



Olanzapine LAI (TEV-'749)  
Phase 3 SOLARIS Data  
Presentation –  
Conference Call

September 22, 2025



# Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. These forward-looking statements include statements concerning our plans, strategies, objectives, future performance and financial and operating targets, and any other information that is not historical information. Important factors that could cause or contribute to such differences include risks relating to:

- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; concentration of our customer base and commercial alliances among our customers; competition faced by our generic medicines from other pharmaceutical companies and changes in regulatory policy that may result in additional costs and delays; delays in launches of new generic products; our ability to develop and commercialize additional pharmaceutical products; competition for our innovative medicines; our ability to achieve expected results from investments in our product pipeline; our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, to sustain and focus our portfolio of generic medicines, and to execute on our organizational transformation and to achieve expected cost savings; and the effectiveness of our patents and other measures to protect our intellectual property rights, including any potential challenges to our Orange Book patent listings in the U.S.;
- our significant indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments; and our potential need to raise additional funds in the future, which may not be available on acceptable terms or at all;
- our business and operations in general, including: the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto; the widespread outbreak of an illness or any other communicable disease, or any other public health crisis; effectiveness of our optimization efforts; significant disruptions of information technology systems, including cybersecurity attacks and breaches of our data security; interruptions in our supply chain or problems with internal or third party manufacturing; challenges associated with conducting business globally, including political or economic instability, major hostilities or terrorism, such as the ongoing conflict between Russia and Ukraine and the state of war declared in Israel; our ability to attract, hire, integrate and retain highly skilled personnel; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; and our prospects and opportunities for growth if we sell assets or business units and close or divest plants and facilities, as well as our ability to successfully and cost-effectively consummate such sales and divestitures, including our planned divestiture of our API business;
- compliance, regulatory and litigation matters, including: failure to comply with complex legal and regulatory environments; the effects of governmental and civil proceedings and litigation which we are, or in the future become, party to; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage, including as a result of the One Big Beautiful Bill signed into law in the U.S. in July 2025 ("OBBBA"), which is expected to result in stricter Medicaid eligibility requirements and work requirements, which may result in reduced Medicaid enrollment and a resulting decline in coverage for purchases of our medicines, and U.S. Executive Orders issued in April and May 2025 intended to reduce the prices paid by Americans for prescription medicines, including most-favored-nation pricing; increased legal and regulatory action in connection with public concern over the abuse of opioid medications; our ability to timely make payments required under our nationwide opioids settlement agreement and provide our generic version of Narcan® (naloxone hydrochloride nasal spray) in the amounts and at the times required under the terms of such agreement; scrutiny from competition and pricing authorities around the world, including our ability to comply with and operate under our deferred prosecution agreement ("DPA") with the U.S. Department of Justice ("DOJ"); potential liability for intellectual property right infringement; product liability claims; failure to comply with complex Medicare, Medicaid and other governmental programs reporting and payment obligations; compliance with sanctions and trade control laws; environmental risks; and the impact of Environmental, Social and Governance ("ESG") issues;
- the impact of the state of war declared in Israel and the military activity in the Middle East, including the risk of disruptions to our operations and facilities, such as our manufacturing and R&D facilities, located in Israel, the impact of our employees who are military reservists being called to active military duty, and the impact of the war on the economic, social and political stability of Israel;
- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our long-lived assets; the impact of geopolitical conflicts including the state of war declared in Israel and the conflict between Russia and Ukraine; potential significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; our exposure to changes in international trade policies, including the imposition of tariffs in the jurisdictions in which we operate, and the effects of such developments on sales of our products and the pricing and availability of our raw materials; and the impact of any future failure to establish and maintain effective internal control over our financial reporting;

and other factors discussed in our Quarterly Report on Form 10-Q for the second quarter of 2025 and in our Annual Report on Form 10-K for the year ended December 31, 2024, including in the sections captioned "Risk Factors" and "Forward-looking Statements." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

# Agenda

## Presenters

1

Teva in Neuroscience



**Eric Hughes, MD, PhD**

EVP, Global R&D  
& Chief Medical Officer

2

Significant unmet need in Schizophrenia



**Christine Fox**

Executive Vice President, U.S.  
Commercial

3

Solaris (TEV-'749) data update



**Christoph Correll, MD**

Professor of Psychiatry  
Zucker School of Medicine, Hempstead, NY  
SOLARIS study coordinating investigator

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Conclusion and Q&A



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Eric Hughes,  
MD, PhD

Executive Vice President,  
Global R&D & Chief Medical Officer

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# Strong Global Neuroscience Legacy, Capabilities & Infrastructure

	Legacy	Marketed	Under Regulatory Review	Phase 3	Phase 2
Legacy, In-line, and Pipeline Assets	<b>COPAXONE</b> (glatiramer acetate injection)	<b>AJOVY</b> (fremanezumab-vfrm)	<b>UZEDY</b> Bipolar	olanzapine LAI (TEV-'749) Schizophrenia	Emrusolmin (TEV-'286) MSA
	<b>AZILECT</b> (rasagiline tablets)	<b>Austedo</b> (deutetrabenazine)			
	<b>PROVIGIL</b> (MODAFINIL) <b>NUVIGIL</b> (ARMODAFINIL) tablets & capsules	<b>UZEDY</b> (risperidone)			

## R&D Capabilities

In house R&D experts with proven track record developing neuroscience products, at all stages of development

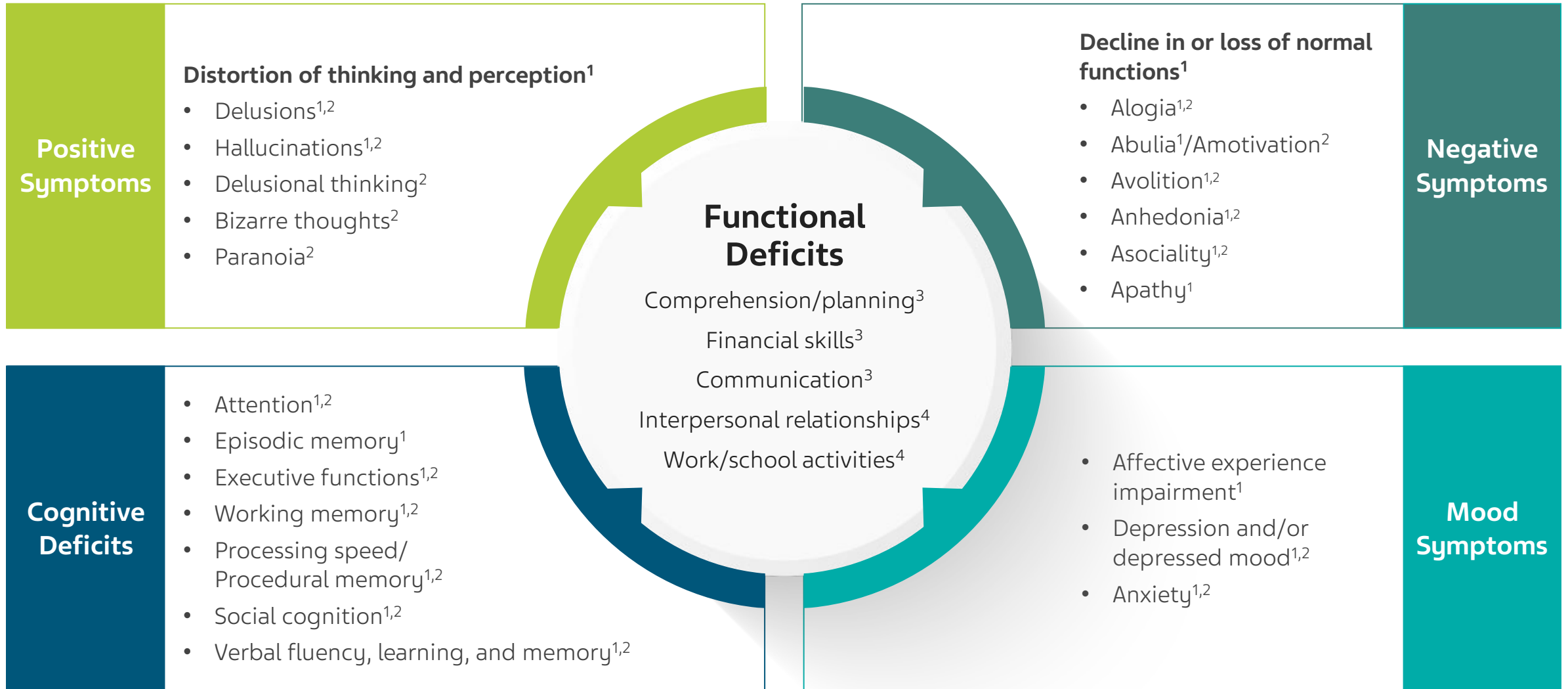
- Discovery
- Non-Clinical
- CMC
- Device
- Clinical
- Regulatory
- Medical Affairs

## Commercial Footprint

Substantial, experienced commercial neuroscience teams with footprints in



# Schizophrenia: Core Symptom Domains and Functional Outcome Deficits



# Schizophrenia is a Severe and Debilitating Lifelong Illness

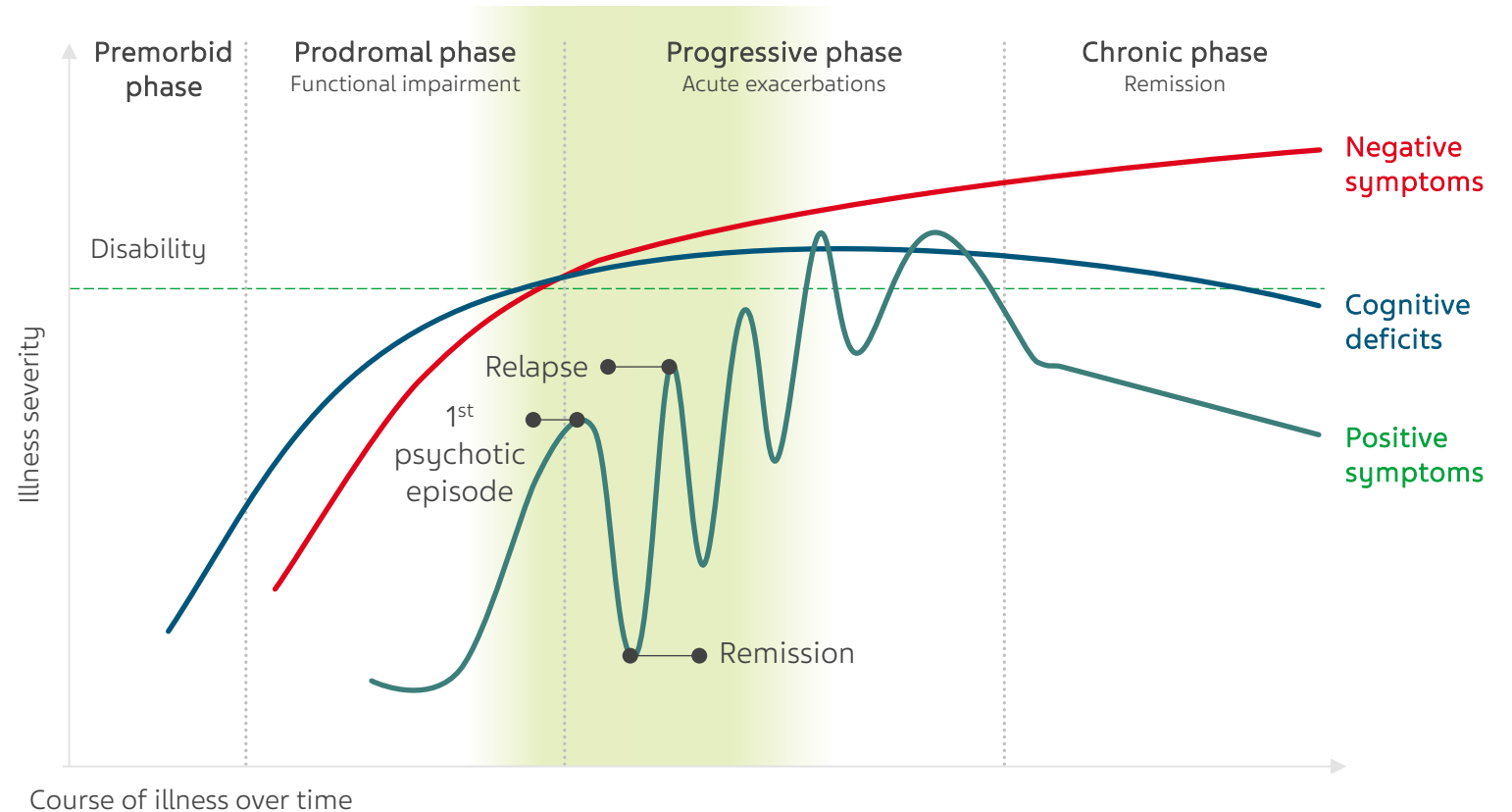
## Long untreated psychosis associated with poor long-term outcomes



Psychosocial outcomes become poorer with an increasing number of relapses<sup>1</sup>

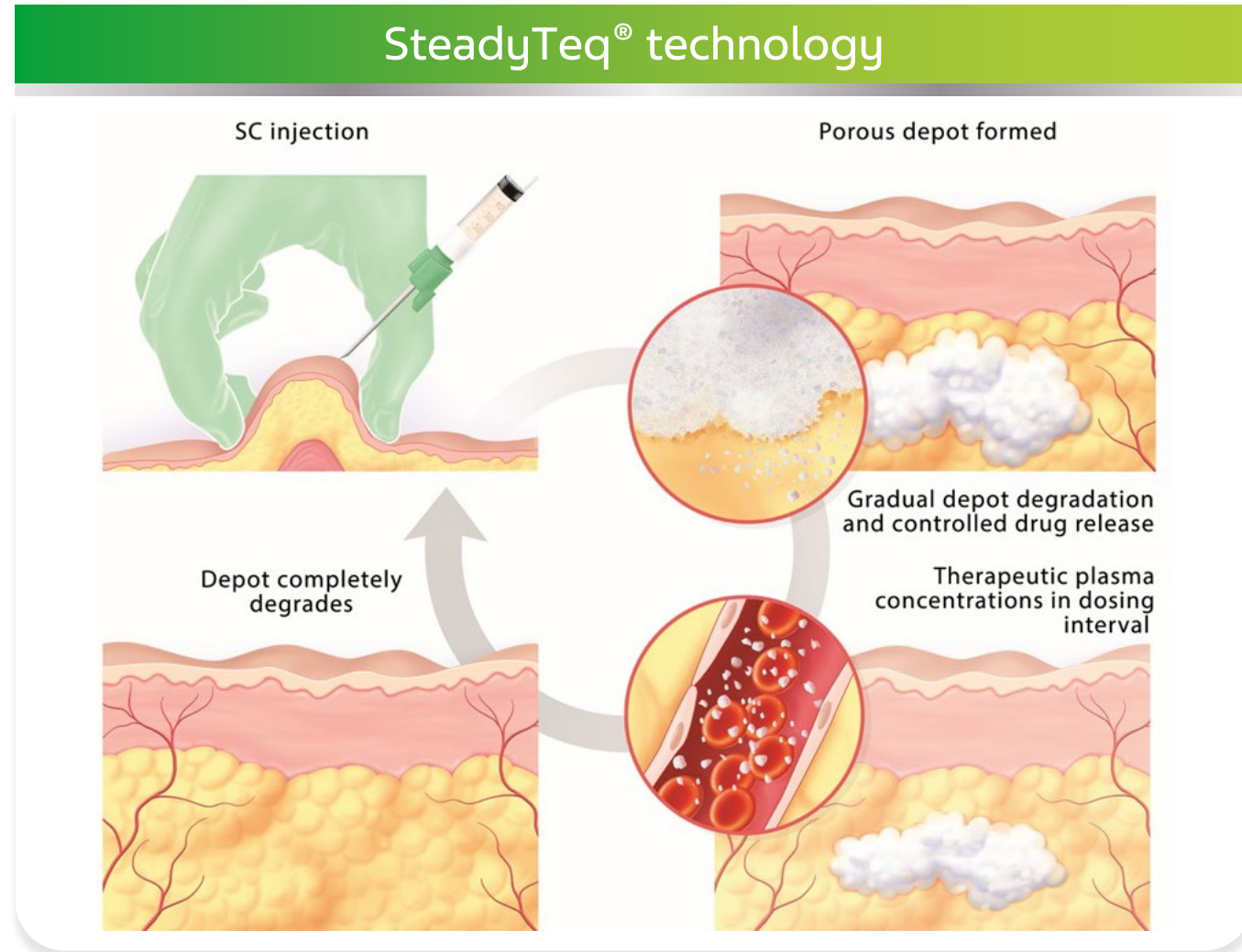
80% of patients experience multiple relapses over the first five years of treatment<sup>2</sup>

Suboptimal medication adherence is a major<sup>2</sup> modifiable<sup>3</sup> risk factor for relapse, highlighting the need for LAIs



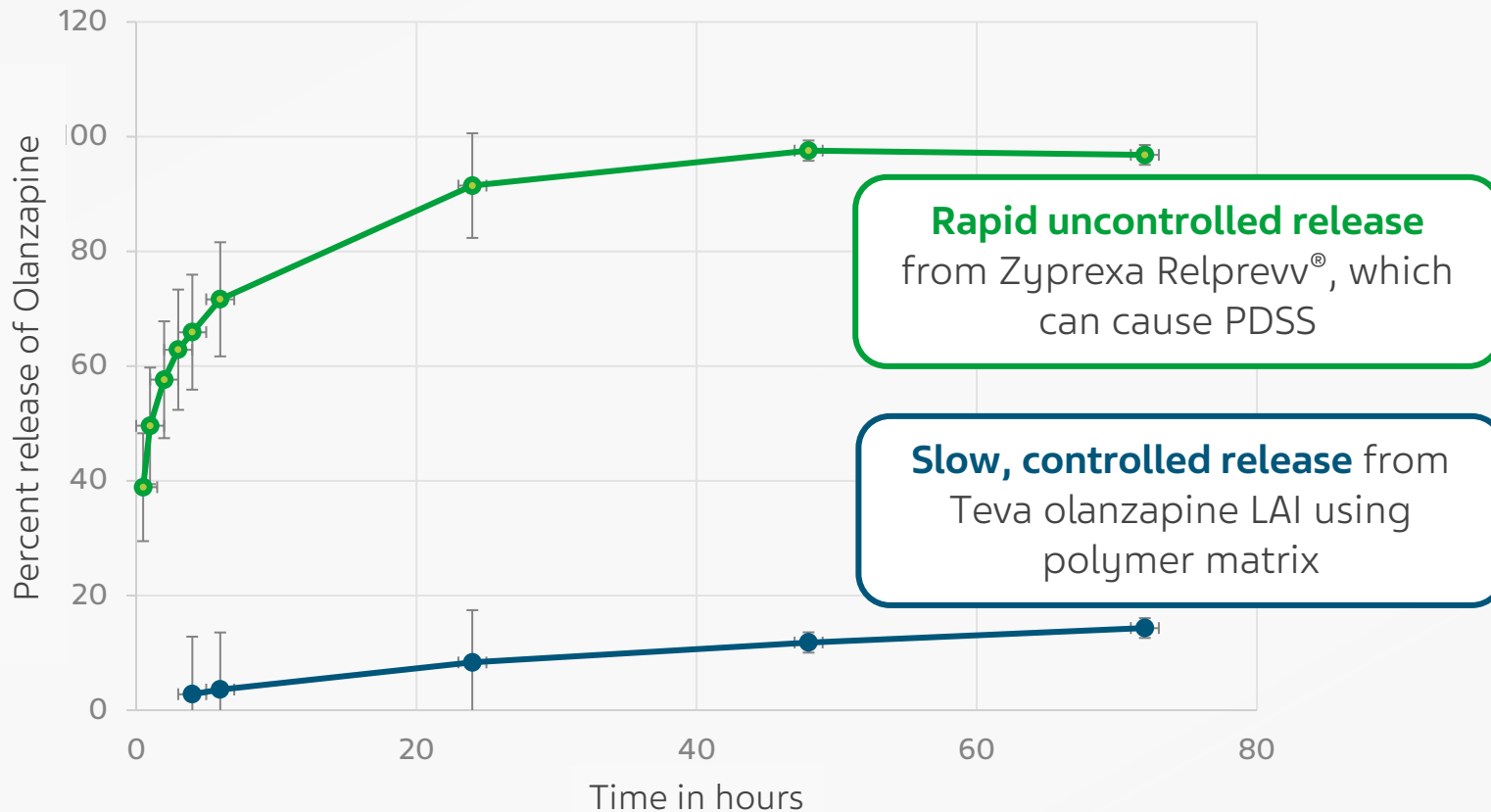
1. Lin D, et al. Front Psychiatry. 2021 Oct 26;12:695672. doi: 10.3389/fpsyt.2021.695672.  
2. Robinson D, et al. Arch Gen Psychiatry. 1999;56(3):241. doi:10.1001/archpsyc.56.3.241.  
3. Bodén R, et al. Schizophr Res. 2011;133(1-3):36-41. doi:10.1016/j.schres.2011.08.024.

# Teva olanzapine LAI Allows For a Controlled Release Maintaining Therapeutic Plasma Concentrations



# Strong Evidence That Teva olanzapine LAI Will Not Cause PDSS

*In vitro* release tested in human plasma



**Rapid uncontrolled release** from Zyprexa Relprevv<sup>®</sup>, which can cause PDSS

**Slow, controlled release** from Teva olanzapine LAI using polymer matrix



~4,000 SC injections across multiple clinical studies, with no PDSS observed

Teva's olanzapine LAI met primary and key secondary efficacy endpoints, at all 3 doses

Efficacy and systemic safety profile of Teva's olanzapine LAI comparable to daily oral olanzapine, with no PDSS to date



teva

Christine Fox

Executive Vice President, U.S. Commercial

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# LAI Schizophrenia Franchise

Building a best-in-class LAI franchise

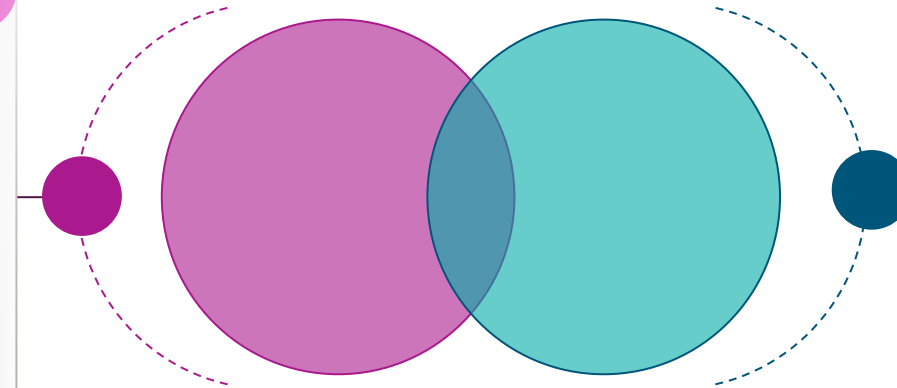


Aim to be the preferred LAI for:

Patients appropriate for oral risperidone or paliperidone

Modestly controlled patients, but seeking additional convenience (earlier in the treatment algorithm)

Estimated ~4.7M<sup>1</sup> prevalent schizophrenia patients in the US and Europe



Olanzapine LAI  
TEV-'749

Anticipated for:

Patients appropriate for oral olanzapine

Patients presenting with agitation or aggression

\$1.5B-\$2.0B

Franchise peak sales expectation

Leveraging our go-to-market expertise in this category

LAI: Long Acting Injectable 1. US & EU combined; Note: EU 5 prevalence

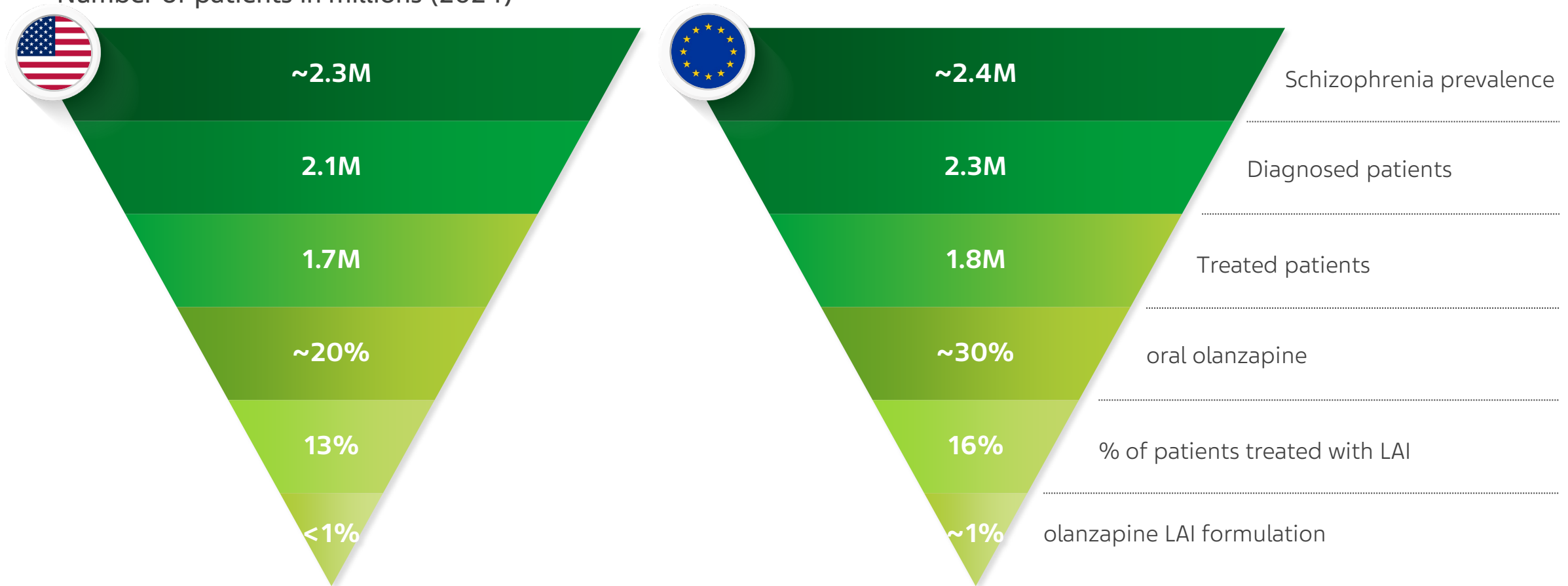
Source: Clarivate's Decision Resources Group (last updated February 2024); LAI penetration based on IQVIA sales in Month of Therapy volume, with MIDAS (sales) dataset for EU and NPA Trx dataset for

# LAI Schizophrenia Franchise

Large patient population with unmet needs

~\$13B schizophrenia market, of which ~\$6B for LAI<sup>1</sup>

Number of patients in millions (2024)



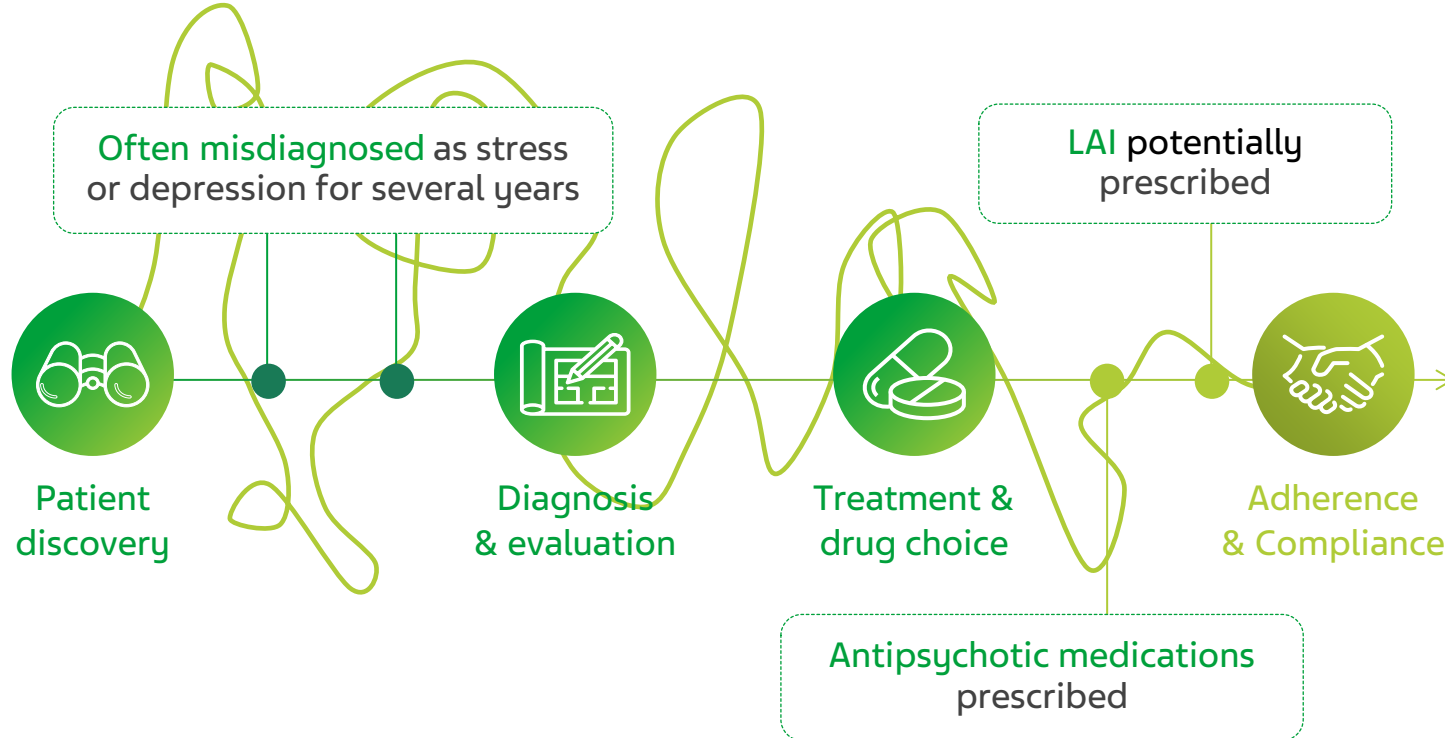
1. US & EU combined; Note: EU 5 prevalence

Source: Clarivate's Decision Resources Group (last updated February 2024); LAI penetration based on IQVIA sales in Month of Therapy volume, with MIDAS (sales) dataset for EU and NPA Trx dataset for US. Market size: , US: Evaluate Pharma 2024 data, EU: IQVIA sales 2024

# LAI Schizophrenia Franchise

## Requirements for success in schizophrenia market

### Complex patient journey creating multiple relapses



### Requirements to increase LAI penetration

- Deep understanding of the patient journey
- Demonstrated safety profile
- Go-to-market capabilities

# LAI Schizophrenia Franchise

## Summarizing the commercial opportunity



Answering a true unmet need with a **differentiated LAI franchise**



**Addressing a broad spectrum of patients with UZEDY and olanzapine LAI:** 65%-80% of patients with potential to switch as currently on similar molecule<sup>1</sup>



**Leveraging best-in-class go-to-market capabilities** to strengthen medical education

**\$1.5B-\$2.0B LAI franchise peak sales expectation**

LAI: Long Acting Injectable

Sources: LAI penetration based on IQVIA sales in Month of Therapy volume, with MIDAS (sales) dataset for EU and NPA Trx dataset for US & DRG; 1. patients considered "potential to switch as currently on a similar molecules" are patients currently on paliperidone oral, aripiprazole Oral, risperidone Oral, olanzapine Oral, and patients currently on an LAI; 65% in the U.S. and 80% in the EU respectively



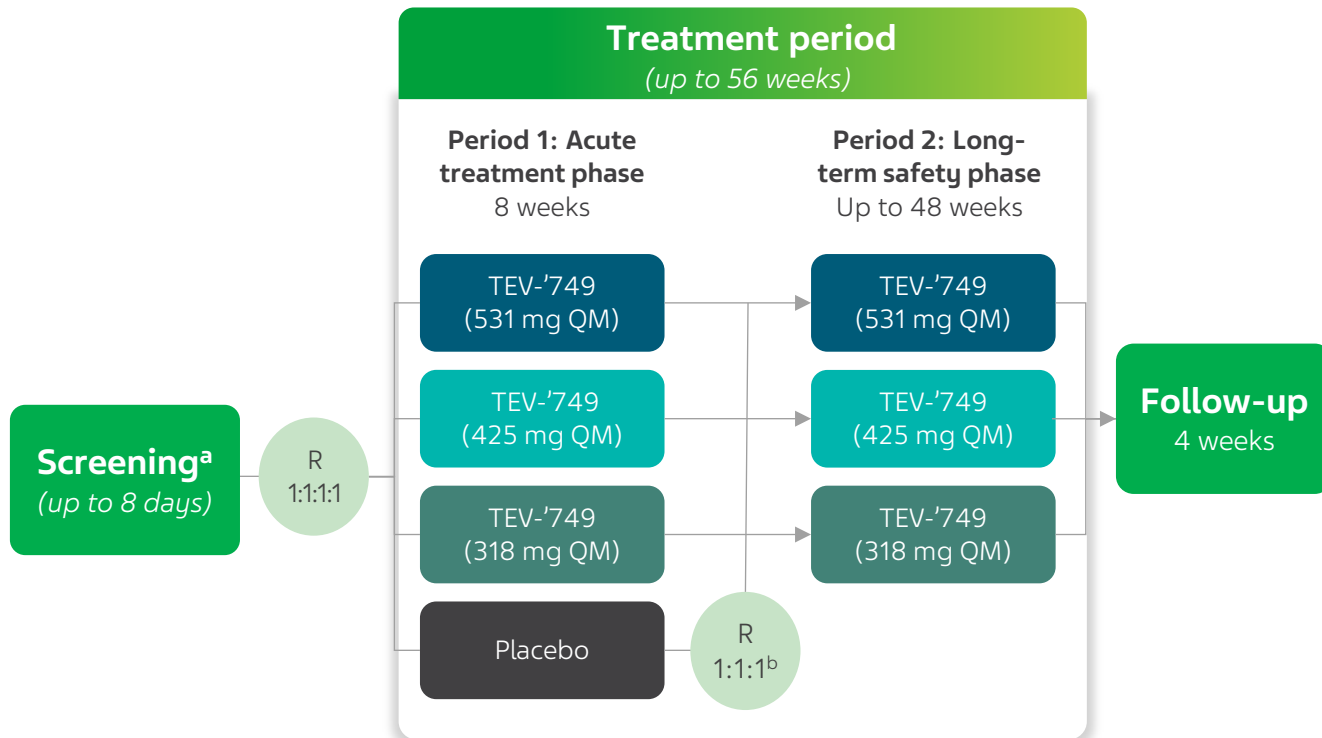
## Christoph Correll, MD

Professor of Psychiatry  
Zucker School of Medicine, Hempstead, NY  
SOLARIS Study Coordinating Investigator

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# SOLARIS Study Design

Phase 3 randomized, double-blind, placebo-controlled (Period 1), open-label long-term safety (Period 2) trial to evaluate efficacy, safety in adult patients with acute exacerbation of schizophrenia



**Period 1** (8 weeks, n=675) aimed to assess the efficacy and safety, of TEV-'749 schizophrenia.

In **Period 2** (n=423), Period 1 TEV-'749 participants retained their treatment, placebo patients were re-randomized 1:1:1 to TEV-'749 (318 mg, 425 mg, or 531 mg).

TEV-'749 doses were comparable to daily oral olanzapine doses of 10 mg, 15 mg, and 20 mg.

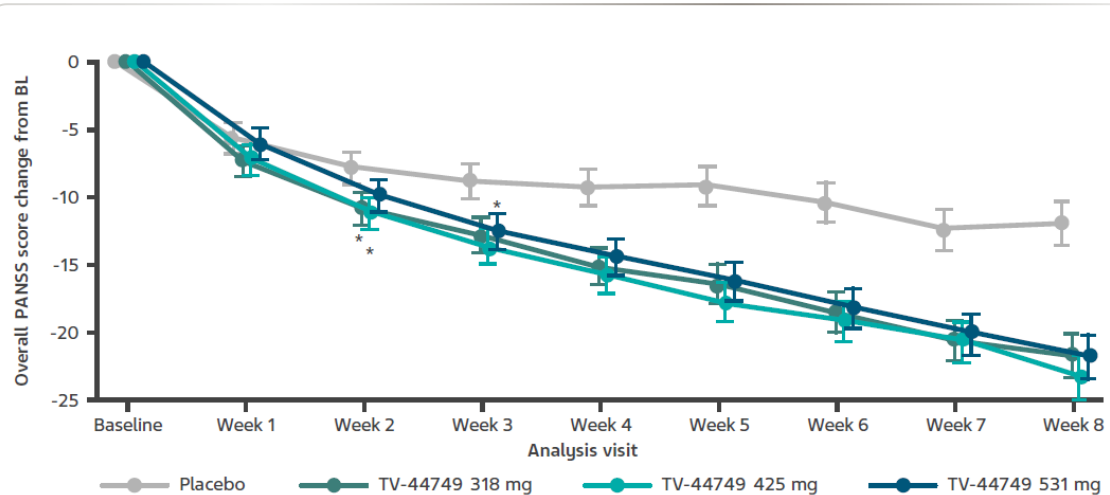
a. Participants entering the trial who had not previously received oral olanzapine within the last year received 2 oral doses of olanzapine for 2 consecutive days at the screening period to assess tolerability. The investigator verified the previous use, tolerability, and duration of olanzapine treatment to assure prior tolerability.

b. To maintain the blinding in Period 1, all participants were re-randomized between Periods 1 and 2; participants previously assigned to the active treatment groups retained their Period 1 treatment assignment (rerandomization was done to maintain blinding of Period 1, and de facto is a deterministic assignment and not randomization), and participants previously assigned to placebo were randomized to one of the active treatment groups in a 1:1:1 ratio. Participants were hospitalized for  $\geq 28$  days after receiving the first injection.

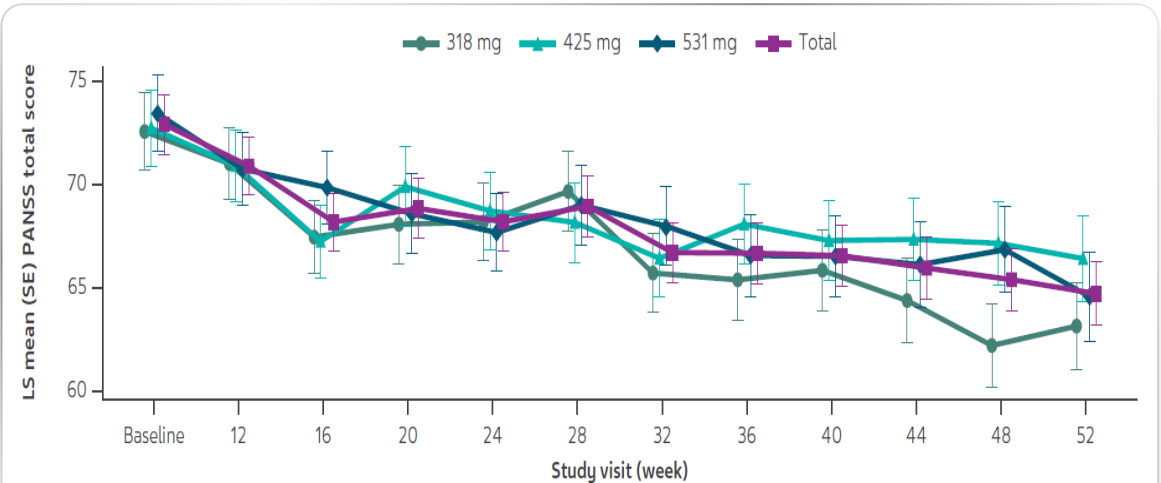
QM, once monthly; R, randomization.

# TEV-'749 Demonstrated Long-Term Clinical Effectiveness with Improvements in PANSS Total Score From Period 2 Baseline Through End of Treatment

LS mean change from baseline to Week 8 in PANSS total score<sup>1</sup>



Mean PANSS total score from Period 2 baseline<sup>a</sup> by visit and treatment group (full analysis set)<sup>2</sup>



- Mean change from baseline to end of treatment at any time for all TEV-'749 groups was -7.2 (SD: 16.21)
- In addition to PANSS total scores, all TEV-'749 groups showed sustained improvement in CGI-S and PSP scale scores to end of treatment

PANSS, Positive and Negative Syndrome Scale; SD, standard deviation; CGI-S, Clinical Global Impression-Severity; PSP, Personal and Social Performance.

1. Correll CU, et al. Poster P5365 presented at the European College of Neuropsychopharmacology; September 21–24, 2024; Milan, Italy. 2. Correll CU, et al. Poster #96 presented at the 38th Psych Congress 2025; September 17–21, 2025; San Diego, CA, USA.

# Long-Term Safety Profile of TEV-'749 is Consistent With Other olanzapine Formulations, With No PDSS Events

Most Common Adverse Events in SOLARIS Integrated Trial Period	318 mg (n=204)	425 mg (n=203)	531 mg (n=197)	Total (N=604)
<b>Participants with treatment-emergent AEs, n (%)</b>				
Weight increased	73 (36)	78 (38)	69 (35)	220 (36)
Injection-site induration	20 (10)	27 (13)	28 (14)	75 (12)
Injection-site pain	25 (12)	25 (12)	24 (12)	74 (12)
Injection-site erythema	15 (7)	24 (12)	22 (11)	61 (10)
Injection-site pruritus	13 (6)	12 (6)	16 (8)	41 (7)
Somnolence	17 (8)	11 (5)	15 (8)	43 (7)
Headache	9 (4)	15 (7)	8 (4)	32 (5)
Injection-site swelling	11 (5)	11 (5)	8 (4)	30 (5)
Constipation	7 (3)	12 (6)	9 (5)	28 (5)

- No new systemic safety signals were identified over the long-term follow-up period, and consistent with other olanzapine formulations
- Injection site reactions (ISRs) were mild/moderate and decrease with continued dosing
- There were no suspected or confirmed PDSS events (3470 injections)

# Conclusions



All TEV-'749 doses exhibited **long-term, continuous symptom improvement** and **maintenance of clinical effectiveness** in the SOLARIS study.



**Long-term safety profile** of TEV-'749 is **consistent** with other olanzapine formulations.



**No suspected or confirmed PDSS events reported in 3470** injections.



TEV-'749 Long-term change in weight and metabolic parameters comparable to other olanzapine formulations.



Potential for TEV-'749 to become the **first LAI** olanzapine to avoid the risk of PDSS.



**teva**

Eric Hughes,  
MD, PhD

Executive Vice President,  
Global R&D & Chief Medical Officer

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# Highlights of Psych Congress 2025

SOLARIS Trial Data Were Selected to Be Featured in Two Special Sessions at Psych 2025



## Invited Oral Session

**Poster title:** Long-Term Safety of Subcutaneous Long-Acting Injectable Olanzapine (TEV-'749) in Schizophrenia: Results From the Phase 3 SOLARIS Trial

- **Session:** Latest Discoveries & Emerging Trends in Psychotic Disorders
- **Presented by:** Professor Christoph Correll



## Poster Award Nomination

**Poster Title:** Long-Term Effectiveness With Subcutaneous Long-Acting Injectable Olanzapine (TEV-'749) in Adults With Schizophrenia: Results From up to 48 Weeks Open Label Treatment in the Phase 3 SOLARIS Trial

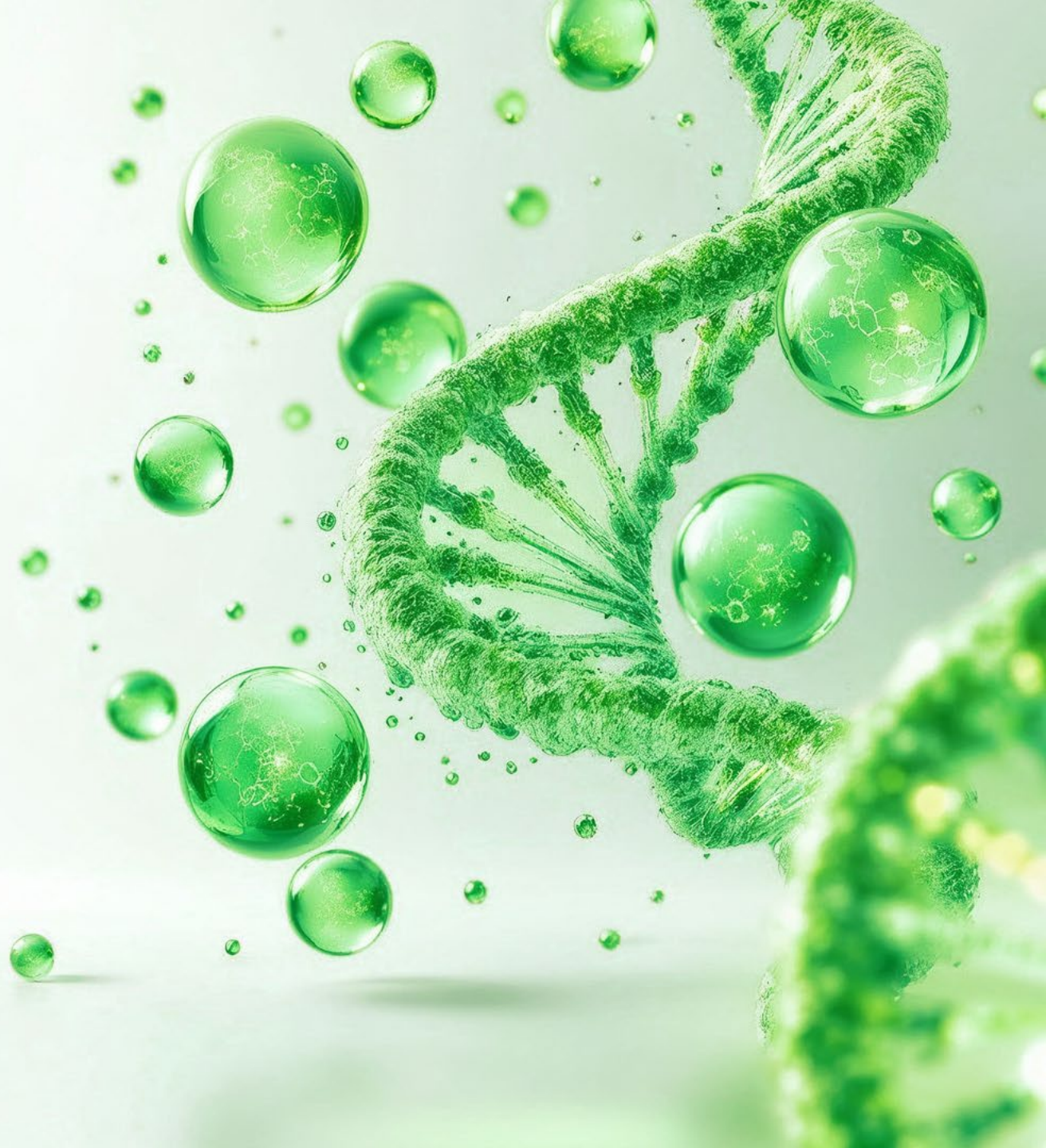
- Poster was chosen as a **Finalist** and was displayed at the **Poster Award Reception**



# Q&A



# Additional Information



# SOLARIS Period 1 Outcomes

Greater clinical improvement at week 8 in PANSS total score with TEV-'749 versus placebo, with safety profile consistent with other approved olanzapine formulations.<sup>1,2</sup>



## Primary and key secondary endpoints met at week 8

Reduction in PANSS total and CGI-S scores

Increase in PSP scale score

Onset of effect started as early as week 2–3



## No new systemic safety signals

No PDSS events

Most common AE: weight increased (35%)



## Acceptable ISR rates

Mostly mild in severity

Rate decreased with second injection



## Low discontinuation due to AEs

Weight gain: <1%

Other metabolic AEs: <1%

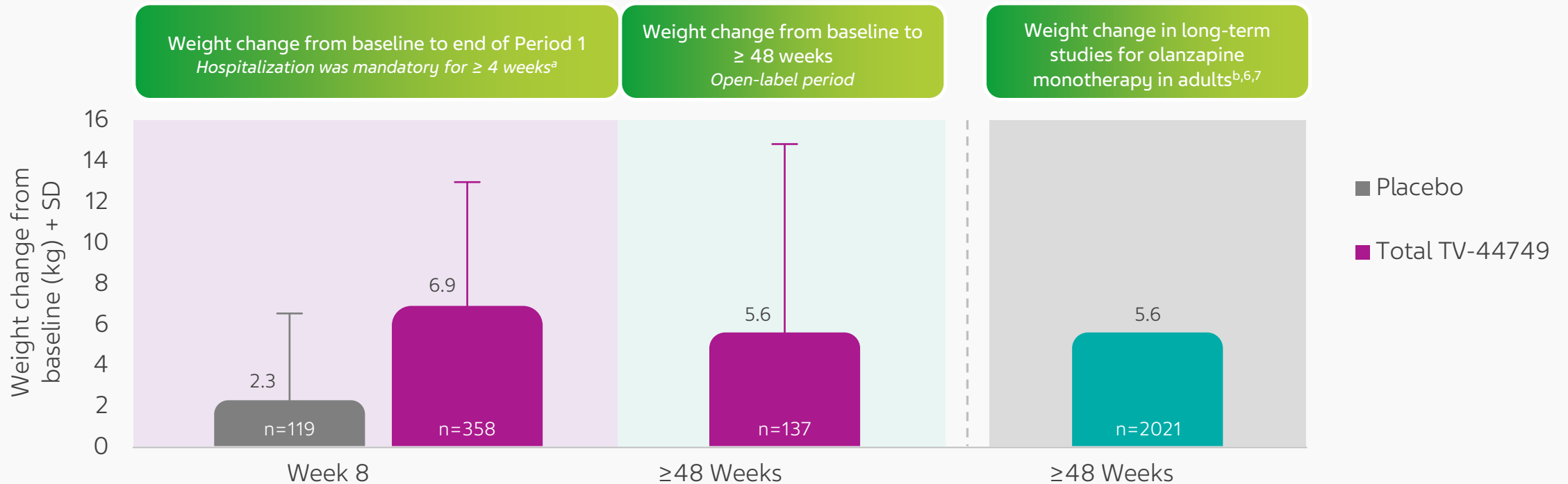
ISRs: 1%

Somnolence: <1%

AE: adverse event; CGI-S: Clinical Global Impression-Severity; ISR: injection-site reaction; PANSS: Positive and Negative Syndrome Scale; PDSS: post-injection delirium/sedation syndrome; PSP: Personal and Social Performance.

1. Correll CU, et al. Poster P5365 presented at the 37th European College of Neuropsychopharmacology Congress 2024; September 21–24, 2024; Milan, Italy. 2. Correll CU, et al. Poster P5367 presented at the 37th European College of Neuropsychopharmacology Congress 2024; September 21–24, 2024; Milan, Italy.

# TEV-'749 Long-Term Change in Weight and Caridometabolic Parameters Comparable to Other olanzapine Formulations



## Treatment and/or trial discontinuation due to metabolic AEs were infrequent:

- Period 1: 7 (1%) participants with TEV-'749; none in the placebo group.
- Integrated trial periods: 18 (3%) participants with TEV-'749.

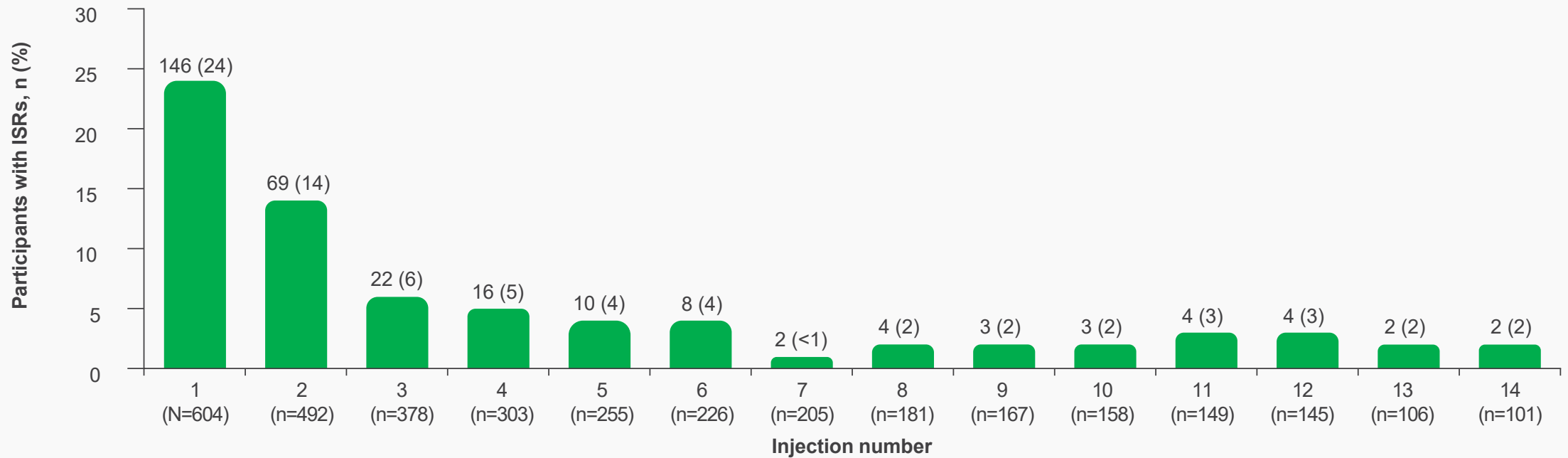
EoT, end of treatment.

Correll CU, et al. Poster #95 presented at the 38th Psych Congress 2025; September 17–21, 2025; San Diego, CA, USA.

1) ZYPREXA RELPREVV (olanzapine) intramuscular [package insert]. Indianapolis, IN: Lilly USA, LLC; 2025; 2) ZYPREXA (olanzapine) oral and intramuscular [package insert]. Indianapolis, IN: Lilly USA, LLC; 2025.

# Long-Term Safety Profile of TEV-'749 Injection Site Reactions Were Mild/Moderate and Decreased Over Time

Participants with ISRs, by injection number (safety analysis set)



No suspected or confirmed PDSS events (3470 injections)

Treatment-emergent AEs are defined as AEs that occurred after the first dose of TEV-'749 was administered through end of the trial.

AE, adverse event.



Thank You

