In addition to improving clinical symptoms of schizophrenia, enhancing functioning is a key goal of antipsychotic therapy as this has a great impact on all areas of patient lives, including quality of life and independence and healthcare resource utilization (HRU).3–4

Paliperidone 3-month formulation (PP3M) was demonstrated favourable efficacy and safety in clinically stable patients during randomized controlled lab RCT.5–6

In one RCT, >90% of patients receiving PP3M achieved functional remission (defined as a score of 70 on the Personal and Social Performance Scale (PSP))

However, due to the nature of these RCTs, only selected patient populations were included and real-world data on functional outcomes are lacking.

Objectives

To conduct a real-world study to assess the impact of conversion from paliperidone palmitate 1-month formulation (PP1M) to PP3M in a diverse population of patients with clinically stable schizophrenia

The primary objective of this study was to assess symptomatic remission and secondary objectives included functionality, satisfaction with treatment and HRU.

This poster was first presented at the 31st Congress of the European College of Neuropsychopharmacology, 6–9 October 2018, Barcelona, Spain.

Study Design

This prospective observational Phase 3b, single-arm, non-randomized, open-label, 52-week study conducted in a diverse population of patients with schizophrenia seen in clinical practice (REMETA, Clinical Affiliation identifier: NCT02713328)

PP3M was administered from Day 1 to Day 385, with the last injection of PP3M at Month 9.

The initial dose of PP3M and subsequent dose changes (possible on clinician discretion) were made according to the product label.

Patients

Patients aged 18–50 years with confirmed schizophrenia (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition).

Adherence to PP3M with at least 3 months (the last two doses of PP3M being the same)

A baseline Positive and Negative Syndrome Scale (PANSS) total score >70

Assessments

Adherence to PP3M at 3-month intervals during the period.

A follow-up call for safety assessments was made at 3 months after Month 12 or study discontinuation.

Outcomes

Changes in PSP score, Subjective Wellbeing Under Neuroleptics (SWN-S) score, and healthcare resource utilization (HRU) from baseline to Month 12.

Results

Patient disposition

A total of 312 patients were screened at 57 study sites across Europe, Asia and the Middle East.

The mITT population comprised 304 patients; however, two patients withdrew at Month 3 without any post-baseline data.

The primary set for efficacy and safety analyses included 303 patients.

A total of 291 patients (96.4%) completed the 12-month study.

Demographics

Baseline characteristics are presented in Table 1.

Table 1. Baseline characteristics (modified ITT population).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Age, years</td>
<td>249 (82.9)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>127 (41.7)</td>
</tr>
<tr>
<td>Median</td>
<td>40 (IQR 30–50)</td>
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<tr>
<td>One-year rate, n (%)</td>
<td>236 (75.8)</td>
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<tr>
<td>Last PP3M dose category, n (%)</td>
<td>231 (76.2)</td>
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<tr>
<td>Therapy prior to PP1M switch, n (%)</td>
<td>205 (66.8)</td>
</tr>
<tr>
<td>Weight loss rate, n (%)</td>
<td>230 (75.1)</td>
</tr>
<tr>
<td>Duration of psychosis, n (%)</td>
<td>230 (75.1)</td>
</tr>
</tbody>
</table>

Notes:

1 Paired samples t-test was used to compare whether weight loss was significantly different between the baseline and LOCF endpoint.

2 A total of 291 patients (96.4%) completed the 12-month study.

3 The primary set for efficacy and safety analyses included 303 patients.

4 The number of patients who achieved all simultaneous (i.e., PP3M) endpoints is 267 (91.4%).

Healthcare resource utilization

At the end of the study, the mild and severe emergency department for psychiatric reasons were less frequent during the study treatment period compared with the already low incidences 12 months prior to baseline (Figure 4).

Figure 4. Healthcare resource utilization during the 12 months prior to study baseline and during the study treatment period.