



COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Company presentation | November, 2025





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> COMPANY HIGHLIGHTS



Proven expertise in CNS drug development

- **Xadago®**

- Global approvals in Parkinson's disease 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
- Positive Phase II/III data; pivotal Phase III program ongoing



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)



01

**THE EVENAMIDE
OPPORTUNITY**



TRANSFORMING SCHIZOPHRENIA TREATMENT WITH EVENAMIDE



Lead program Evenamide: First-in-class glutamate modulator

Addresses 25 million patients

worldwide with schizophrenia



Potential first add-on therapy

for TRS or poor responders to current antipsychotics



Completely novel MoA

Modulates glutamate release and targets hippocampal hyperexcitability – the core pathology of schizophrenia



Phase II/III clinically validated

Broad symptom improvement, >25% remission after 1 year



Excellent tolerability

Low incidence of treatment-emergent adverse events and minimal drop out due to intolerance



No need to change current therapy, minimizing risk

of patient relapse



Potential beyond schizophrenia

Mechanism relevant to other CNS indications (bipolar, depression, dementia)



Strong IP Position

Exclusivity to 2033/2035 (composition of matter: RoW, US) 10 yrs exclusivity in EU; additional patents granted/pending up to 2044





TRANSFORMING SCHIZOPHRENIA TREATMENT WITH EVENAMIDE (II)



PIVOTAL LANDMARK PHASE III ENIGMA-TRS program underway

ENIGMA-TRS 1

52-week, ≥600 patients, add-on to SGAs (incl. clozapine); first patients enrolled Aug 2025

ENIGMA-TRS 2

12-week, ≥400 patients in US and select countries; FDA-approved; to be initiated

Data in Q4 2026 / NDA HY1/2027

STRONG PARTNER FOR JAPAN/ASIA, further opportunities in discussion

EA Pharma (Eisai Group)

Dec 2024

Japan & Asia deal
worth **up to €117 m**
(total upfront +
milestones) plus royalties



Myung In Pharm (South Korea)

Jan 25

Contributing **10%**
of patients and to
study costs of
ENIGMA-TRS 1

Cash runway beyond 12 weeks result supports pivotal
ENIGMA-TRS 1 study, additional financing required to take
pivotal study to full size (ENIGMA-TRS 2 to 12 weeks read out)

SCHIZOPHRENIA – HIGH MEDICAL NEED FOR 23 MILLION PATIENTS WORLDWIDE



- 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 – DIFFERENTIATION & 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

Up to 70% of Chronic schizophrenia population (every ~18 months)

Add-on therapy with **no dose-limiting side effects** a key advantage for patients and prescribers

First drug for 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 known* option as add-on to clozapine

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

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

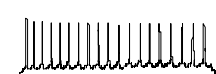


Evenamide 1 μM

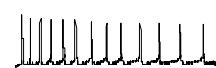


Low frequency firing

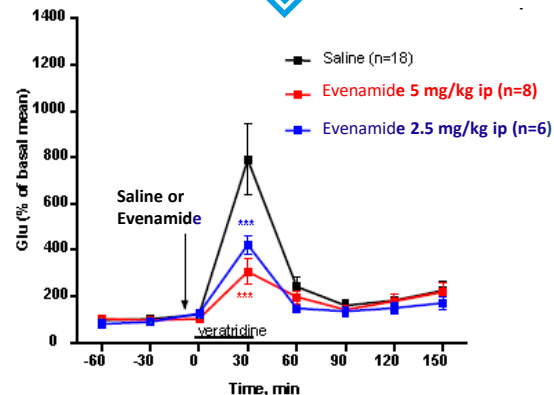
Control



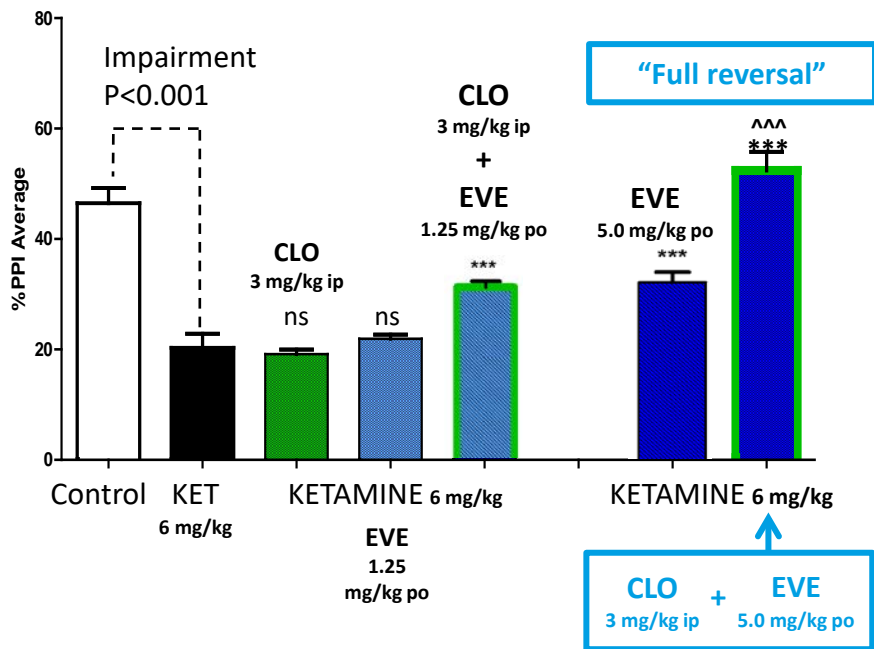
Evenamide 1 μM



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

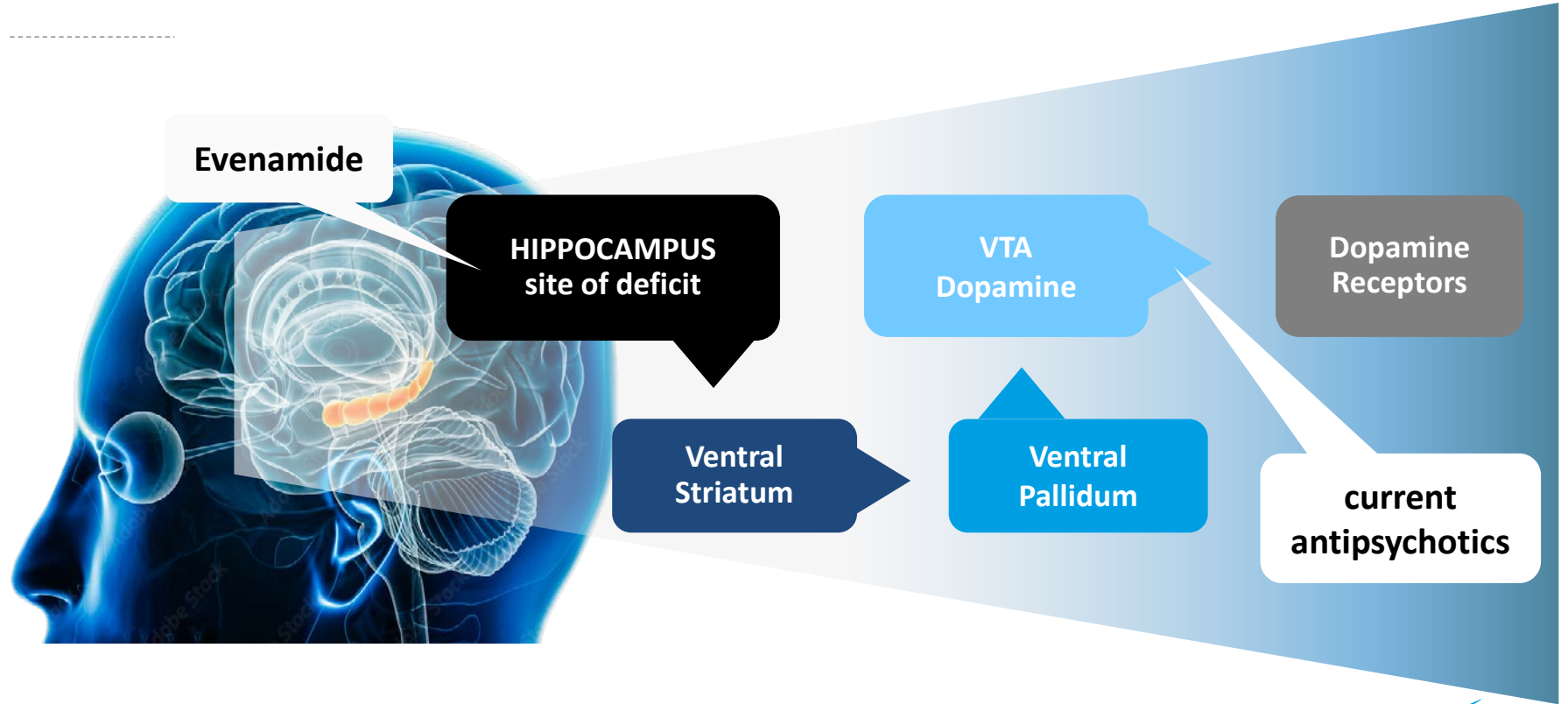
Combination of ineffective doses of Evenamide with antipsychotics (APs) was associated with improvement in animal models of psychosis

2

Potential to benefit:
positive, negative and cognitive symptoms



STRAIGHT TO THE HEART OF THE BRAIN

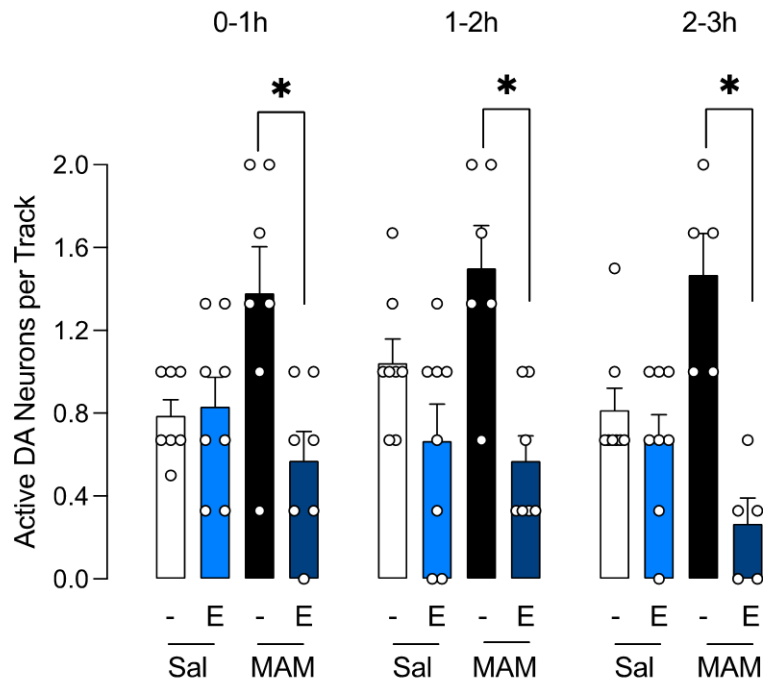




EVENAMIDE: SIGNIFICANT EFFICACY IN THE MAM MODEL POINTS TO LONG TERM NEUROPLASTICITY EFFECTS

| 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 |

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



02

**STRONG PHASE II/III
DATA PACKAGE**



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



PHASE II STUDY 014/015: PATIENT DISPOSITION BY STUDY AND DURATION

| | | | | |
|--|---|--|--|--|
| Randomized N = 161* 7.5/15/30 mg bid N=50/60/51 | Completed N = 153 (95%) Discontinued N = 8 | Entered extension N = 144 (89%) Did not enter extension N = 9 | Completed N = 132 (82%) Discontinued N = 12 | Completed N = 121 (75%) Discontinued N = 11 |
| Day 0/1 Randomization | WEEK 6 | | WEEK 30 6-MONTH | WEEK 52 1-YEAR |

| | |
|--------------------|---|
| STUDY 014: 6 weeks | STUDY 015: Additional 46 weeks of treatment |
|--------------------|---|

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 |

* One patient not dosed

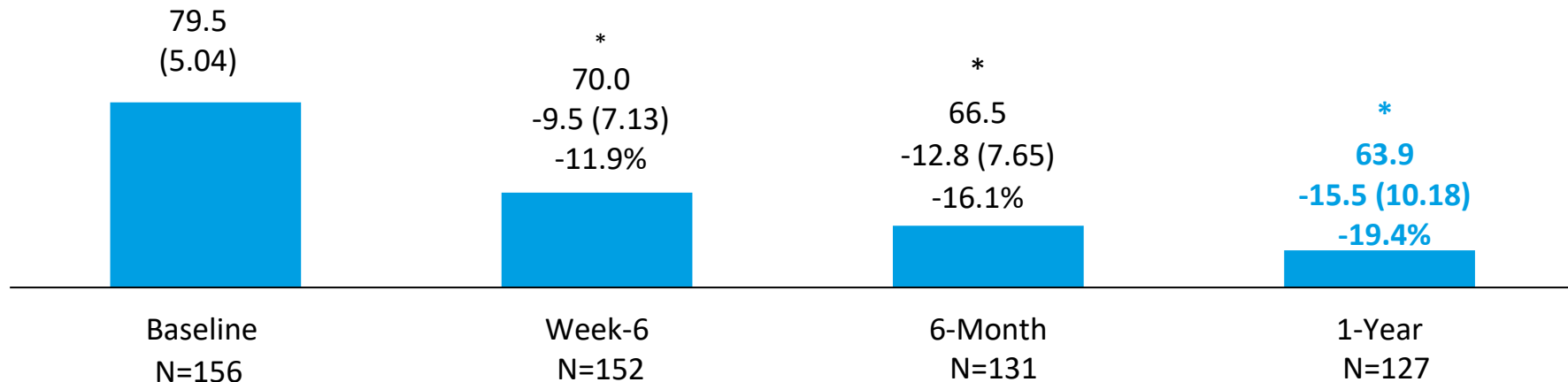




STUDY 015: 1-YEAR PANSS DATA CONFIRM UNIQUE LONG-TERM BENEFIT OF EVENAMIDE

MEAN CHANGE FROM BASELINE (SD) – mITT

% Change from baseline



Evenamide treatment led to a statistically significant and sustained improvement in PANSS total scores, with a 19% reduction from baseline after one year

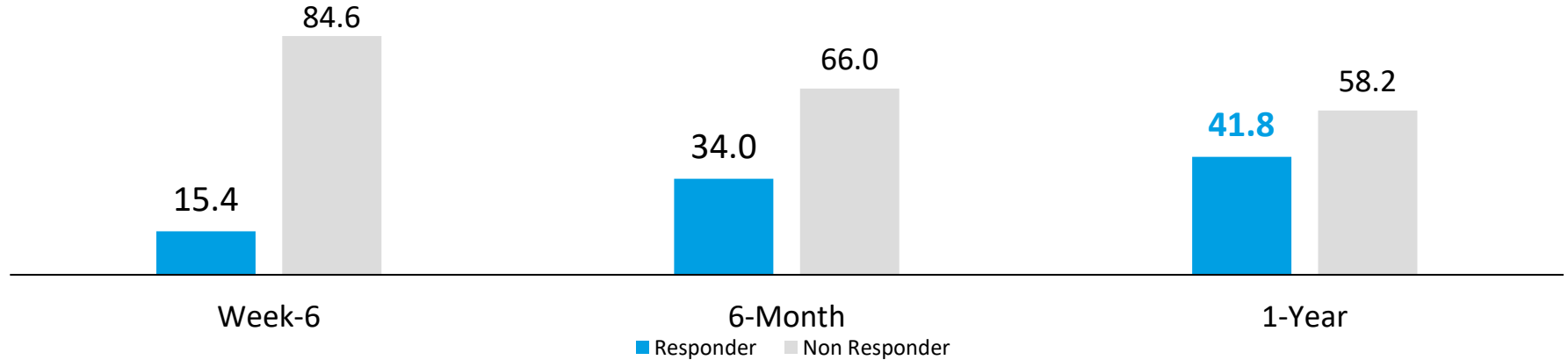
* p-value vs baseline < 0.001, paired t-test, OC



STUDY 015: RESPONDER RATE NEARLY TRIPLES OVER 1 YEAR OF TREATMENT

PANSS RESPONDER ANALYSIS (%) – mITT

PANSS Total \geq 20% Improvement from baseline



The proportion of patients achieving a clinically meaningful ($\geq 20\%$) improvement in PANSS scores increased steadily over time, reaching 42% at one year

STUDY 015: NEARLY 50% NO LONGER MET TRS CRITERIA AFTER 1 YEAR

| 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) |

An increasing proportion of patients no longer met TRS severity criteria after long-term treatment with Evenamide, with nearly half no longer classified as TRS after 1 year

* 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: UP TO 28% OF PATIENTS ACHIEVED SUSTAINED REMISSION

| Method | Criteria | Maintenance requirement | N=156 n (%) of patients meeting remission criteria |
|-----------------------|---|-------------------------|---|
| Lieberman et al, 1993 | P1, P2, P3, P6, G5 \leq 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 \leq 3 | 24 weeks | 39 (25.0%) |



Up to 28% of patients met established remission criteria after treatment with Evenamide, demonstrating clinically meaningful and sustained symptom improvement – not reported before



PHASE III 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:

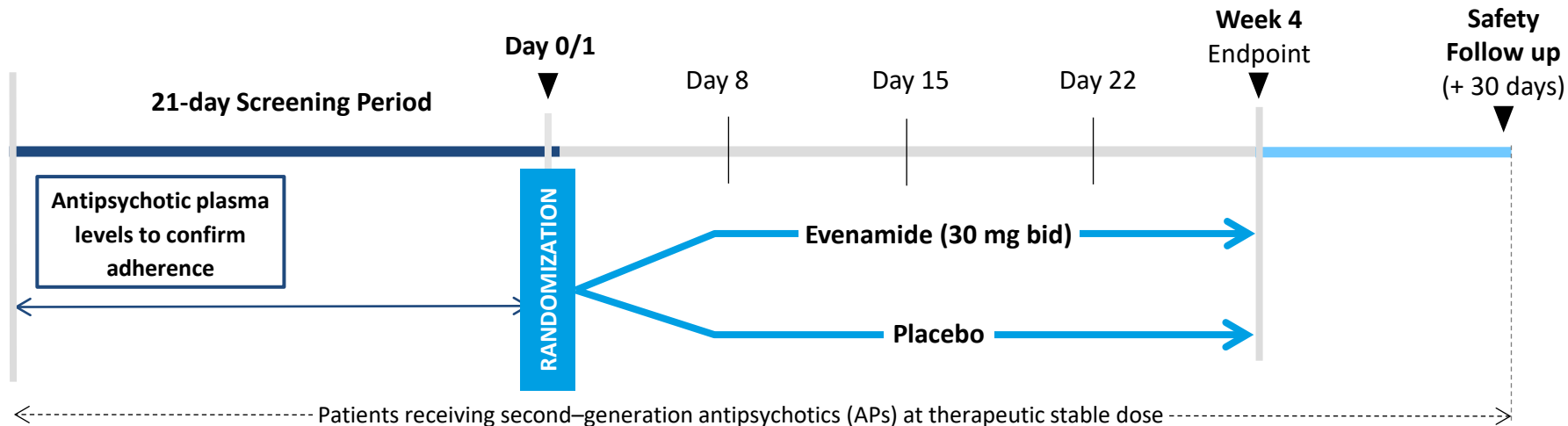
- Outpatients with chronic schizophrenia (DMS-5) on therapeutic doses of SGAs who are still symptomatic, despite ≥ 4 weeks of treatment at a stable dose (adherence confirmed by plasma levels)
- Current symptoms present for at least one month
- Total PANSS 70-85
- CGI-S rating of moderately (4) to severely 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: FAVORABLE SAFETY & TOLERABILITY COMPARABLE TO PLACEBO

| 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) |

Evenamide was well tolerated, with a low incidence of treatment-emergent adverse events (TEAEs) comparable to placebo and no new safety signals observed

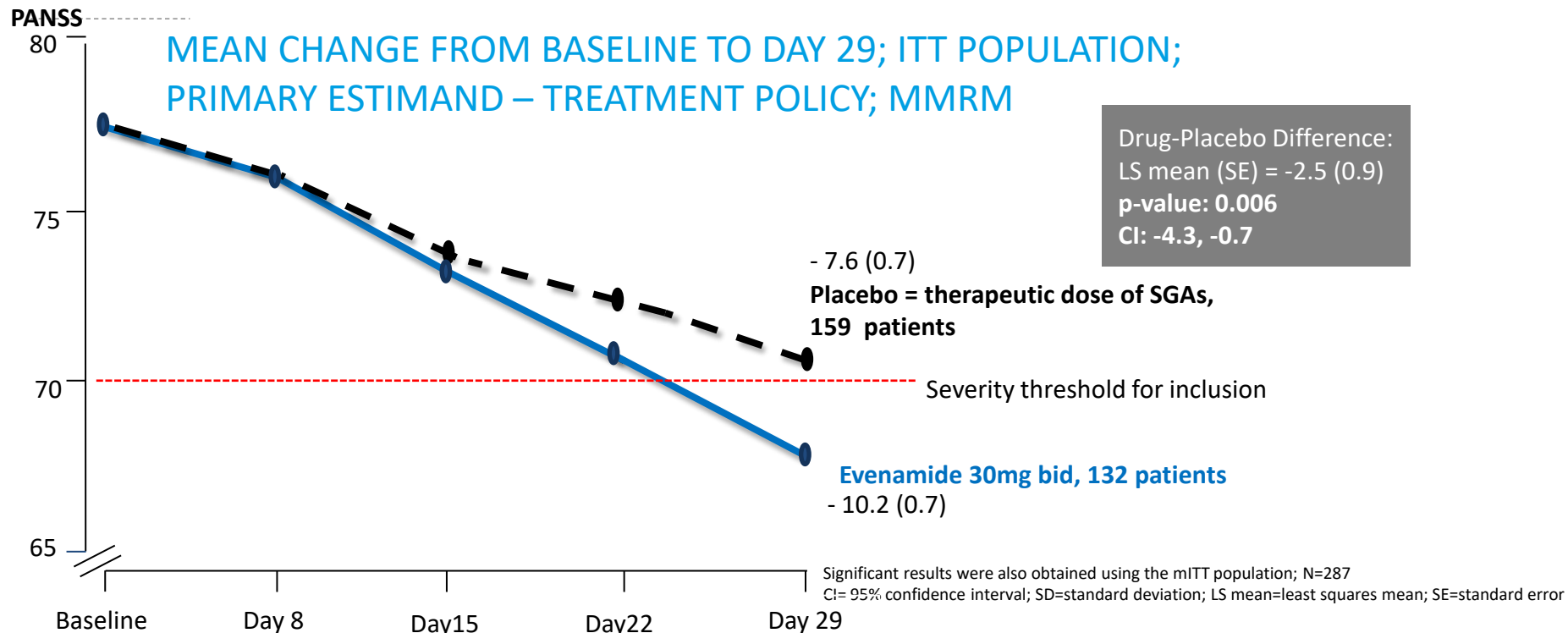
STUDY 008A: SIGNIFICANT SYMPTOM IMPROVEMENT VS. PLACEBO AFTER JUST 4 WEEKS

| 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) | |
| | <i>p-value [CI]</i> | 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) | |
| | <i>p-value [CI]</i> | 0.037 [-0.3, -0.0] | |

Evenamide achieved statistically significant improvements versus placebo in both PANSS total score and CGI-S after 29 days, demonstrating early efficacy and clinical benefit in patients with schizophrenia

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

STUDY 008A: SIGNIFICANT PANSS IMPROVEMENT VS. PLACEBO AFTER 4 WEEKS



Evenamide produced a statistically significant greater reduction in PANSS total score compared with placebo at Day 29, confirming early and clinically meaningful improvement in schizophrenia symptoms

STUDY 008A: FIRST ADD ON SHOWING CONSISTENT EFFICACY ACROSS ALL STANDARD ANTIPSYCHOTICS

| 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) |

Evenamide improved PANSS scores across all background antipsychotic treatments, including in patients receiving clozapine
- supporting its potential as an effective add-on therapy regardless of co-medication

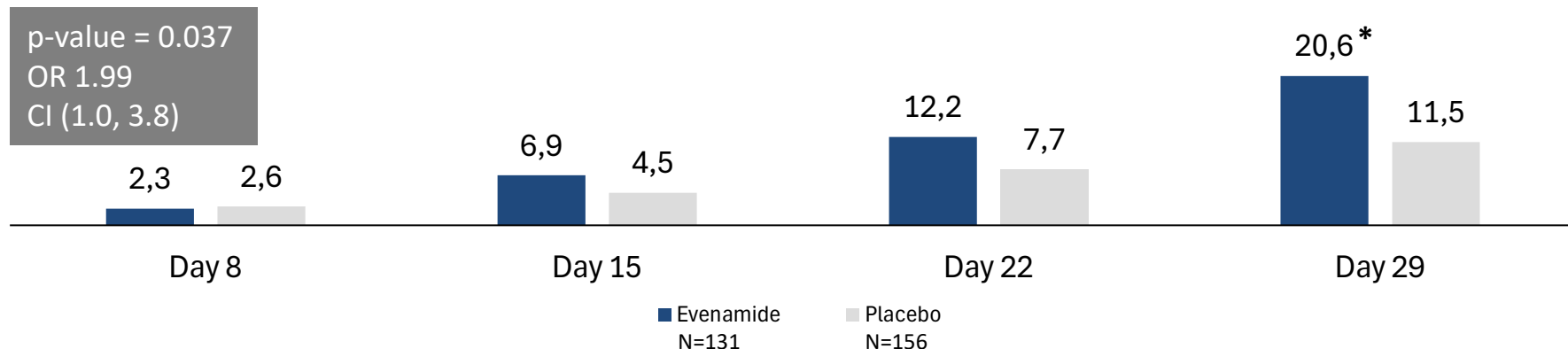
SD=standard deviation



STUDY 008A: RESPONDER RATE VS. PLACEBO AFTER 4 WEEKS NEARLY DOUBLED

PANSS RESPONDER ANALYSIS –

Proportion of patients (%) improving $\geq 20\%$ from baseline; mITT; OC



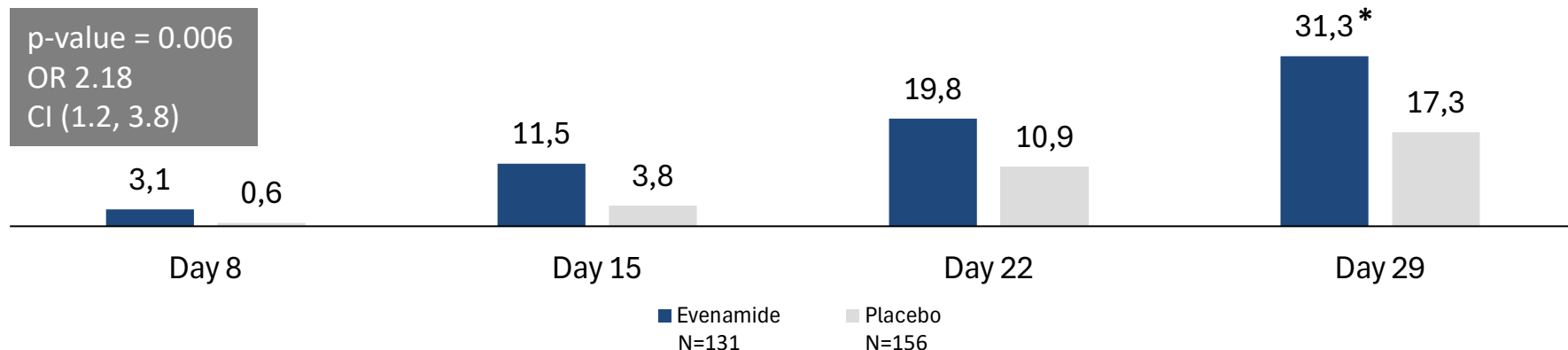
A significantly higher proportion of patients treated with Evenamide achieved $\geq 20\%$ improvement in PANSS total score at Day 29 compared with placebo, nearly doubling the responder rate

CI=95% confidence interval; OR=odds ratio

STUDY 008A: CLINICIAN-RATED IMPROVEMENT NEARLY DOUBLED VS. PLACEBO AT DAY 29

CGI-C RESPONDER ANALYSIS –

Proportion of patients (%) “At least much improved”; mITT



A significantly higher proportion of patients treated with Evenamide were rated as “much improved” or better on the CGI-C scale at Day 29 compared with placebo, confirming meaningful clinician-assessed improvement

CI=95% confidence interval; OR=odds ratio

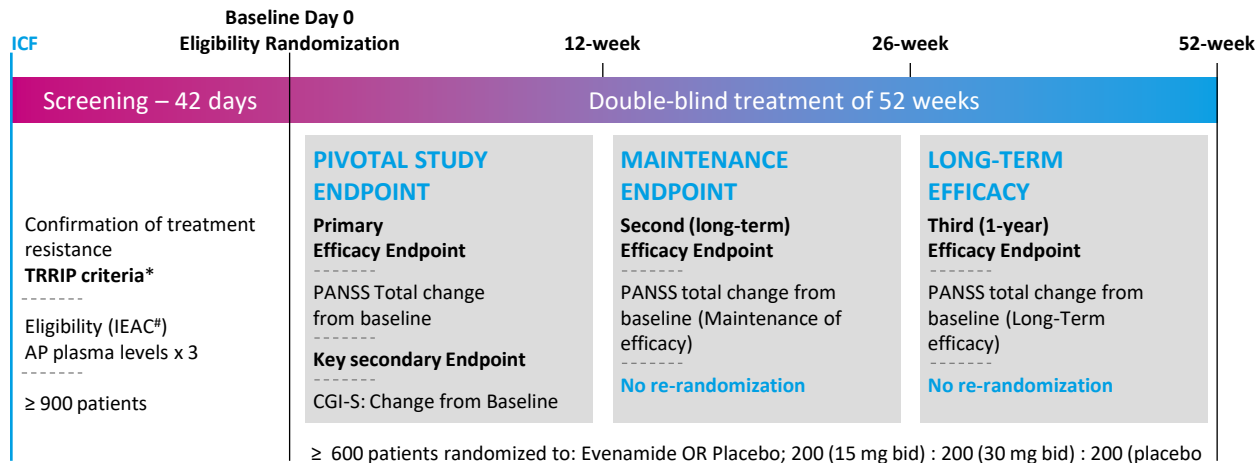


03

**PIVOTAL ENIGMA TRIALS
ONGOING**

ENIGMA-TRS 1: PIVOTAL 1-YEAR PHASE III STUDY EVALUATING EVENAMIDE AS ADD-ON THERAPY IN TRS

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)

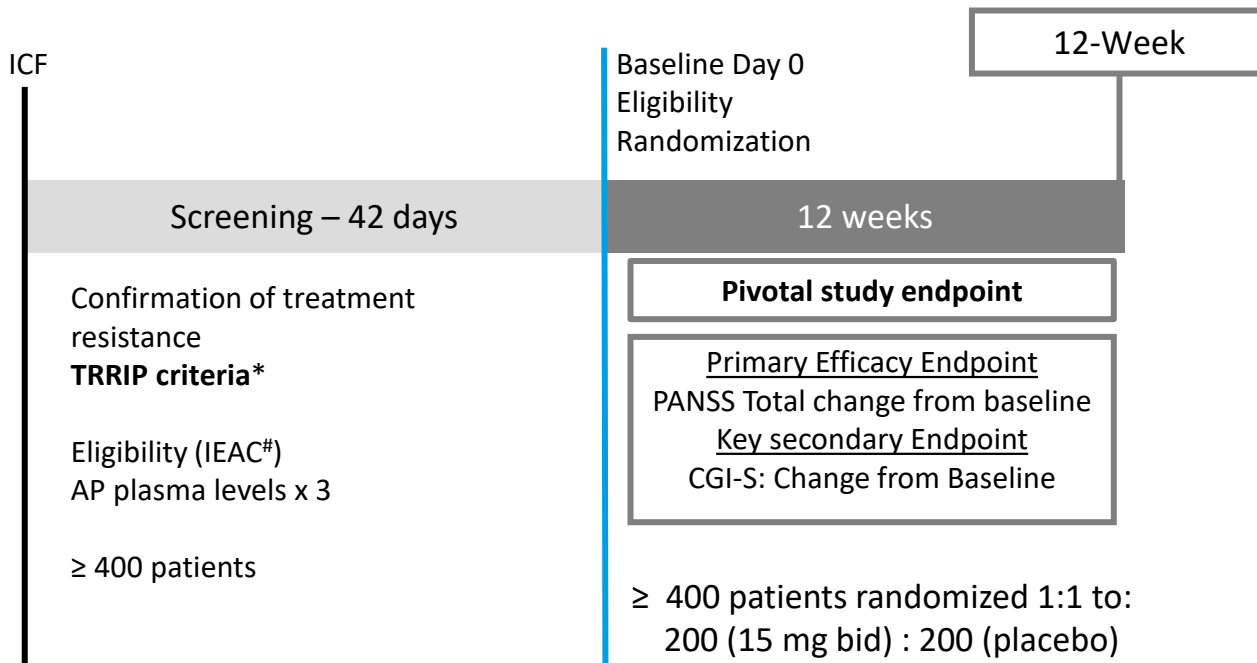


* TRRIP Working Group Howes et al., 2017

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: PIVOTAL 12-WEEK STUDY EVALUATING EVENAMIDE AS ADD-ON THERAPY IN TRS



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



04

SUMMARY

EVENAMIDE RESULTS SUMMARY: EFFICACY

Sustained and robust efficacy over one year

- 1-year Phase II study demonstrated permanent improvement in all efficacy endpoints, with an extremely low dropout rate
- Responder rates doubled or tripled; 50% of patients were no longer diagnosable as TRS
- 25% achieved remission lasting ≥ 6 months
- No relapses reported during the 1-year treatment period

Phase III confirms Phase II results

- 4-week Phase III study confirmed Phase II findings across all endpoints (PANSS total, CGI-S, responder rates)
- All endpoints reached high statistical significance
- As expected after 4 weeks, moderate absolute treatment effect observed – consistent with the progressive improvement seen in the 1-year study, at that point in time

Favorable safety and tolerability profile

- Low incidence of treatment-emergent adverse events and minimal drop out due to intolerance
- No pattern of QTc prolongation, cardiac or laboratory abnormalities
- No typical antipsychotic-related side effects (EPS, weight gain, sexual dysfunction, hormonal changes or CNS effects)

CLINICAL EXPOSURE



120 patients
treated for one year

>500 unique subjects

>400 patients
with schizophrenia
treated with Evenamide



KEY TAKEAWAYS: A CLEAR PATH TO VALUE CREATION



Evenamide:
A transformative, de-risked asset

- **First-in-class glutamate modulator** with compelling Phase II/III efficacy & safety data
- **Addresses large, underserved TRS population** with no approved add-on therapy
- **Potential expansion into other neuropsychiatric and neurodegenerative disorders**



Near-term catalysts and investment opportunity

- **Pivotal ENIGMA program** launched and enrolling – regulatory-grade design aligned for registration
- **12-week Phase III** readout expected Q4 2026; further data points at week 26 & 52
- **Financing need** to fully execute pivotal ENIGMA TRS-2 study and reach data readout on path to commercialization

Strong clinical foundation, global partnerships, and a clear path to the first new treatment option in decades for TRS

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