COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Stefan Weber, CEO

H.C. Wainwright 6th Annual Neuro Perspectives Hybrid Conference

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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** – Only (add-on)- compound with scientific evidence of efficacy in treating poorly responding/treatment resistant schizophrenia patients, since and beyond clozapine

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 weathered industry experts (Abbvie, Bayer, Aventis, GW Pharma, Abbott, Jazz)

Significant value drivers for leading candidate Evenamide

- First partnered territory: Japan/Asia with EA Pharma/Eisai: 12/2024
- Start of ENIGMA-TRS Phase III program: May 2025
- Additional partnering transactions
- Results from ENIGMA-TRS Phase III program from data points at:
  - 12 weeks
  - 26 weeks
  - 52 weeks
- Partnering/M&A strategic territory USA
- NDA submission
- First launches

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
    - *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 step:** Pivotal 1-year study ENIGMA-TRS 1, Pivotal 12-week study ENIGMA-TRS 2
- **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) granted/under review: up to 2044
- **Validation by**: EA Pharma / Eisai

EVENAMIDE

VALIDATION OF
- MOA
- RESULTS SO FAR
- INDICATION

BY PARTNERING AGREEMENT WITH EA PHARMA/EISAI (DEC. 2024)

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

Implied value of evenamide, based on rNPV of €100m = €1bln (Baader Helvea, Dec. 13, 2024)

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 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 | **~30% TRS**

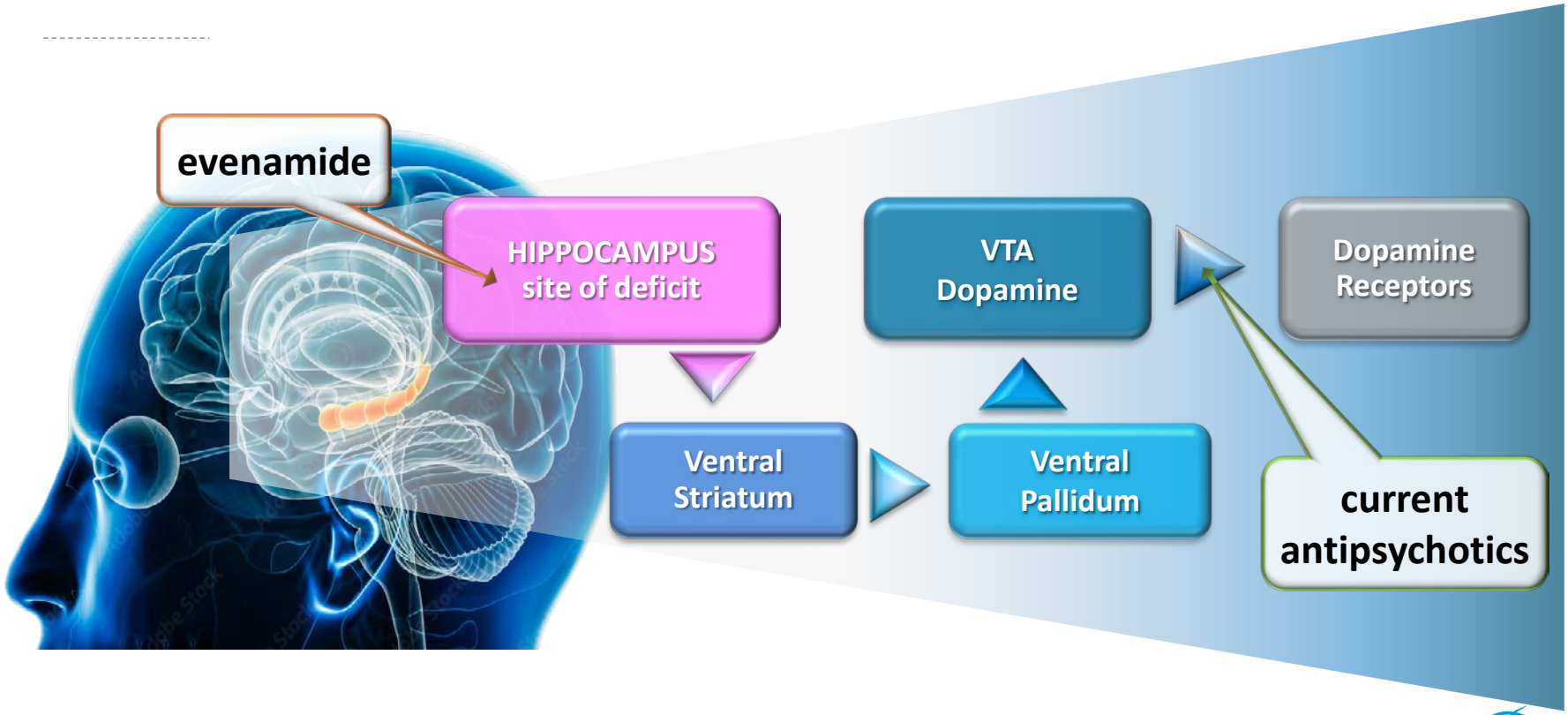
~40% Inadequate Response

~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

STRAIGHT TO THE HEART OF THE BRAIN



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)

25

K_{inact} (µM)

0.4

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

High frequency firing

Control

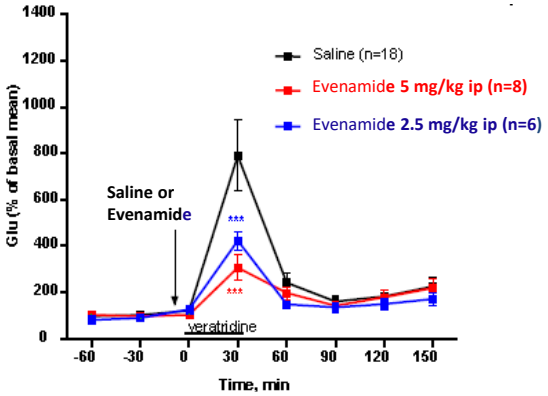
Evenamide 1µM

Low frequency firing

Control

Evenamide 1µM

Inhibits Glutamate Release



EVENAMIDE: SIGNIFICANT EFFICACY IN THE MAM MODEL

DOMAIN	KEY FINDINGS ON EVENAMIDE
Neuronal Activity	Reverses 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

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	**First drug for Treatment Resistant Schizophrenia (TRS)** since clozapine (1989)	**Only 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	

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

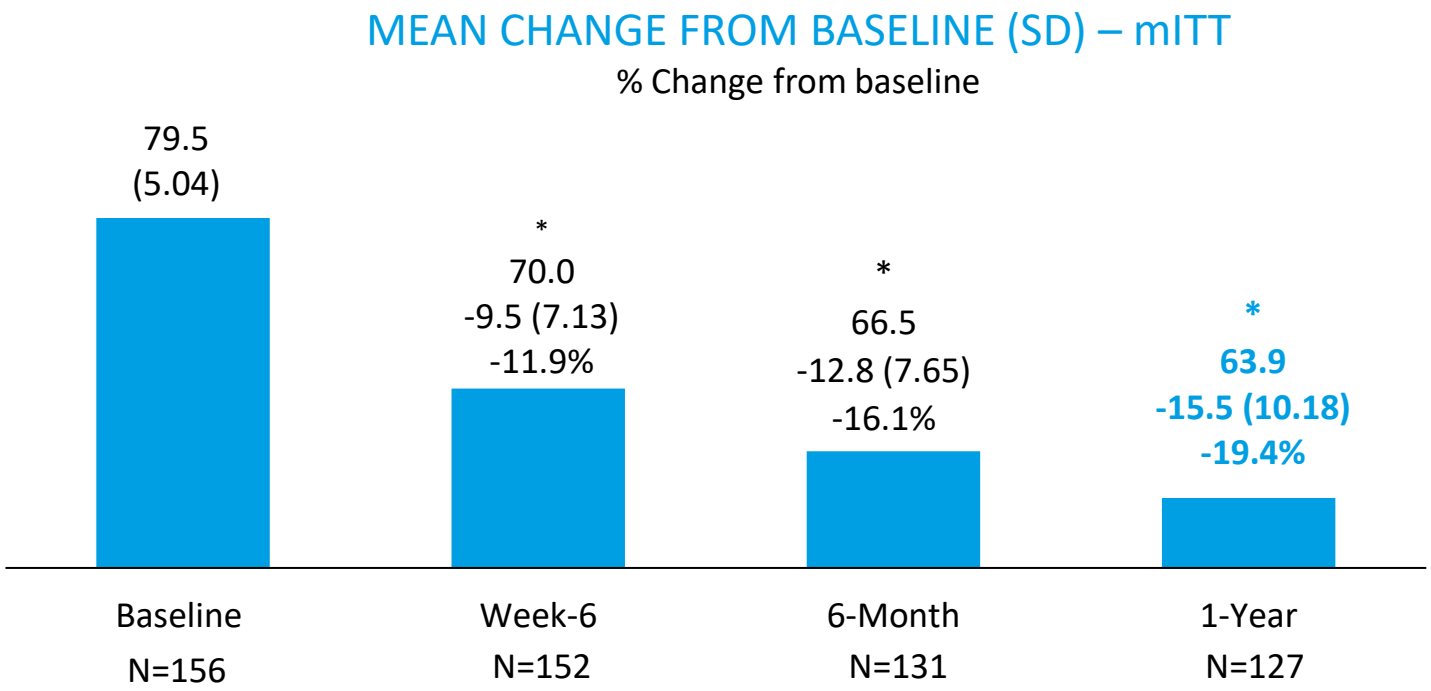
Study Population:

- **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 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

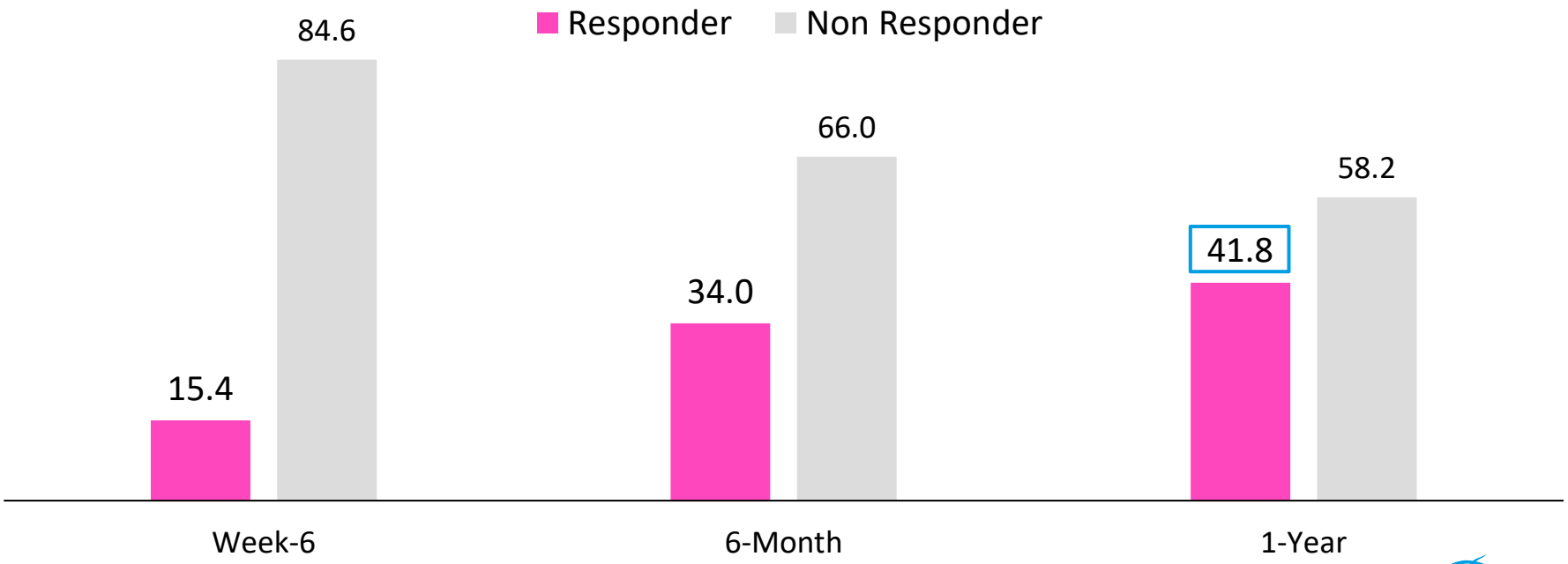


* p-value vs baseline < 0.001, paired t-test, OC

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 - USAGE OF BACKGROUND ANTIPSYCHOTIC MEDICATION

Antipsychotic	Evenamide 30 mg bid N=132; n (%)	Placebo N=159; n (%)	Overall N=291; n (%)
Risperidone	51 (38.6)	63 (39.6)	114 (39.2)
Olanzapine	32 (24.2)	32 (20.1)	64 (22.0)
Clozapine	19 (14.4)	17 (10.7)	36 (12.4)
Paliperidone	15 (11.4)	24 (15.1)	39 (13.4)
Aripiprazole	11 (8.3)	14 (8.8)	25 (8.6)
Quetiapine	2 (1.5)	7 (4.4)	9 (3.1)
Cariprazine	2 (1.5)	2 (1.3)	4 (1.4)

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)

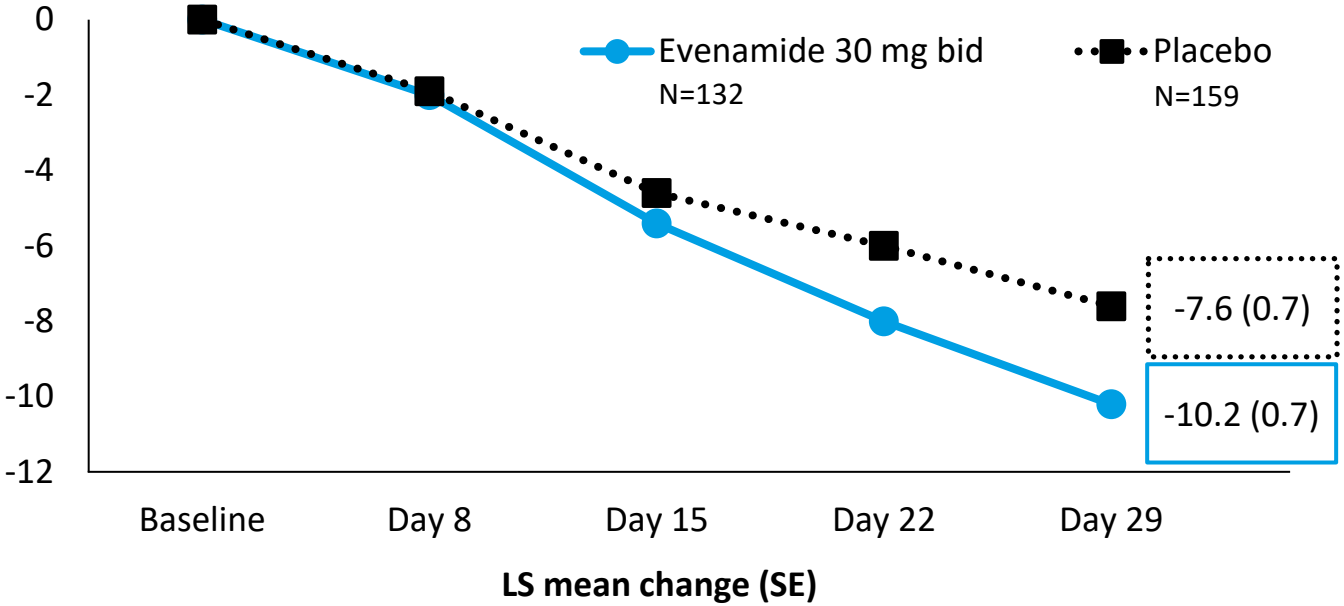
STUDY 008A - PRIMARY, KEY SECONDARY EFFICACY ENDPOINT – ITT POPULATION
PRIMARY ESTIMAND – TREATMENT POLICY, MEAN CHANGE FROM BL – DAY 29

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



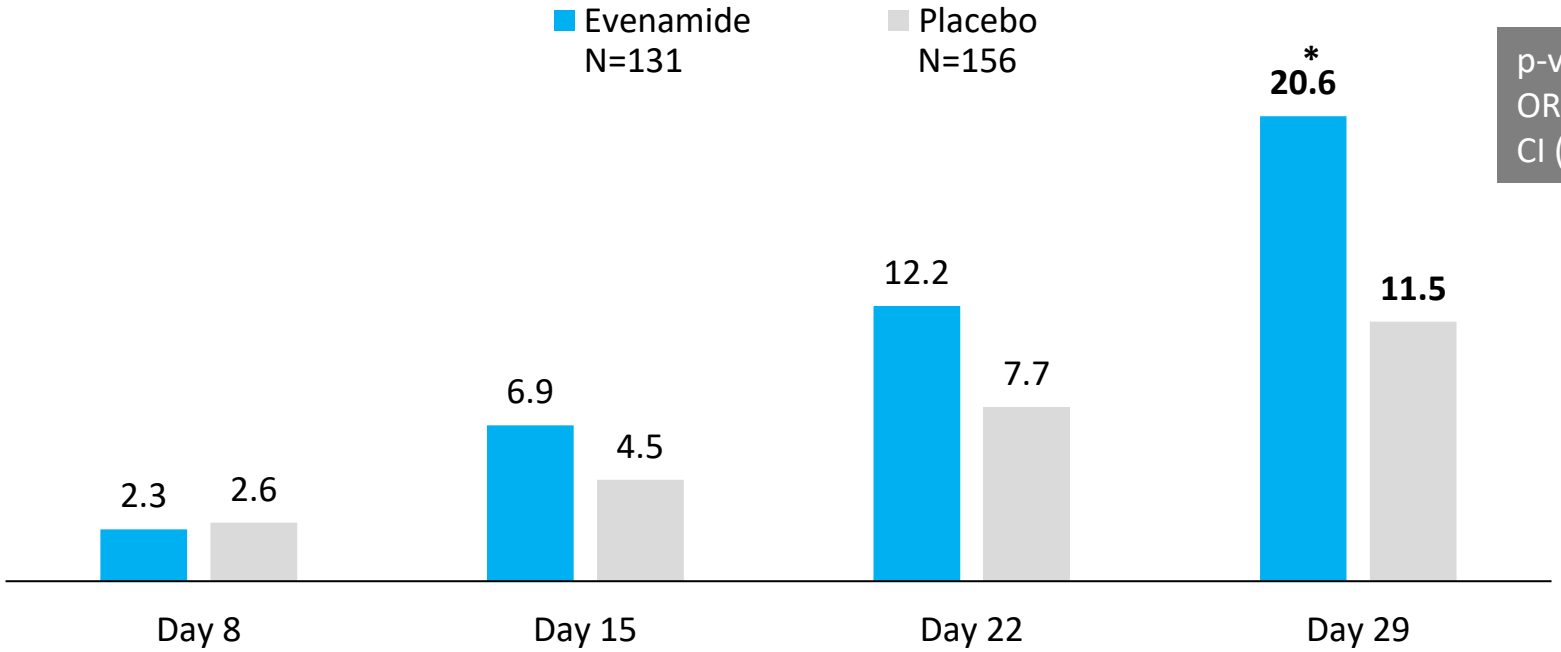
Drug-Placebo Difference:
LS mean (SE) = -2.5 (0.9)
p-value: 0.006
CI: -4.3, -0.7

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 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS –

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

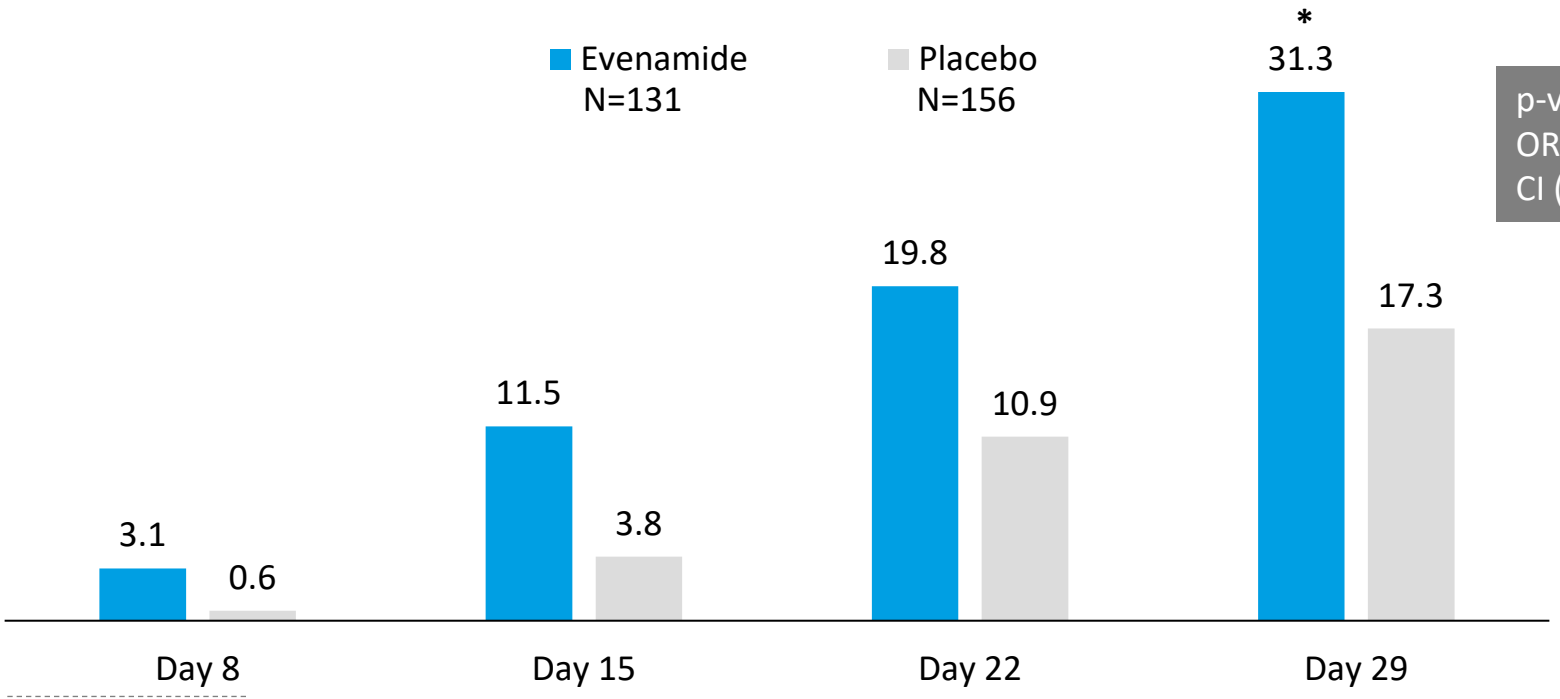


p-value = 0.037
OR 1.99
CI (1.0, 3.8)

21 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

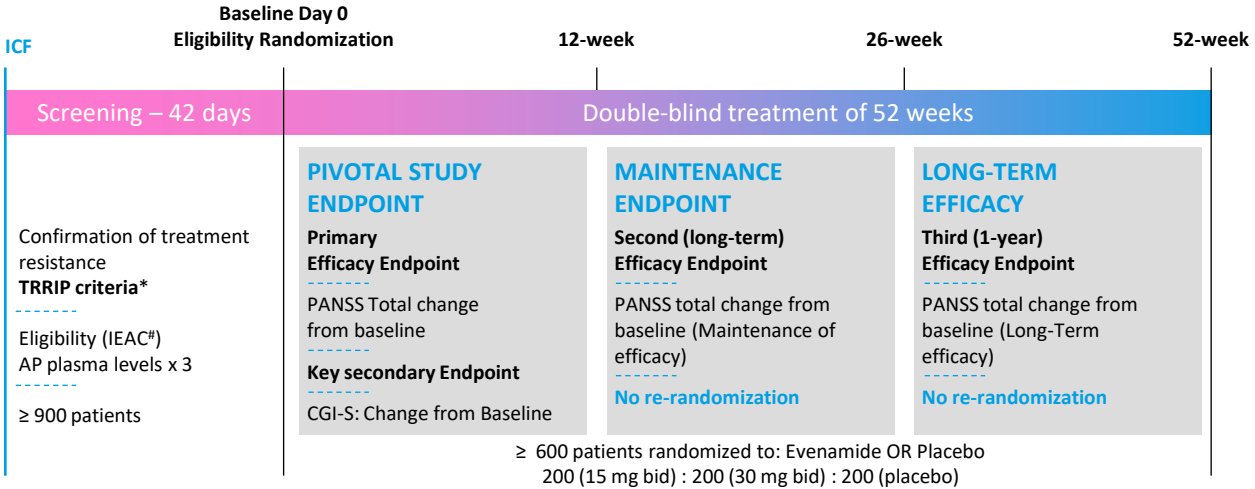


p-value = 0.006
OR 2.18
CI (1.2, 3.8)

 CI=95% confidence interval; OR=odds ratio

ENIGMA-TRS 1
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)

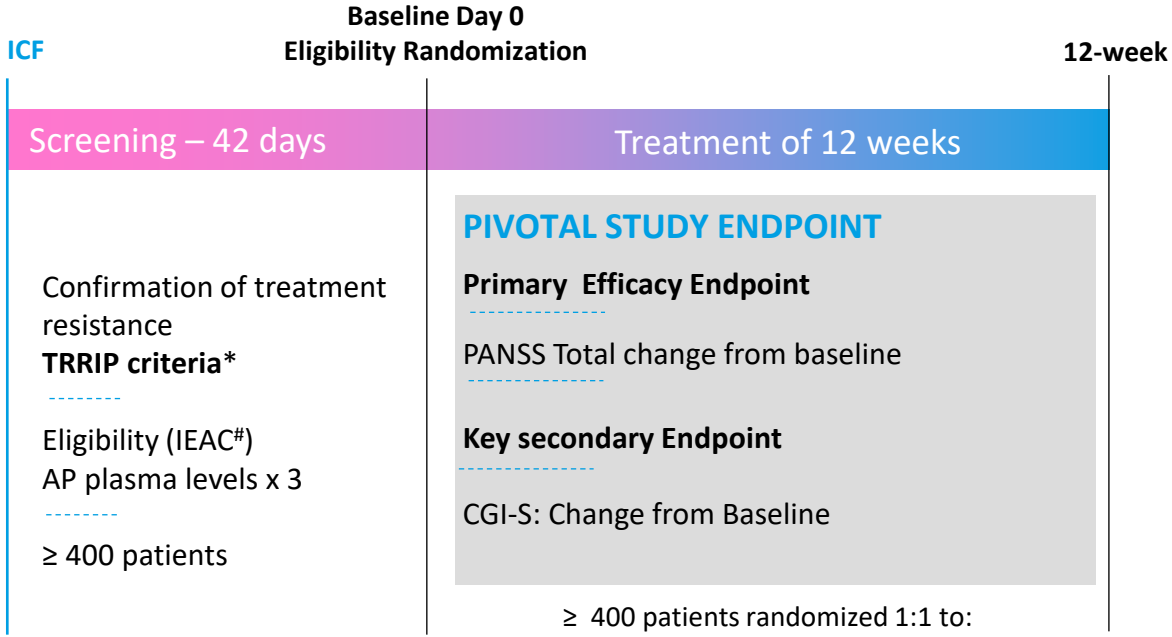


* TRRIP Working Group Howes et al., 2017

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
PLACEBO-CONTROLLED, 12-WEEK STUDY (US & SELECTED COUNTRIES)



* TRRIP Working Group Howes et al., 2017

\# Independent Eligibility Assessment Committee

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
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