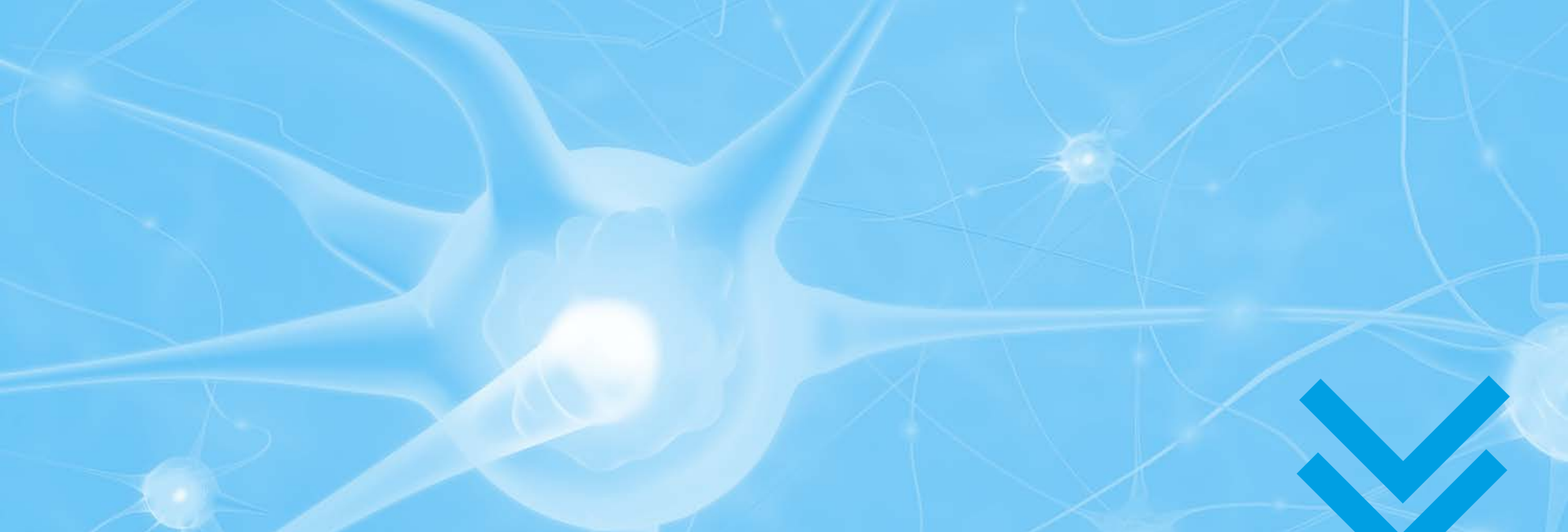




COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Stefan Weber, CEO
German Spring Conference
May 13, 2024





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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** – 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

- Cash balance of € 12.6 million (Dec. 31, 2023)
- Proceeds from March 14, 2024 subscription agreement: min. € 5.5 up to €15.0* million
- Royalty income, R&D tax credit: approx. €16 m (2 yrs.)
- Cash reach well into 2025

* At current roe CHF-EUR





EVENAMIDE – CHANGING THE TREATMENT PARADIGM IN SCHIZOPHRENIA

- 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
 - Opportunity to keep niche indication within TRS for commercialization
- **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 step:** Pivotal 1-year study in TRS
- **Regulatory strategy:** Approval in TRS
- Chance for early market access
- Exclusivity: 2034 (COMP, US) 2033 (COMP, RoW) and beyond (10 yrs exclusivity post approval in the EU)

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 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

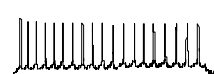


Evenamide 1 μM

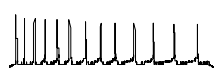


Low frequency firing

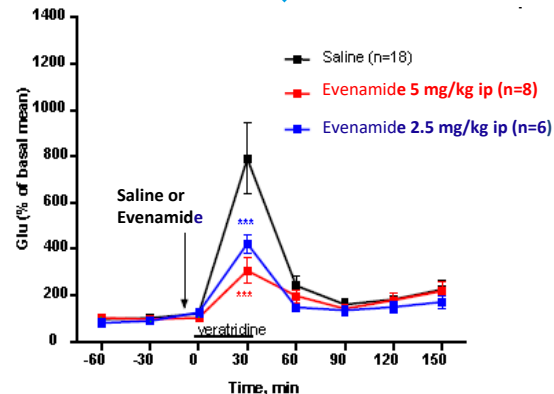
Control



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 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
- 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** 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** (except ERA and carcinogenicity – 1 species, 6 months) **accepted by health authorities**
- **Acceptance of registration dossier based on 1 sufficiently positive TRS study** expected



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



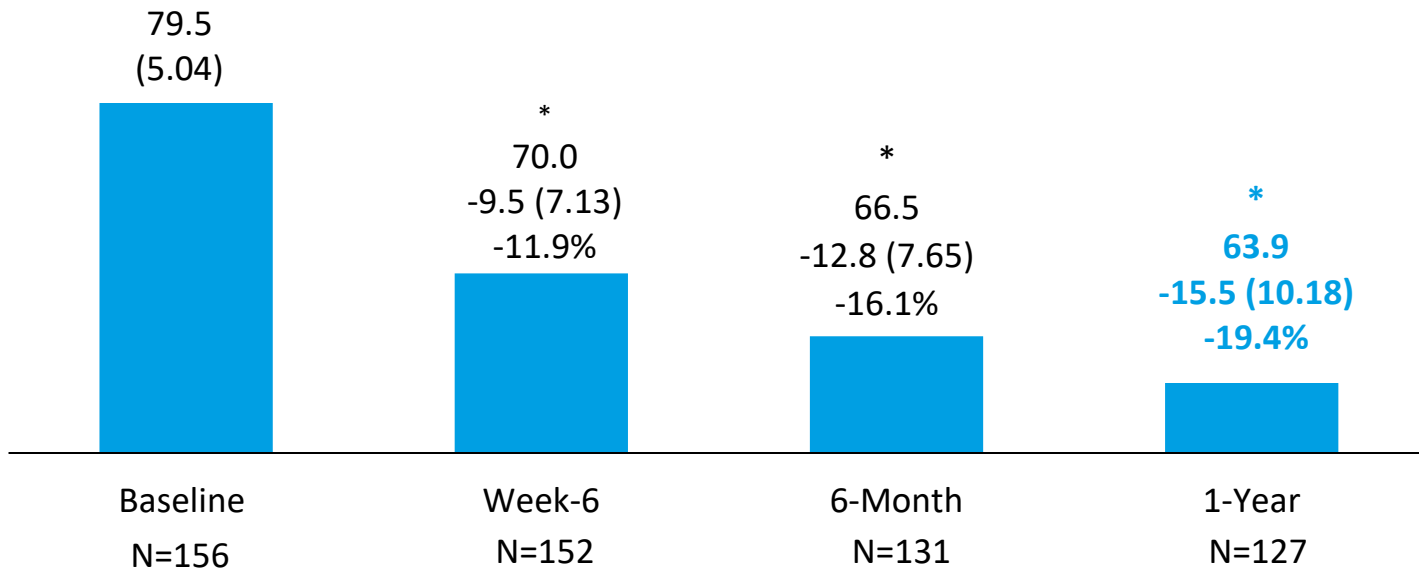
Randomized N = 161	Completed N = 153	Discontinued N = 8	Completed N = 132	Completed N = 121	Total Discontinued	31
	Entered Extension N = 144	Did not enter extension N = 9	Discontinued N = 12	Discontinued N = 11	Withdrawal of consent	23
					Lost to follow-up	5
					Adverse event	2
					Death	1
Day 0 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 – 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

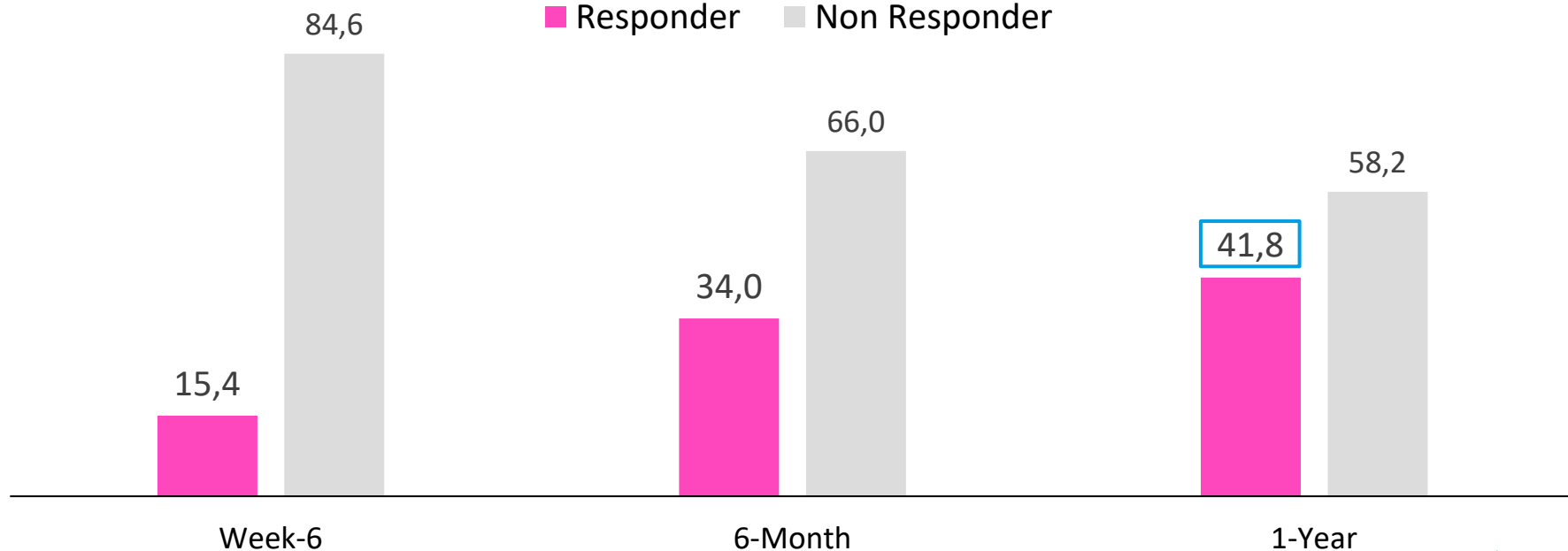


STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS (%) – mITT

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

■ Responder ■ Non Responder





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%)





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

> DESIGN AND KEY FEATURES

>>> A potentially pivotal, phase II/III, 4-week, randomized, double-blind, placebo-controlled study 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

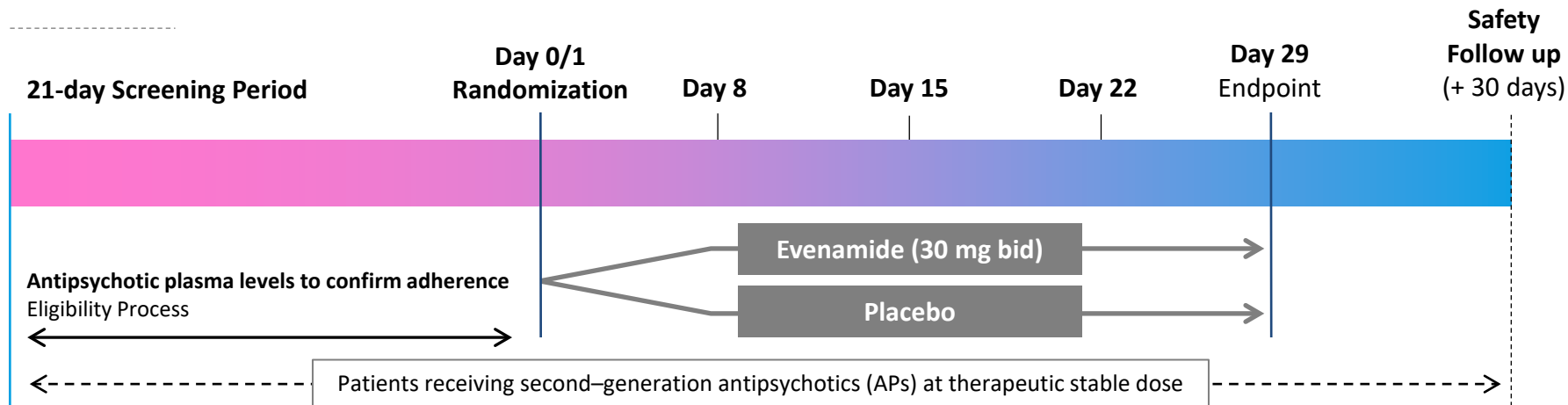
Countries: EU (CZ, EST, HUN, ITA, RO, SPA), IND, MEX, ARG

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

Objectives: **Primary** – Efficacy (PANSS Total score), Safety and Tolerability

DESIGN AND KEY FEATURES



KEY STUDY FEATURES

Double-blind, randomized (1:1)
Evenamide 30 mg BID vs Placebo
Add-on treatment to SGAs*
11 countries; 45 sites
Europe, India, and LATAM

KEY SELECTION CRITERIA

Outpatients still symptomatic despite ≥ 4 weeks of AP treatment at a stable dose
Total PANSS: 70-85; CGI-S: 4 to 6
Score of ≥ 4 (moderate) on at least 2 of the 4 core symptoms of psychosis

KEY OUTCOME MEASURES

PANSS Total score
CGI of Severity
CGI of Change
Strauss-Carpenter LOF
Medication Satisfaction Questionnaire (MSQ)

> PATIENT DISPOSITION

	Evenamide 30 mg bid n (%)	Placebo n (%)	Overall n (%)
Screened	-	-	428
Randomized	132	159	291
ITT/Safety population	132 (100)	159 (100)	291 (100)
mITT population	131 (99.2)	156 (98.1)	287 (98.6)
Discontinued	6 (4.5)	5 (3.1)	11 (3.8)
<i>Withdrawal of consent</i>	<i>4 (3.0)</i>	<i>4 (2.5)</i>	<i>8 (2.7)</i>
<i>Adverse event*</i>	<i>2 (1.5)</i>	<i>1 (0.6)</i>	<i>3 (1.0)</i>
Completed Day 29	126 (95.5)	154 (96.9)	280 (96.2)

* Placebo: 1 death; Evenamide: 1 sinus bradycardia; 1 vomiting

- Safety population: all subjects who took at least a dose of study medication (evenamide or placebo)

- ITT pop: all subjects who were randomized to either of the two treatments, regardless any dose has been taken or not

- mITT pop: all subjects who have a baseline and at least one post-baseline efficacy assessment for PANSS and received at least one IP dose



SAFETY: OVERALL SUMMARY OF TEAEs

Subject	Evenamide 30 mg bid N=132; n (%)	Placebo N=159; n (%)	Overall N=291; n (%)
With at least one TEAE	33 (25.0)	41 (25.8)	74 (25.4)
<i>Mild</i>	22 (16.7)	30 (18.9)	52 (17.9)
<i>Moderate</i>	11 (8.3)	10 (6.3)	21 (7.2)
<i>Severe</i>	0 (0.0)	1 (0.6)	1 (0.3)
With adverse event leading to death	0 (0.0)	1 (0.6)	1 (0.3)
With at least one emergent serious TEAE*	2 (1.5)	1 (0.6)	3 (1.0)
With any TEAE leading to IP discontinuation [#]	3 (2.3)	1 (0.6)	4 (1.4)

*Evenamide = 1 panic attack; 1 exacerbation of schizophrenia after arbitrary discontinuation of antipsychotic medication;
Placebo = 1 death due to accidental fall/suspected suicide

[#] Evenamide = 1 panic attack; 1 sinus bradycardia; 1 vomiting; Placebo = 1 paranoia

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)	
	<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]	

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

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 are ongoing and are likely to show similar benefits as the analyses performed to date

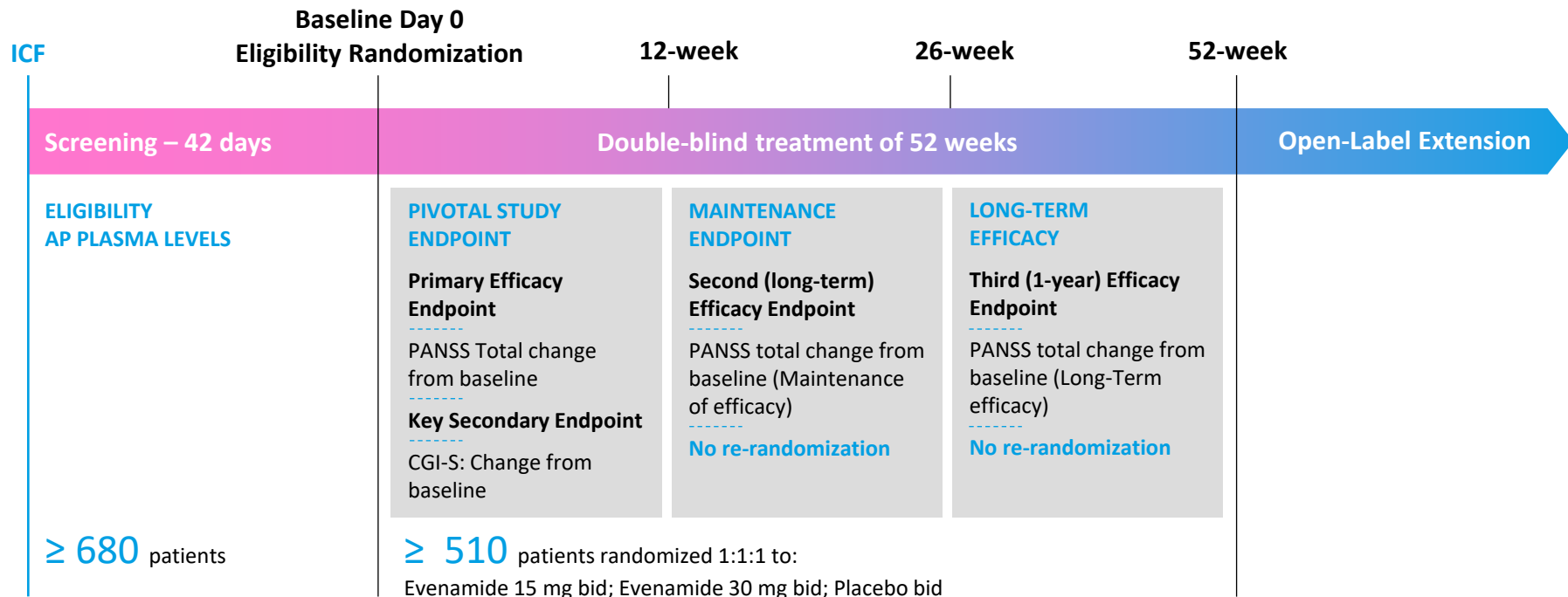


The side effect profile of evenamide is similar to placebo with no increases in EPS, weight gain, blood glucose, metabolic syndrome, sexual dysfunction, CNS or cardiac effects, or laboratory abnormalities



Phase III pivotal study in patients with TRS is expected to be initiated in the near future

PHASE III TRS STUDY – DESIGN*



* Conditional to final agreement by potential partners and regulatory bodies



XADAGO IN PARKINSON'S DISEASE MARKETED COMPOUND



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



Globally licensed



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

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