Risk of Relapse with PP1M versus the Most Commonly Utilized OAPs in the US in Adults with Schizophrenia: A Pooled Analysis of PRIDE and PROSIPAL

AUTHORS: Nia Josiah[1], Camilo Obando[2], Ibrahim Turkoz[2], Monica Doring[2], Zachariah Smith[2], Lisa Lim[2], Karen Johnston[2], Martha Sajatovic[3]

AFFILIATIONS: [1]University of Pennsylvania, Philadelphia, PA; [2]Johnson & Johnson, Titusville, NJ [3]University Hospitals Cleveland Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH

Background

- Prior studies have demonstrated the benefits of paliperidone palmitate 1-month (PP1M) over oral antipsychotics (OAP) including delayed time to relapse in adults with schizophrenia[1,2]
- Despite this, OAPs are still widely used among patients. In a 2025 US claims analysis, the most common OAPs identified were risperidone, olanzapine, quetiapine, and aripiprazole **(Table 1)**[3]
- The objective of this analysis was to evaluate the risk of relapse within commonly used oral antipsychotics in comparison to PP1M in adults with schizophrenia

TABLE 1: Utilization of OAPs in the US Based on a January 2025 – September 2025 Claims Analysis[3]

Oral Antipsychotic	Market Share	Oral Antipsychotic	Market Share
Olanzapine	21.1%	Aripiprazole	12.2%
Quetiapine	18.8%	Conventional Orals	10.2%
Others	15.4%	Clozapine	7.9%
Risperidone	14.4%		

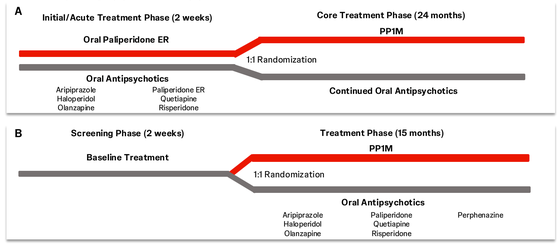
Methods

- Patients from the Janssen-sponsored PRIDE (NCT01157351) & PROSIPAL (NCT01081769) studies were included in the pooled analysis **(Figure 1)**
  - While the individual trials were not powered to compare PP1M with each OAP, an integrated analysis allows a more robust powered evaluation of relapse risk with PP1M versus groups of OAPs for adults with schizophrenia
  - The two studies were selected because they shared comparable inclusion and exclusion criteria, consistent definitions for relapse or treatment failure (TF), and similar follow-up periods and study-conduct procedures
- The primary analysis set included all randomized patients who received ≥1 dose of any study intervention in the double-blind phase

Assessments

- Cumulative distribution functions of time to relapse were estimated using the Kaplan-Meier method. Differences in time to relapse distributions were assessed using the Log-Rank test statistics. Hazard ratios (HRs) and 95% confidence intervals (CIs) for between-group differences in risk of relapse were based on a Cox proportional hazards model
- Treatment-emergent adverse events (TEAEs) were documented

FIGURE 1: Study Design (A) PROSIPAL (B) PRIDE



Time to relapse was defined as any of the following: psychiatric hospitalization, an increase in the level of psychiatric care and an increase of 25% from baseline in the PANSS total score (or an increase of 10 points if baseline score ≤40), deliberate self-injury, suicidal or homicidal ideation, violent behavior resulting in injury to another person or property damage, substantial clinical deterioration, or required dose of antipsychotic exceeds the maximum approved dose

Results

Patient Baseline Characteristics

- A total of 1159 patients were included in the primary analysis set (based on the combining of core intention-to-treat [ITT] efficacy analysis set of PROSIPAL and enriched-ITT analysis set of PRIDE)
- Patient demographics and baseline characteristics are summarized in **Table 2**
  - All standardized mean differences were close to zero

Table 2. Baseline Characteristics

Characteristic, Mean (SD)	PP1M N=578	OAP N=581	Standardized Mean Differences PP1M vs OAP
Mean age, years	34.6 (10.93)	34.9 (10.57)	-0.03
Male, n (%)	406 (70.2)	391 (67.9)	0.06
Age at first psychiatric diagnosis, years	25.9 (10.58)	26.2 (10.43)	-0.03
Age at start of first antipsychotic treatment	26.8 (10.59)	27.0 (10.41)	-0.02
Age at start of first psychiatric hospitalization, years	27.2 (10.43)	27.3 (10.06)	-0.01
Number of previous hospitalizations	4.6 (10.08)	4.0 (3.90)	0.08
Baseline mean CGI-S score	3.8 (0.57)	3.8 (0.53)	0.02
Baseline mean PSP score	55.1 (11.92)	55.2 (11.71)	-0.01

CGI-S, Clinical Global Impression-Severity Scale; OAP, oral antipsychotic; PP1M, paliperidone palmitate 1-month formulation; PSP, Personal and Social Performance scale; SD, standard deviation.

Safety

- The most common TEAEs (≥10%) included weight increased, insomnia, and injection site pain; no new safety signals were identified

Table 3. TEAEs in ≥5% of Patients in Any Treatment Group

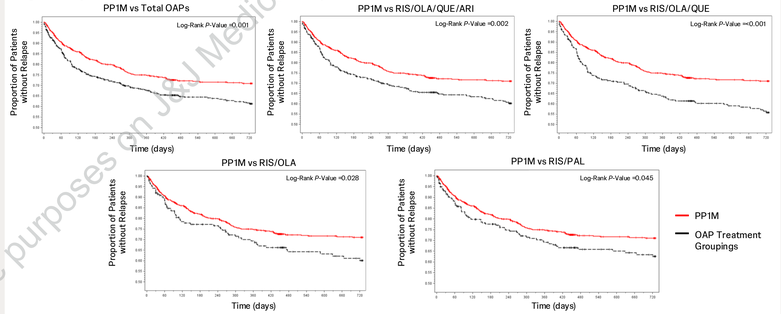
n (%)	PP1M N=578	OAP N=581
Patients with TEAE	446 (77.16)	403 (69.36)
Weight Increased	86 (14.88)	79 (13.60)
Insomnia	76 (13.15)	56 (9.64)
Injection Site Pain	66 (11.42)	0 (0)
Headache	56 (9.69)	50 (8.61)
Schizophrenia	39 (6.75)	51 (8.78)
Anxiety	45 (7.79)	34 (5.85)
Akathisia	41 (7.09)	31 (5.34)
Nasopharyngitis	40 (6.92)	32 (5.51)
Suicidal Ideation	24 (4.15)	37 (6.37)

OAP, oral antipsychotic; PP1M, paliperidone palmitate 1-month formulation; TEAE, treatment-emergent adverse event

Risk of Relapse

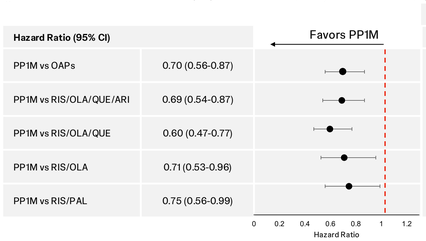
- Overall, fewer relapses were observed with PP1M vs OAPs (24.6% and 33.2%, respectively) **(Figure 2)**
- Risk of relapse was reduced by 30% in patients on PP1M compared to total OAPs **(Figure 3).** In addition, risk of relapse was reduced by:
  - 31% in PP1M vs 4 OAPs [RIS/OLA/QUE/ARI] (HR 0.69 CI 0.54-0.87)
  - 40% in PP1M vs 3 OAPs [RIS/OLA/QUE] (HR 0.60 CI 0.47-0.77)
  - 29% in PP1M vs 2 OAPs [RIS/OLA] (HR 0.71 CI 0.53-0.96)
  - 25% in PP1M vs 2 OAPs [RIS/PAL] (HR 0.75 CI 0.56-0.99)

Figure 2. Days to Relapse by Treatment: Kaplan-Meier Analysis



ARI, aripiprazole; OAP, oral antipsychotic; OLA, olanzapine; PAL, paliperidone; PP1M, paliperidone palmitate 1-month formulation; QUE, quetiapine; RIS, risperidone.

Figure 3. Forest Plot of Hazard Ratios (HR) of Time to Relapse by Treatment Group (PP1M vs OAP [95% CI])



Hazard Ratio (95% CI)		PP1M (N=578) Relapsed	PP1M (N=578) Censored	Comparator Relapsed	Comparator Censored
PP1M vs OAPs	0.70 (0.56-0.87)	142 (24.6%)	436 (75.4%)	N=581 193 (33.2%)	N=581 388 (66.8%)
PP1M vs RIS/OLA/QUE/ARI	0.69 (0.54-0.87)			N=387 132 (34.1%)	N=387 255 (65.9%)
PP1M vs RIS/OLA/QUE	0.60 (0.47-0.77)			N=273 105 (38.5%)	N=273 168 (61.5%)
PP1M vs RIS/OLA	0.71 (0.53-0.96)			N=179 59 (33.0%)	N=179 120 (67.0%)
PP1M vs RIS/PAL	0.75 (0.56-0.99)			N=219 70 (32.0%)	N=219 149 (67.0%)

The hazard ratios and 95% confidence intervals (CI) are derived from a Cox proportional hazards model with factors for treatment and study ID.

Conclusions

- This analysis showed that PP1M provides significant benefits in reducing relapse rates compared to OAP treatment groups.
- These findings reinforce the use of PP1M for adult patients with schizophrenia compared to the most commonly utilized OAPs.

Limitations

- Patients may not be fully representative of the real-world population with recent onset schizophrenia due to patients being enrolled in clinical trials with specific inclusion/exclusion criteria.
- Individual studies were not powered to detect difference between PP1M and individual OAP treatment groupings.

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References: **1.** Alphs L, et al. *Clin Psychiatry.* 2014;75(12):1388-1393. **2.** Schreiner A, et al. *Schizophr Res.* 2015;169(1-3):393-399. **3.** Data on File. Johnson and Johnson 2025.

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