Patient and Clinician Satisfaction and Quality of Life of Patients with Schizophrenia Using Paliperidone Palmitate 1-Month and 3-Month Long Acting Injectables in Rwanda

AUTHORS: Jordy Mehawej,[1*] José Antunes,[2] Ibrahim Turkoz,[1] Rutakayile Bizoza,[3] Larry Alphs,[4] Leslie Killion,[5] R. Karl Knight[1]

AFFILIATIONS: [1]Johnson & Johnson, Titusville, NJ, USA; [2]Johnson & Johnson, Porto Salvo, Portugal; [3]Ndera Neuro Psychiatric Teaching Hospital, University of Rwanda, Kigali, Rwanda; [4]Larry Alphs Consulting LLC, Princeton, NJ, USA; [5]Johnson & Johnson, Horsham, PA, USA

Presenting Author

Background

- Schizophrenia is a chronic, debilitating mental disorder with a high burden of disease. Schizophrenia impacts all aspects of a patient's life and can have a negative impact on a patient's overall quality of life (QoL).[1,2]
- Treatment for schizophrenia includes oral antipsychotics (OAPs) that require daily dosage and can have challenges such as non-adherence to treatment.[3]
- Long-acting injectables (LAIs) with reduced dosing frequency and hence, better adherence to treatment can lead to improved treatment outcomes.[3]
- In resource-limited settings like Rwanda where standard-of-care for schizophrenia treatment is OAPs, there is an unmet need to introduce LAI antipsychotics as a treatment option for these patients.[4]
- Paliperidone palmitate (PP) available as 1-month (PP1M) and 3-month (PP3M) LAI formulations provides sustained therapeutic concentrations for longer duration improving treatment adherence along with reduced relapse rates and hospitalization.[5]

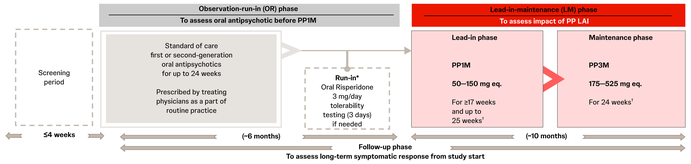
Objective

- **To evaluate the impact of PP1M and PP3M LAI treatment on QoL; patient and clinician satisfaction in patients with schizophrenia from Rwanda**

Methods

- In this open-label, interventional phase 4 study (NCT04940039), adults >18 to <35 years with current schizophrenia diagnosis requiring treatment initiation or change were enrolled.
- The study comprised of the following phases:
  - **Observation-run-in (OR) phase:** Patients received OAP treatment from Week (W)1 to W24
  - **Run-in:** Patients with no exposure to risperidone or paliperidone or PP previously, underwent oral tolerability (oral risperidone 3 mg/day, 3 days)
  - **Lead-in-maintenance (LM) phase:** Patients received LAI treatment from W25 to W66
    - Lead-in: Patients received PP1M for at least 17 weeks up to maximum of 25 weeks
    - Maintenance: Patients stable on PP1M entered the maintenance phase and received PP3M treatment (24 weeks)

FIGURE 1: Study design



*Plus 3 days run-in (as needed)
†PP3M treatment was started only after a stable dose for PP1M was identified, i.e., when the last 2 doses of PP1M administered at consecutive visits were the same. If a stable dose of PP1M was after 4 monthly injection cycles (approximately 17 weeks of Lead-in treatment), then PP1M continued up to 2 more cycles until a stable dose (with 2 successive equivalent doses) was identified.
LAI, Long-acting injectable; PP, Paliperidone palmitate; PP1M, Paliperidone palmitate 1-month; PP3M, Paliperidone palmitate 3-month.

Study endpoints:
This study included the QoL and patient and clinician satisfaction endpoints. Primary efficacy endpoints and safety are not presented here.

Endpoints

- **Mean change from baseline (CFB) in QoL:** measured using Schizophrenia Quality of Life Scale (SQLS R4)[6]
- **Patient and clinician satisfaction scores:**
  - Using a 6-point scale, ranges from 0 (very dissatisfied) to 5 (very satisfied)

Analysis sets

- **Mid-term intent-to-treat (mITT) analysis set:** Included all patients who received at least one dose of OAPs in the OR phase regardless of their compliance with the protocol
- **Intent-to-treat (ITT) analysis set:** Included all patients who received at least one dose of PP in LM phase regardless of their compliance with the protocol

Results

Baseline Characteristics

- Total 93 patients (81.7% were men) received OAPs in OR phase and 92 of them received PP1M and PP3M in LM phase. The mean (SD) time since schizophrenia diagnosis was 5.9 (4.66) years.

TABLE 1: Baseline characteristics (ITT analysis set)

Characteristic	N=92
Age at screening visit, years, mean (SD)	28.2 (4.48)
≥18–<24 years, n (%)	22 (23.9)
>24–<35 years, n (%)	70 (76.1)
Sex, n (%)	
Male / Female	75 (81.5) / 17 (18.5)
Time since schizophrenia diagnosis, years, mean (SD)	5.9 (4.67)
PP1M injection	
Treatment duration[a], days, mean (SD)	125.8 (22.18)
PP3M injection	
Treatment duration[b,c], days, mean (SD)	165.3 (17.58)

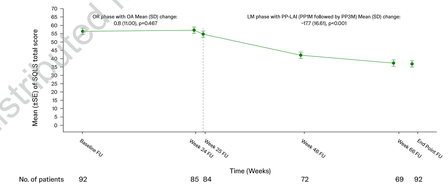
[a]Patients may appear in more than one category; [b]Total duration of exposure is defined as treatment disposition date or first PP3M date - first PP1M date + 1; [c]Based on 89 patients with 1 or more PP3M injection; [d]Total duration of exposure to PP3M is defined as treatment disposition date - first PP3M date + 1
ITT, Intent-to-treat; PP, Paliperidone palmitate; PP1M, Paliperidone palmitate 1-month; PP3M, Paliperidone palmitate 3-month; SD, Standard deviation.

Improvements in SQLS

SQLS

- The SQLS total score showed no CFB (W1) to end of run-in (W24) in OR phase; mean (SD) CFB was 0.8 (11.00), p=0.467.
- During LM phase, clinically meaningful and significant improvements were observed in SQLS total score from W25-W66 (mean [SD] CFB was –17.7 (16.61), p<0.001).

FIGURE 2: SQLS during OR and LM phase

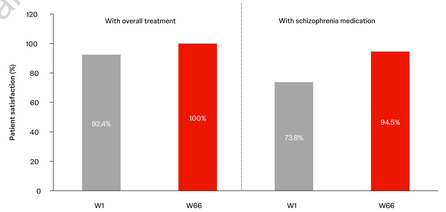


FU, Follow-up; LM, Lead-in-maintenance; OR, Observation-run-in; SD, Standard deviation; SE, Standard error; SQLS, Schizophrenia Quality of Life Scale.

Patient satisfaction

- Patient satisfaction (slight satisfied, satisfied and very satisfied) with overall treatment and with schizophrenia medications increased from OR phase (W1) to end of LM phase (W66).

FIGURE 3: Patient satisfaction, FU Phase (ITT analysis set)

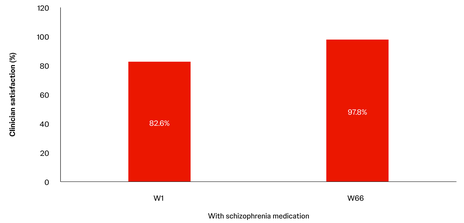


FU, follow-up; ITT, Intent-to-treat; W, Week.

Clinician satisfaction

- Similarly, clinician satisfaction (slight satisfied, satisfied and very satisfied) with schizophrenia medication increased from OR phase (W1) to end of LM phase (W66).

FIGURE 4: Clinician satisfaction, FU Phase (ITT analysis set)



FU, Follow-up; ITT, Intent-to-treat; W, Week.

Conclusion

- **Patients with schizophrenia in Rwanda treated with PP1M and PP3M long-acting injectable showed clinically meaningful and statistically significant improvements in QoL.**
- **The patient satisfaction with overall treatment and schizophrenia medications as well as clinician satisfaction with schizophrenia medications increased from OR phase to end of LM phase.**
- **Overall improvement in QoL and in patient and clinical satisfaction was observed after switch in treatment from oral antipsychotics to long-acting injectable PP1M/PP3M for management of schizophrenia in resource-limited setting of Rwanda.**

Acknowledgements

Kalpana Tilekar, PhD (SIRO Medical Writing Pvt. Ltd., India) and Jordy Mehawej, MD (Johnson & Johnson) provided editorial assistance. Layout design for this presentation was provided by Samita Warang (SIRO Medical Writing Pvt. Ltd., India), with funding from Johnson & Johnson.

Disclosures

Jordy Mehawej, José Antunes, Ibrahim Turkoz, Leslie Killion, R. Karl Knight: Are employees of Johnson & Johnson and may hold stocks in Johnson & Johnson. **Rutakayile Bizoza:** Coordinating investigator and Principal Investigator at Ndera Hospital Siter for Johnson & Johnson sponsored CASPAR Study. **Larry Alphs:** Was an employee of Johnson & Johnson currently consultant for Merck, Otsuka, NetraMark, Neymarker and Neushen.

Neuropsychiatry

Scan the QR code

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.
https://www.congresshub.com/Neuroscience/PsychCongress2025/PaliperidonePalmitate/Mehawej-Patient

Presented at: Psych Congress 2025; September 17–21, 2025; San Diego, CA, USA

REFERENCES:

1. Millier A, et al. *J Psychiatr Res.* Jul 2014;54:85–93. **2.** Bobes J, et al. *Dialogues Clin Neurosci.* 2007;9(2):215–26. **3.** Fagiolini, Andreaa, et al. *International Clinical Psychopharmacology.* Jan 2025; 10–1097. **4.** Rwanda standard treatment guidelines. 2022. URL: https://www.nrs.gov.rw/fileadmin/user_upload/nrs2024/Mental_Health_Standard_Treatment_guidelines.pdf. **5.** Spoelstra SK, et al. *Patient Prefer Adherence.* Mar 2022;16:615–624. **6.** Martin CR, et al. *Psychol Health Med.* 2007;12:126-134.

This material is distributed for scientific purposes on J&J Medical Connect, and is not for promotional use