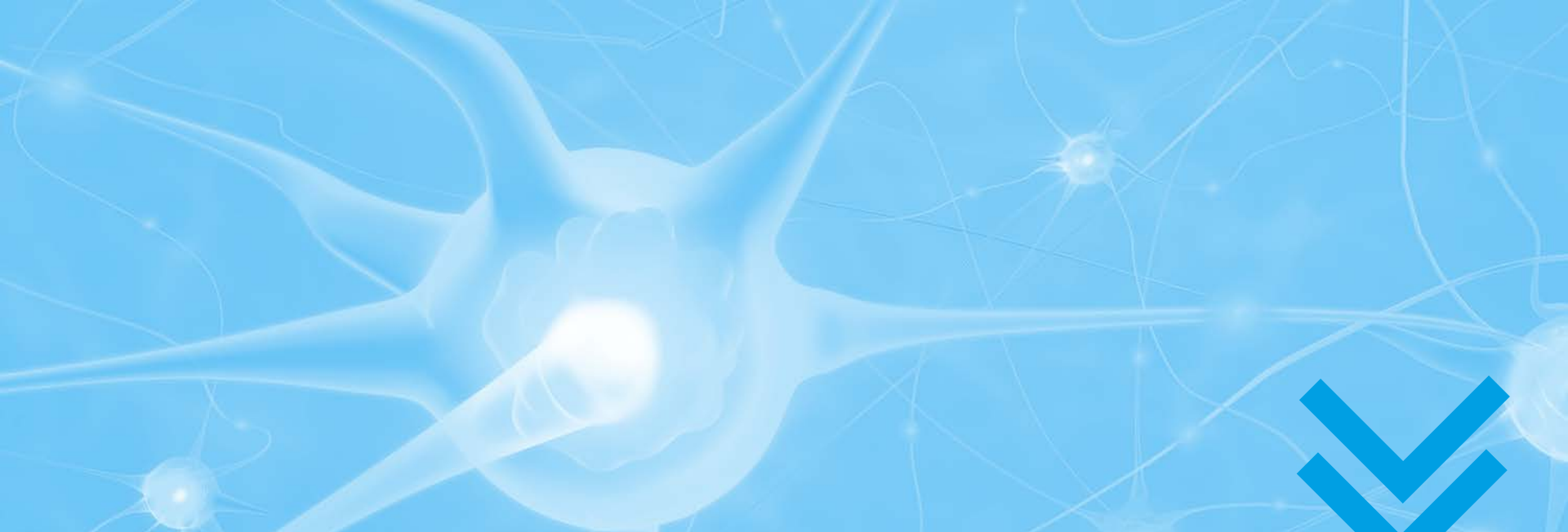




COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Stefan Weber, CEO

21st Baader Helvea Swiss Equities Conference

Bad Ragaz, January 10, 2025





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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 pivotal study in TRS: H1/2025
- Additional partnering transactions
- Results from pivotal TRS study 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 in TRS
- **Regulatory strategy:** Approval in TRS - Chance for early market access
- **Strong IP position:** Exclusivity: 2034 (COMP, US), 2033 (COMP, RoW) and beyond (10 yrs exclusivity post approval in the EU); additional patents under review: 2040+
- **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 pivotal study, 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 ex-territories' Phase III pivotal study
Newron to initiate the study in HYI/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



- 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 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

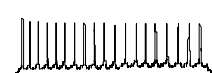


Evenamide 1 μM



Low frequency firing

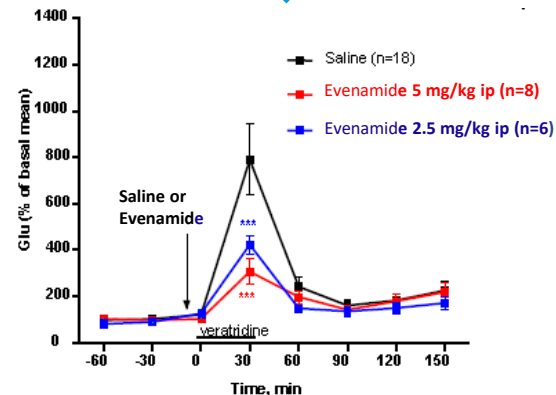
Control



Evenamide 1 μM

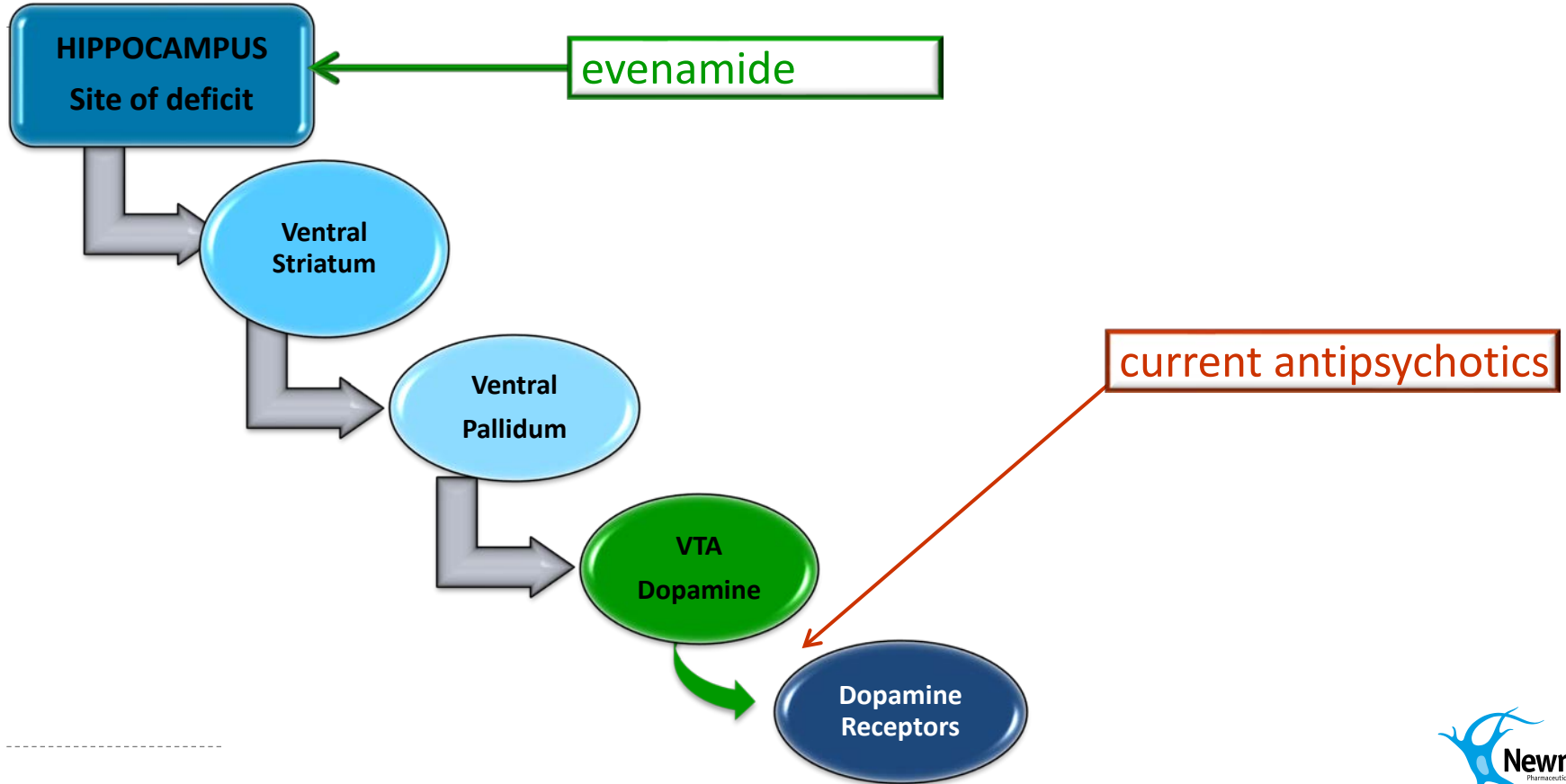


Inhibits Glutamate Release





STRAIGHT TO THE HEART OF THE BRAIN





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 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 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

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



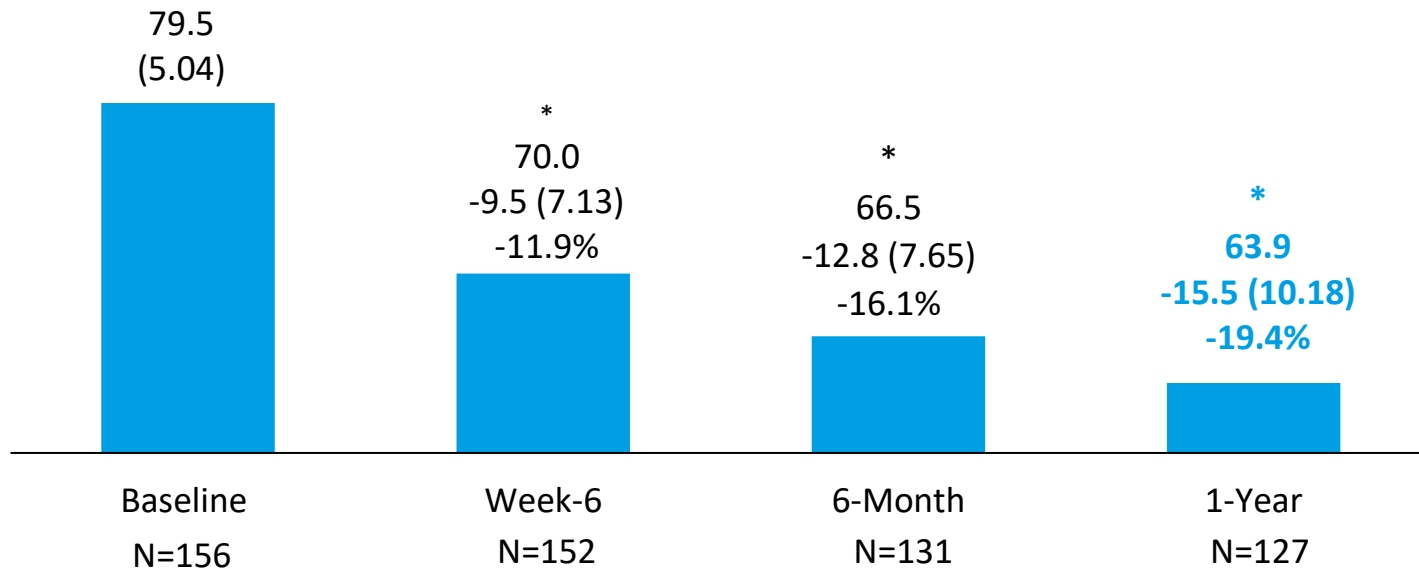
Based on above results, and efficacy/safety profile **positive health technology assessment opinion** is deemed likely



STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

MEAN CHANGE FROM BASELINE (SD) – mITT

% Change from baseline



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

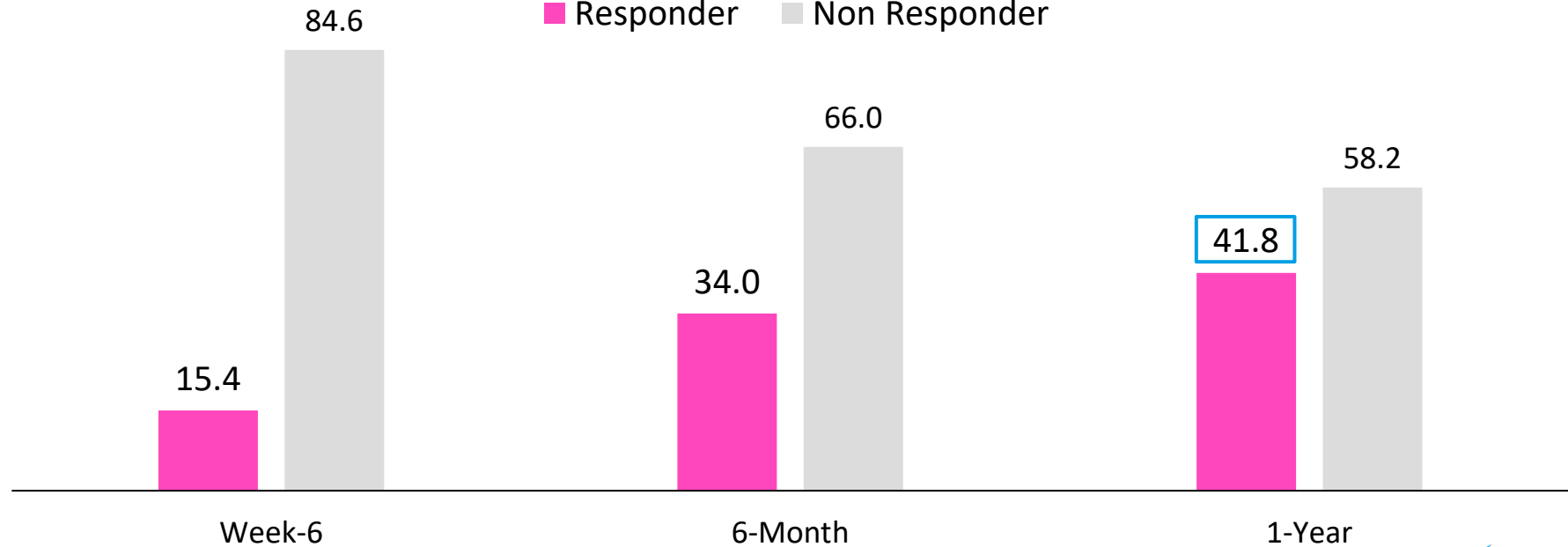


STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS (%) – mITT

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

■ Responder ■ Non Responder





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

EVENAMIDE

FIRST EVIDENCE OF BENEFIT OF ADD-ON THERAPY IN INADEQUATE RESPONDERS

FIRST SELECTIVE SODIUM CHANNEL BLOCKER SHOWING BENEFIT IN THIS POPULATION



Evenamide add-on treatment in patients with chronic schizophrenia not responding adequately to their current antipsychotic



An international, randomized, double-blind, placebo-controlled trial: pivotal study 008A



Enrollment by region (n=291): Europe 116, Asia 112, LATAM 63



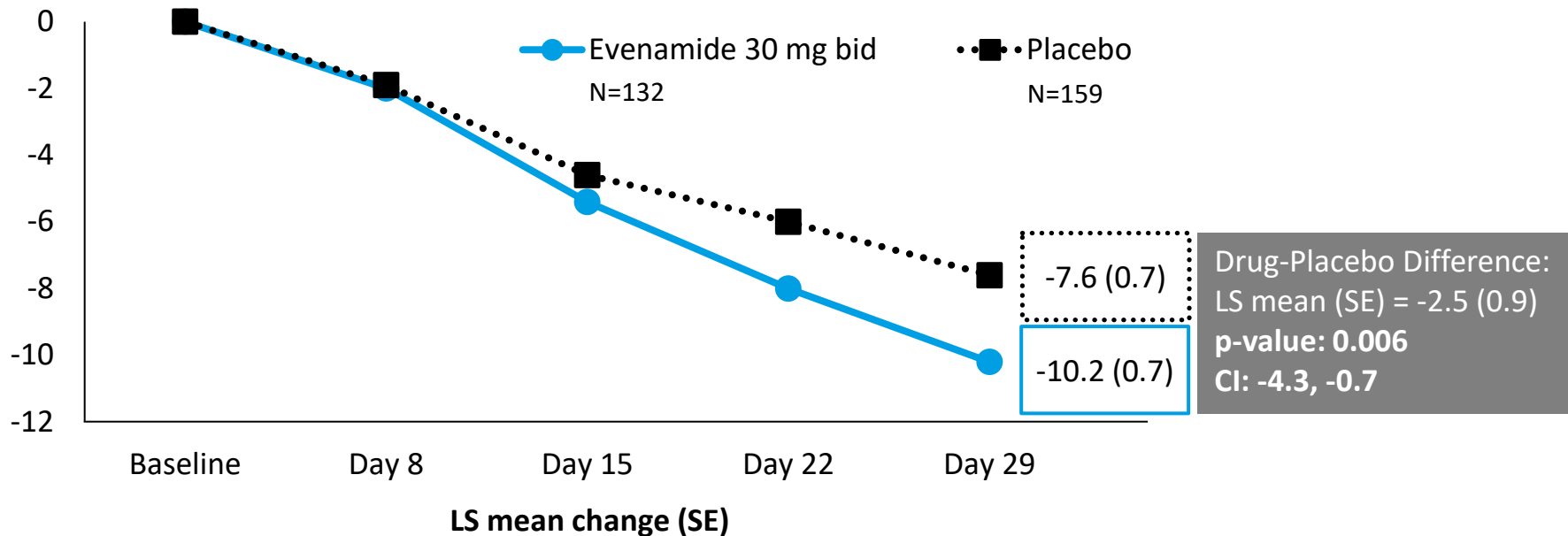
Subjects used broad variety of background antipsychotic medication, e.g. Risperidone, Olanzapine and Clozapine



Evenamide was very well tolerated (similar to placebo); no increases in EPS, weight gain, blood glucose, metabolic syndrome, sexual dysfunction, CNS or cardiac effects, or laboratory abnormalities; most prevalent adverse event was nasopharyngitis (<3%)

> STUDY 008A - PANSS TOTAL SCORE

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



Significant results were also obtained using the mITT population; N=287

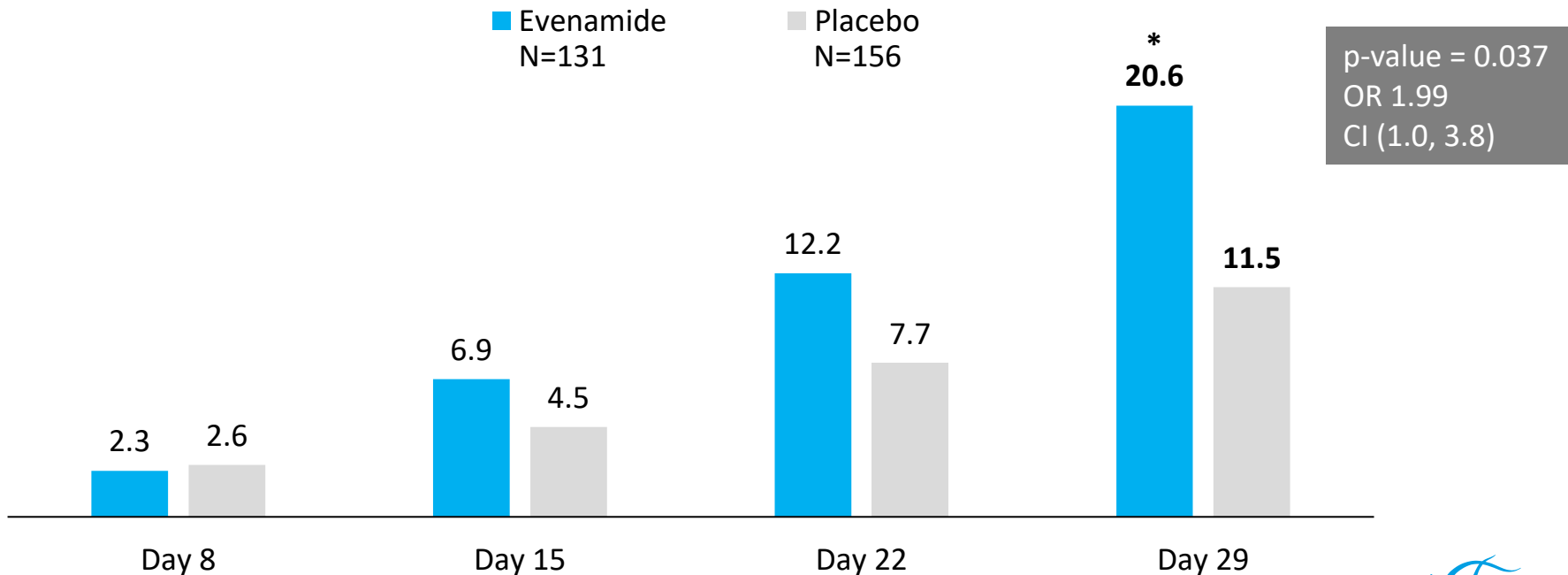
CI= 95% confidence interval; SD=standard deviation; LS mean=least squares mean; SE=standard error



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

PANSS RESPONDER ANALYSIS –

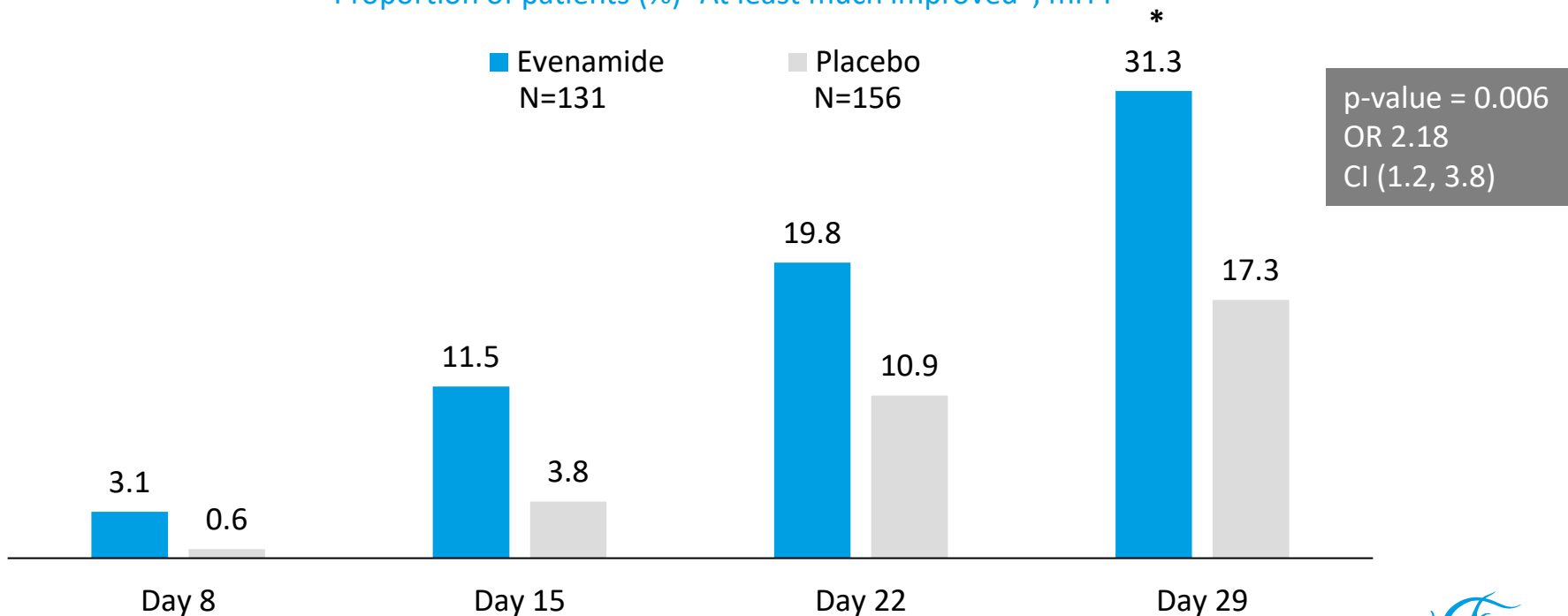
Proportion of patients (%) improving $\geq 20\%$ from baseline; mITT; OC





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

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





STUDY 008A – SUMMARY OF EFFICACY RESULTS – MEAN CHANGE FROM BASELINE TO ENDPOINT

Efficacy Parameter/ Analysis/ Population	LS Mean Difference (SE)*	95% CI	p-value
PANSS Total Score MMRM (Primary Estimand Treatment Policy) ITT Population	-2.5 (0.90)	-4.3, -0.7	0.006
CGI-S MMRM ITT Population	-0.16 (0.08)	-0.3, -0.0	0.037
CGI-C mean rating at endpoint ANOVA mITT Population	-0.2 (0.04)	-0.3, -0.1	<0.001
PANSS Subscales score ANCOVA Using LOCF mITT Population	POS: -1.16 (0.36) NEG: -0.63 (0.26) GP: -0.59 (0.44)	-1.9, -0.5 -1.1, -0.1 -1.5, 0.3	0.001 0.016 0.184



STUDY 008A – SUMMARY OF EFFICACY RESULTS – RESPONDER ANALYSES

Efficacy Parameter/ Analysis/ Population	Responder Category	Responders [n/N (%)]	Odds Ratio (95% CI)	p-value*
PANSS OC (mITT N as denominator) mITT Population	≥ 20% improvement from baseline	EVE: 27/131 (20.6) PBO: 18/156 (11.5)	1.99 (1.0, 3.8)	0.037
CGI-C OC (mITT N as denominator) mITT Population	Any improvement at endpoint	EVE: 94/131 (71.8) PBO: 90/156 (57.7)	1.86 (1.1, 3.1)	0.014
CGI-C OC (mITT N as denominator) mITT Population	At least “Much improved” at endpoint	EVE: 41/131 (31.3) PBO: 27/156 (17.3)	2.18 (1.2, 3.8)	0.006

KEY FINDINGS FROM STUDY 008A



Study 008A results indicate that the primary (PANSS) and the key secondary (CGI-S) endpoints required by regulators for a pivotal study were met and showed significant superiority compared with the benefits observed in patients on placebo



Benefit with Evenamide appears to be distributed equally among the seven (7) second-generation antipsychotics (including clozapine) allowed in the trial



Analyses to determine the effect of Evenamide on secondary measures, and different analyses population show similar benefits



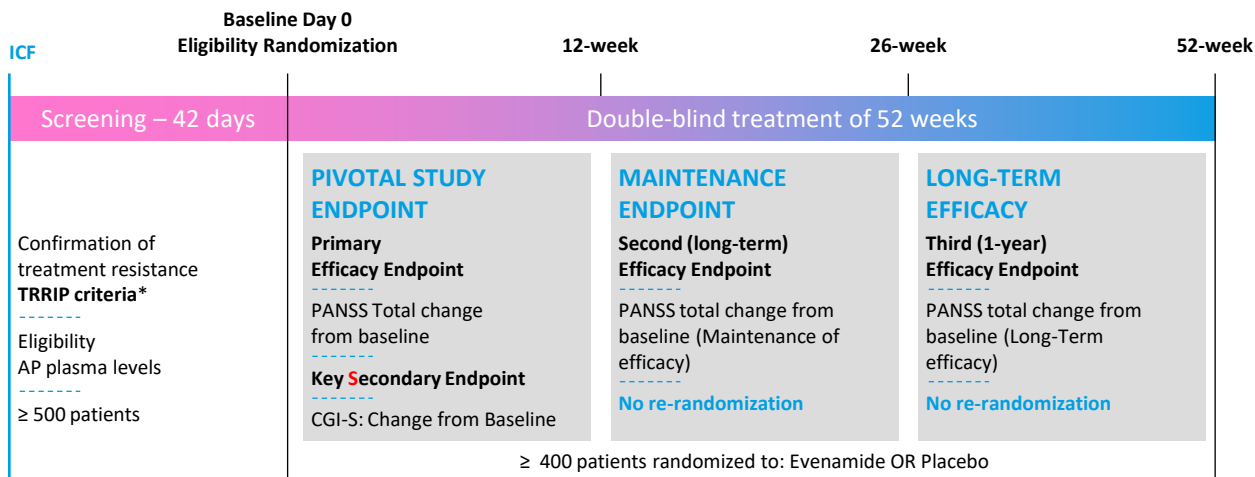
The side effect profile of Evenamide is similar to placebo with no increases in EPS, weight gain, blood glucose, metabolic syndrome, sexual dysfunction, CNS or cardiac effects, or laboratory abnormalities



Phase III pivotal study in patients with TRS is expected to be initiated in H1/2025

UPCOMING PIVOTAL (PHASE III), PLACEBO-CONTROLLED, 1-YEAR STUDY IN PATIENTS WITH 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



XADAGO - MARKETING COMPOUND IN PARKINSON'S DISEASE



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



Globally licensed



Double digit/single digit % royalties
>€85 million milestones/royalties collected

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