, J&J)

Fully independent Board of Directors with seasoned industry experts (Abbvie, Bayer, Aventis, GW Pharma, Abbott, Jazz)

*Based on information available to the company regarding drugs approved for study

EVENAMIDE – CHANGING THE TREATMENT PARADIGM IN SCHIZOPHRENIA

TPP

- Large market opportunity
- 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 (treatment resistant schizophrenia) drug since/beyond clozapine**
    - 30-50% of total population
    - *Est. c.20-30% poor responders*

CLINICAL EVIDENCE

- **TRS patients:** Positive results from 1-year pilot study 014/015 in 161 TRS patients
- **NON-TRS patients:** Positive results from pivotal Phase II/III Study 008A

NEXT STEPS

- **Next clinical inflexion points:** Pivotal 1-year study ENIGMA-TRS 1, Pivotal 12-week study ENIGMA-TRS 2 results
- **Regulatory strategy:** Approval in TRS - Chance for early market access
- **Strong IP position:** Exclusivity: 2035 (COMP, US), 2033 (COMP, RoW) and beyond (10 yrs exclusivity post approval in the EU); additional patents (process, solid form-COMP) granted/under review: up to 2044
- **Industry confidence evidenced by:** EA Pharma/Eisai & additional development cooperations

EVENAMIDE: LICENSING AGREEMENT WITH EA/EISAI

EA Pharma / EISAI (top 10 Japan: donepezil/Aricept, lecanemab, Leqembi) to develop evenamide in all indications in Japan and other designated Asian territories*

Newron to receive
- €44m downpayment
- €11m of contribution to upcoming Phase III program in TRS, up to
- €62m of regulatory and commercial milestones, up to
  €117m total, up to
- tiered royalties up to a double-digit percentage of net sales
- about €100m NPV for less than 10% of the market

Funds raised to cover upcoming ENIGMA-TRS 1 Phase III study

Study initiated in May 2025

**Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, the Socialist Republic of Vietnam*

SCHIZOPHRENIA - HIGH MEDICAL NEED FOR 23 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 — **~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

EVENAMIDE'S DIFFERENTIATED MODE OF ACTION 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

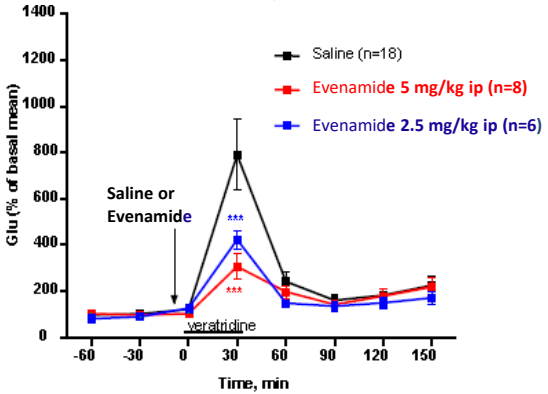
Inhibition of native sodium channels expressed in rat cortical neurons

K_{rest} (μM)	K_{inact} (μM)
25	0.4

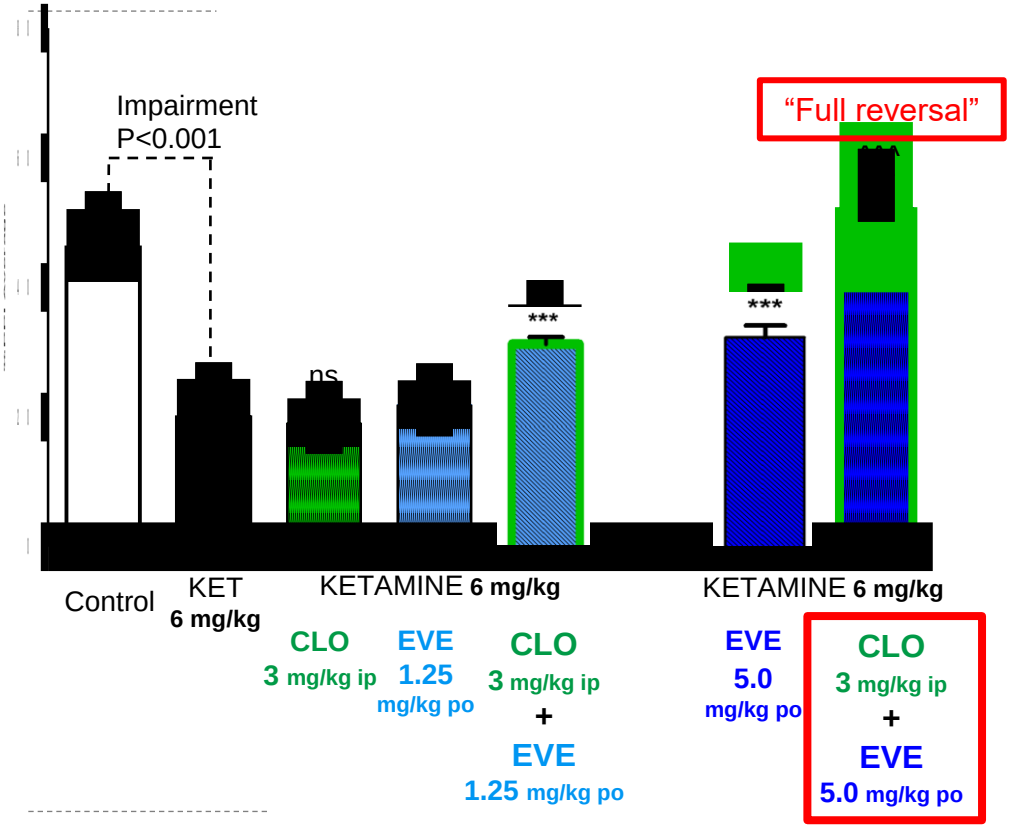
Modulates sustained repetitive firing without inducing impairment of the normal neuronal excitability

High frequency firing	Low frequency firing
Control	Control
	
Evenamide 1μM	Evenamide 1μM
	

Inhibits Glutamate Release



KETAMINE-INDUCED DETERIORATION OF PPI IS RESCUED BY COMBINATION OF INEFFECTIVE DOSES OF CLOZAPINE AND EVENAMIDE



Statistics: 3-way, repeated-measure ANOVA;
***P<0.001 vs KET; ^^^ P<0.001 vs EVE 5 (Tukey's post-hoc test) (n=16/group)

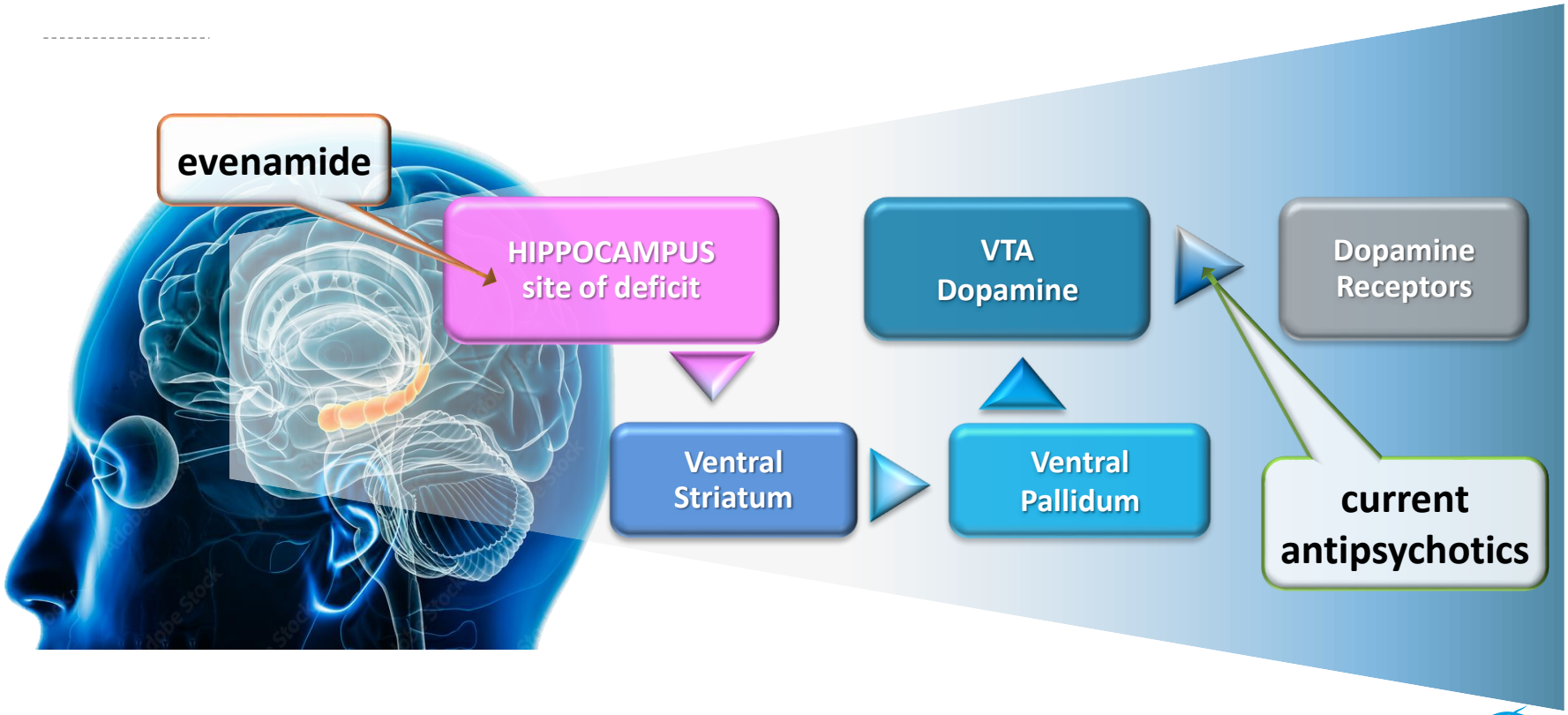
Evenamide + **FGAs/SGAs**

1. Combination of ineffective doses of evenamide with antipsychotics (APs) was associated with improvement in animal models of psychosis

2. Potential to benefit:

   positive, negative and cognitive symptoms

STRAIGHT TO THE HEART OF THE BRAIN



EVENAMIDE: SIGNIFICANT EFFICACY IN THE MAM MODEL

DOMAIN	KEY FINDINGS ON EVENAMIDE
Neuronal Activity	Reduces Hippocampal Pyramidal Neuron Hyperactivity
	Normalizes VTA Dopamine Neuron Population Activity
	Impacts Primarily Lateral VTA Dopamine
	Effects of evenamide outlast its presence in the brain → Induction of Long-Term Plasticity (after a single dose) → Potential for disease modification
Cognition	Normalizes Novel Object Recognition Model of Cognition
Negative symptoms	Normalizes Social Approach/Interaction Model of Negative Symptoms

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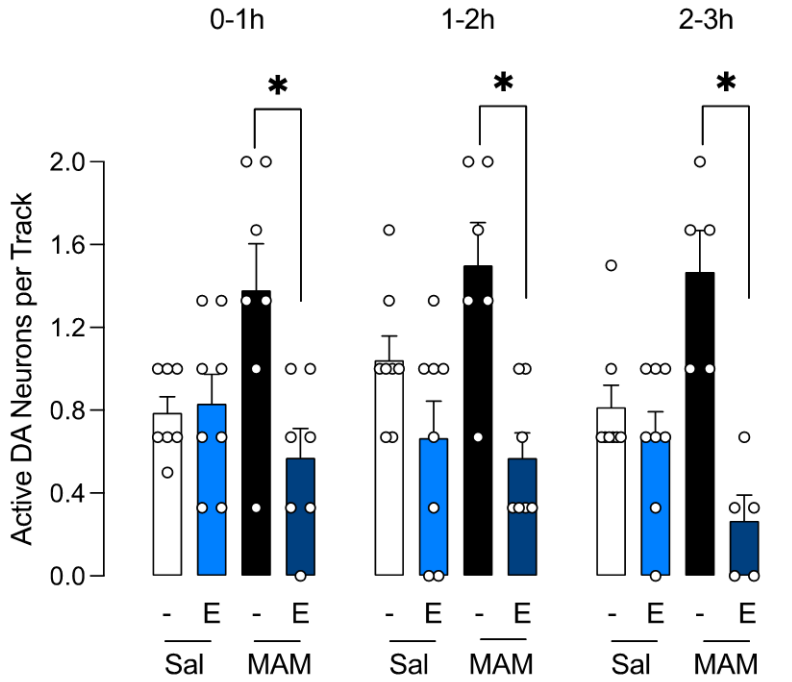
MAM MODEL: EVENAMIDE EFFECTS PERSIST WELL BEYOND THE DRUG HALF-LIFE THIS IMPLIES INDUCTION OF LONG-TERM PLASTICITY AFTER A SINGLE DOSE

- : no drug
E : evenamide



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

Potential to be first add-on antipsychotic to be approved for inadequately responding patients	**First drug for Treatment Resistant Schizophrenia (TRS)** since clozapine (1989)	**Only known* option as add-on to clozapine**
Up to 70% of Chronic schizophrenia population (every ~18 months)	**More than 30%** of schizophrenia population (with upside to **50%**)	No antipsychotic has demonstrated benefit as augmenting therapy for clozapine (~30k CLZ-TRS patients in each key territory)
Add-on therapy with **no dose-limiting side effects** a key advantage for patients and prescribers	in routine practice, the use of clozapine is limited by safety, tolerability, and monitoring requirements	
	Strong HTA value story to support pricing and coverage	

Based on information available to the company regarding drugs approved for study

EVENAMIDE

FIRST POTENTIAL BREAKTHROUGH FOR TRS PATIENTS 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
- Placebo-controlled study in 291 subjects demonstrated significant efficacy of Evenamide 30 mg bid across measures and analyses in poor AP responders
- **Low incidence of treatment-emergent adverse events**, or drop out due to intolerance
- **No** pattern of QTc prolongation, cardiac abnormalities, 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 accepted by health authorities,** ERA and carcinogenicity – 1 species, 6 months only outstanding work
- **Acceptance of registration dossier based on 1 sufficiently positive TRS study** expected
- Based on above results, and efficacy/safety profile **positive health technology assessment opinion** is deemed likely

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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

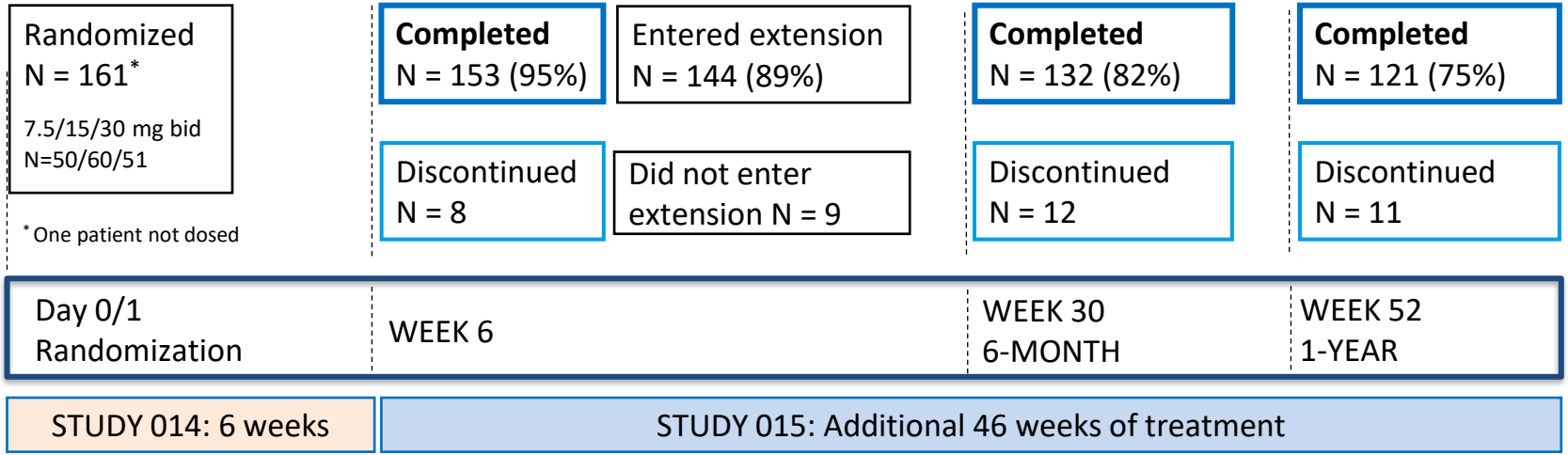
Study Population:

- **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

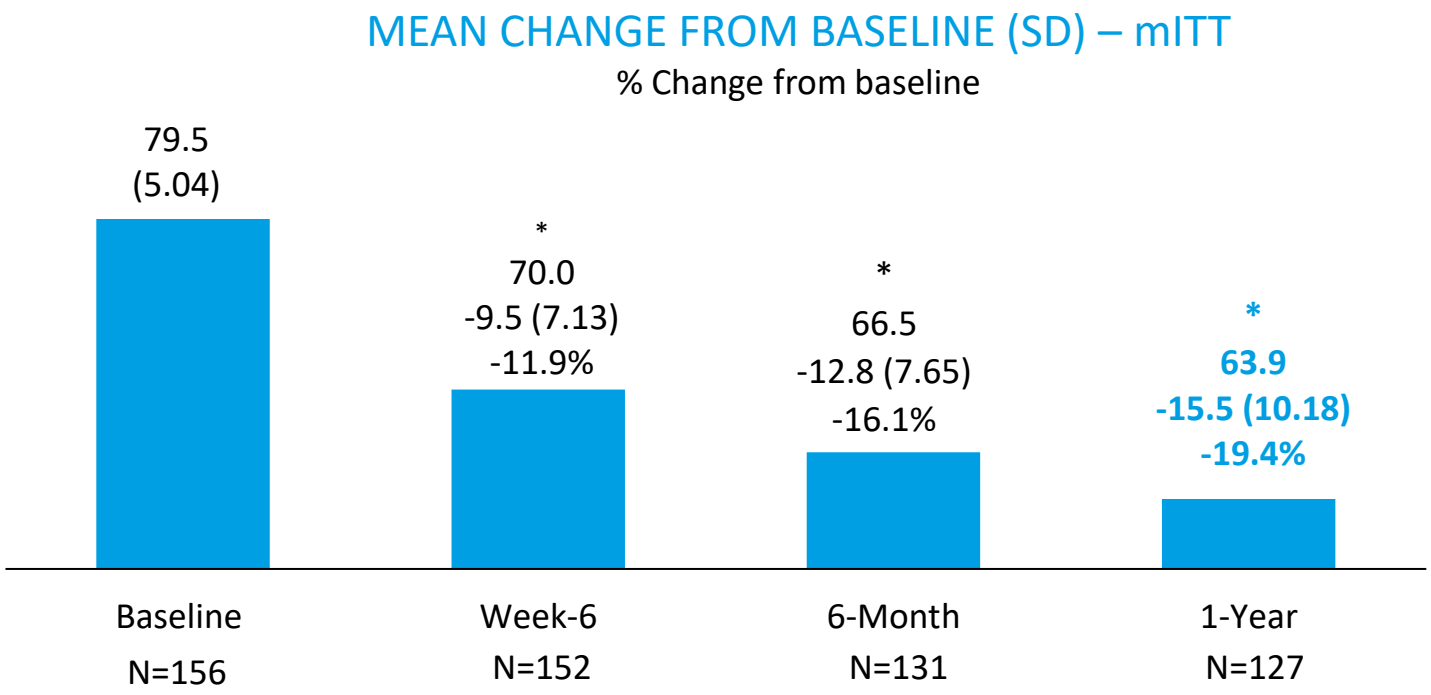


Continuation rate into extension (Study 015) → 144/153 (94%)

Completion rate of Study 015 alone → 121/144 (84%)

Total Discontinued	**31**
Withdrawal of consent	23
Lost to follow-up	5
Adverse event	2
Death	1

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

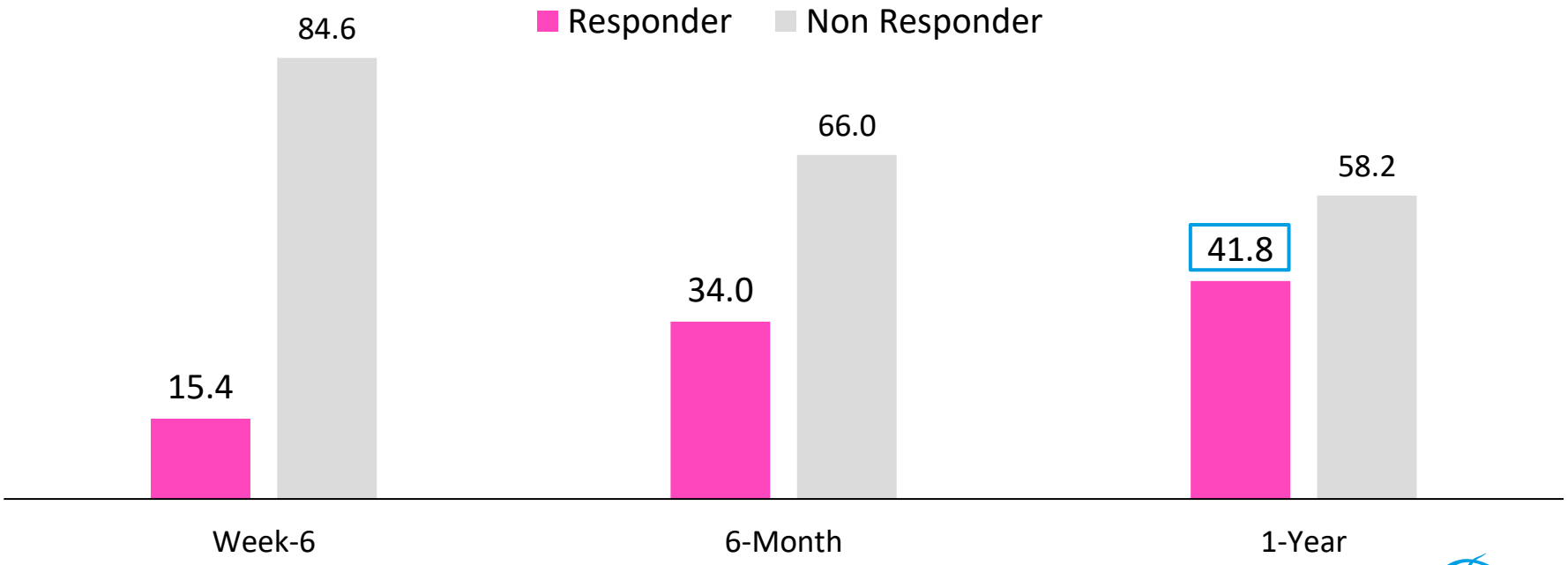


* p-value vs baseline < 0.001, paired t-test, OC

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS (%) – mITT

PANSS Total ≥20% Improvement from baseline



STUDY 015 - PATIENTS NO LONGER MEETING SEVERITY CRITERIA FOR TRS (mITT; LOCF/OC)

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

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

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%)**

STUDY 008A - DESIGN AND KEY CHARACTERISTICS

Study design:
A potentially pivotal, phase II/III, 4-week, international randomized, double-blind, placebo-controlled study

Objectives:
to evaluate the efficacy, safety, tolerability, of evenamide 30 mg bid vs placebo in patients who are inadequate responders to SGAs

Sample size: 291 patients randomized in a 1:1 ratio → Evenamide 30 mg bid OR matching Placebo

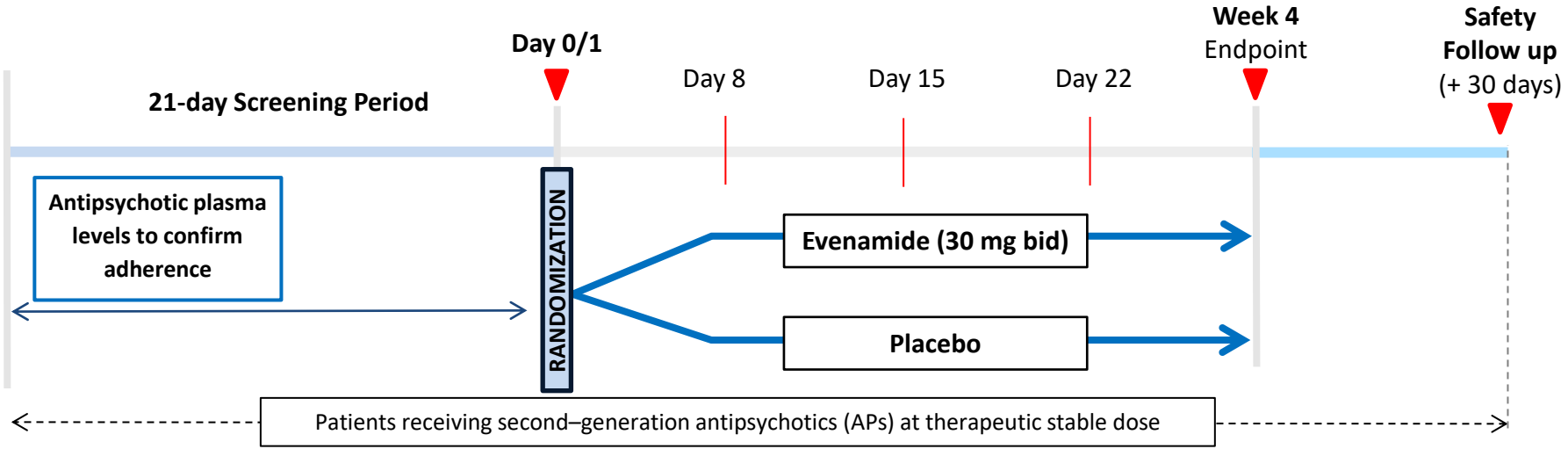
Efficacy measures: :
PANSS, CGI-S, CGI-C, LOF

Study Population:

- Outpatients with chronic schizophrenia (DMS-5) on therapeutic doses of SGAs who are still symptomatic, despite ≥ 4 weeks of treatment at a stable dose (adherence confirmed by plasma levels)
- Current symptoms present for at least one month
- Total PANSS 70-85
- CGI-S rating of moderately (4) to severely ill (6)
- Patients with ≥2 core positive symptoms (hallucinations, suspiciousness, conceptual disorganization and unusual thought content) rated moderately severe or higher

Countries:
EU (CZ, EST, HUN, ITA, RO, SPA), IND, MEX, ARG

STUDY 008A - STUDY DESIGN AND KEY FEATURES



Allowed SGAs → Aripiprazole; Clozapine; Olanzapine; Paliperidone; Quetiapine; Risperidone; Cariprazine

STUDY 008A - MOST COMMON TEAEs BASED ON EVENAMIDE INCIDENCE

System Organ Class (SOC) ≥4.5% on Evenamide	Evenamide 30 mg bid N=132; n (%)	Placebo N=159; n (%)	Overall N=291; n (%)
Nervous system disorders	9 (6.8)	12 (7.5)	21 (7.2)
Psychiatric disorders	6 (4.5)	12 (7.5)	18 (6.2)
Gastrointestinal disorders	9 (6.8)	5 (3.1)	14 (4.8)
Infections and infestations	7 (5.3)	4 (2.5)	11 (3.8)

Preferred Term (PT) ≥1.5% on Evenamide	Evenamide 30 mg bid	Placebo	Overall
Nasopharyngitis	3 (2.3)	1 (0.6)	4 (1.4)
Headache	3 (2.3)	4 (2.5)	7 (2.4)
Vomiting	3 (2.3)	1 (0.6)	4 (1.4)
Diarrhoea	2 (1.5)	0 (0.0)	2 (0.7)
Somnolence	2 (1.5)	5 (3.1)	7 (2.4)

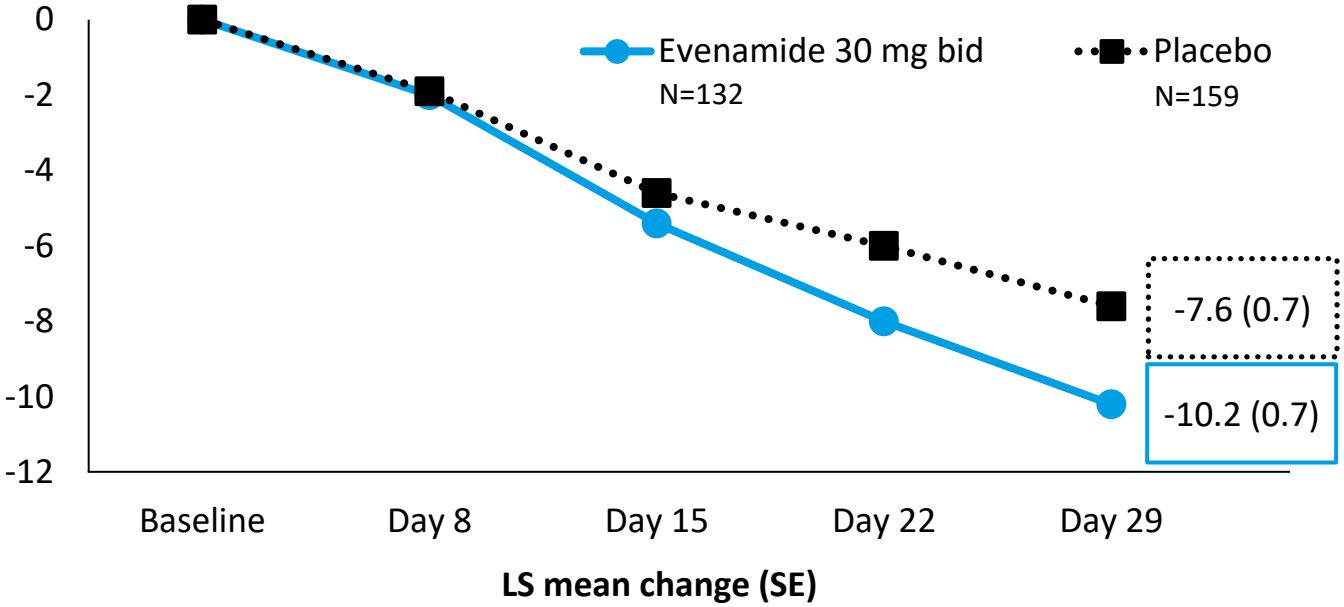
STUDY 008A - PRIMARY, KEY SECONDARY EFFICACY ENDPOINT – ITT POPULATION PRIMARY ESTIMAND – TREATMENT POLICY, MEAN CHANGE FROM BL – DAY 29

Scale	Visit	Evenamide 30 mg bid N=132	Placebo N=159
PANSS total score	Baseline – mean (SD)	78.4 (4.1)	78.7 (4.0)
	Day 29 – LS mean (SE)	-10.2 (0.7)	-7.6 (0.7)
	LS mean difference (SE)	-2.5 (0.9)	
	p-value [CI]	**0.006 [-4.3, -0.7]**	
CGI of Severity (CGI-S)	Baseline – mean (SD)	4.4 (0.6)	4.5 (0.6)
	Day 29 – LS mean (SE)	-0.6 (0.1)	-0.5 (0.1)
	LS mean difference (SE)	-0.16 (0.08)	
	p-value [CI]	**0.037 [-0.3, -0.0]**	

Significant results were also obtained using the mITT population; N=287
CI= 95% confidence interval

STUDY 008A - PANSS TOTAL SCORE

MEAN CHANGE FROM BASELINE TO DAY 29; ITT POPULATION; PRIMARY ESTIMAND – TREATMENT POLICY; MMRM



Drug-Placebo Difference:
LS mean (SE) = -2.5 (0.9)
p-value: 0.006
CI: -4.3, -0.7

Significant results were also obtained using the mITT population; N=287
CI= 95% confidence interval; SD=standard deviation; LS mean=least squares mean; SE=standard error

STUDY 008A - PANSS MEAN CHANGE FROM BASELINE BY CURRENT ANTIPSYCHOTIC MEDICATION; ITT; OC

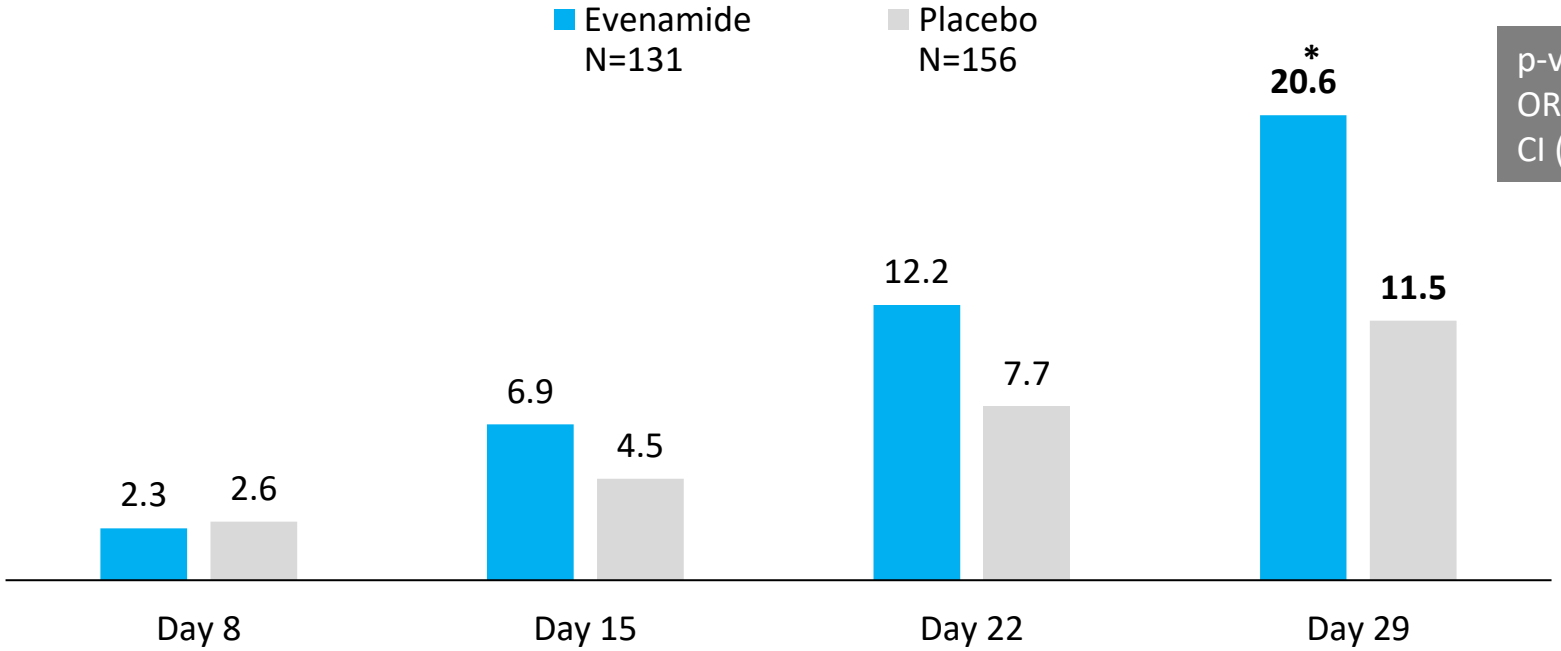
Antipsychotic	Evenamide 30 mg bid N=132		Placebo N=159	
	n (%)	PANSS change from baseline (SD)	n (%)	PANSS change from baseline (SD)
Risperidone	**51 (38.6)**	**-8.8 (6.5)**	**63 (39.6)**	**-7.3 (7.4)**
Olanzapine	**32 (24.2)**	**-13.4 (8.6)**	**32 (20.1)**	**-7.9 (6.5)**
Clozapine	**19 (14.4)**	**-7.3 (6.2)**	**17 (10.7)**	**-4.4 (4.4)**
Paliperidone	**15 (11.4)**	**-7.9 (9.5)**	**24 (15.1)**	**-5.5 (8.4)**
Aripiprazole	11 (8.3)	-11.9 (9.6)	14 (8.8)	-11.8 (10.9)

SD=standard deviation

STUDY 008A – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS –

Proportion of patients (%) improving ≥20% from baseline; mITT; OC

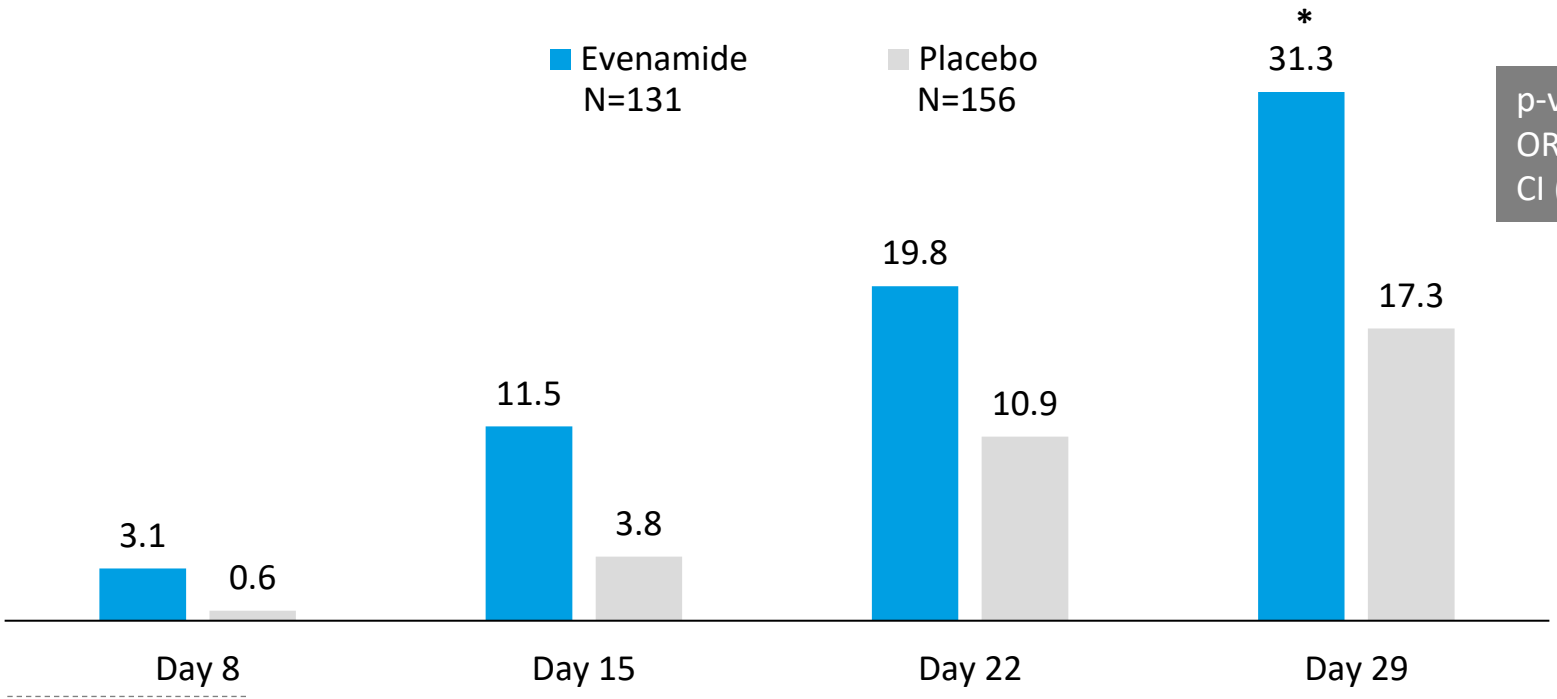


p-value = 0.037
OR 1.99
CI (1.0, 3.8)

 CI=95% confidence interval; OR=odds ratio

STUDY 008A – CLINICAL GLOBAL IMPRESSION OF CHANGE (CGI-C)

CGI-C Responder Analysis –
Proportion of patients (%) “At least much improved”; mITT

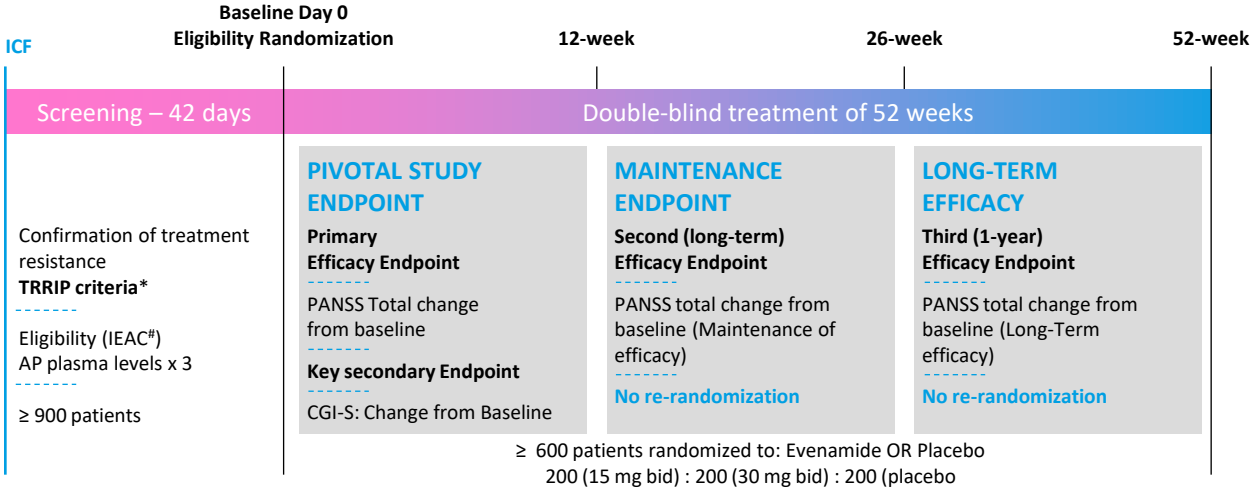


p-value = 0.006
OR 2.18
CI (1.2, 3.8)

 CI=95% confidence interval; OR=odds ratio

ENIGMA-TRS 1
PROPOSED PLACEBO-CONTROLLED, 1-YEAR STUDY (INTERNATIONAL)

A Phase III, 52-week, prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center study, with a primary efficacy endpoint at 12 weeks, to determine the efficacy, safety, and tolerability of Evenamide as add-on in patients with documented treatment-resistant schizophrenia (TRS), which is not adequately controlled by a stable therapeutic dose of the patient's current antipsychotic medication(s)

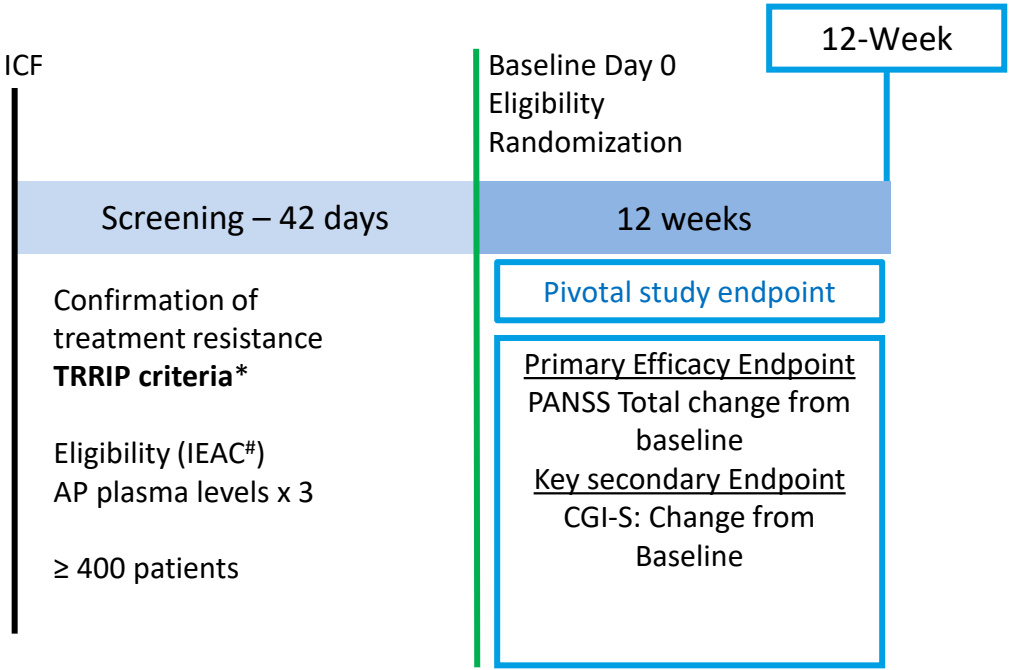


* TRRIP Working Group Howes et al., 2017

KEY SELECTION CRITERIA

- Treatment resistance (**TRS**) according to **TRRIP** working group (Howes et al., 2017)
- Antipsychotic treatment as per **'Standard of Care'**, minimally one oral or depot antipsychotic at a stable therapeutic dose
- **BPRS** total score ≥ 45 at Screening
- **Prominent positive** symptoms as measured by the BPRS
- **CGI-S** rating of mildly ill to severely ill (score of 3 to 6)
- Antipsychotic (AP) **plasma levels** tested at screening and throughout the study to confirm adherence to the background AP therapy and Evenamide therapy

ENIGMA-TRS 2
PROPOSED PLACEBO-CONTROLLED, 12-WEEK STUDY (US & SELECTED COUNTRIES)



KEY SELECTION CRITERIA

- Treatment resistance (**TRS**) according to **TRRIP** working group (Howes et al., 2017)
- Antipsychotic treatment as per **'Standard of Care'**, minimally one oral or depot antipsychotic at a stable therapeutic dose
- **BPRS** total score ≥ 45 at Screening
- **Prominent positive** symptoms as measured by the BPRS
- **CGI-S** rating of mildly ill to severely ill (score of 3 to 6)
- Antipsychotic (AP) **plasma levels** tested at screening and throughout the study to confirm adherence to the background AP therapy and Evenamide therapy

* TRRIP Working Group Howes et al., 2017

Independent Eligibility Assessment Committee

≥ 400 patients randomized 1:1 to:
200 (15 mg bid) : 200 (placebo)

EVENAMIDE VALUE DRIVERS

Significant value drivers for leading candidate Evenamide

- First partnered territory: Japan/Asia with EA Pharma/Eisai: 12/2024
- Start of ENIGMA-TRS Ph III program: 05/2025
  - Start enrolment ENIGMA-TRS 1: 08/2025
  - Expected start of ENIGMA-TRS 2: Within the next few weeks
- Additional partnering transactions
- Results from ENIGMA-TRS Phase III program from data points at:
  - 12 weeks
  - 26 weeks
  - 52 weeks
- NDA submission
- First launch

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