Key Takeaways

- **JUNGLE** is a non-interventional, prospective, 3-year, multi-centre cohort study in people living with HIV (PLHIV) on suppressive antiretroviral therapy (ART) switched to co-formulated dolutegravir/rilpivirine (DTG/RPV) in accordance with the label in Germany.

- Discontinuations of DTG/RPV were mainly attributed to non-drug-related reasons consistent with a sustained and significant improvement in treatment satisfaction in PLHIV remaining on DTG/RPV for 3 years.

- In a real-world setting, DTG/RPV was effective in maintaining virologic suppression with no discontinuations for virologic reasons over 3 years.

**Introduction**

- Switching to DTG/RPV for maintenance of viral suppression is supported by large randomized clinical trials, retrospective cohorts and is a recommended switch strategy in European guidelines.

- The German JUNGLE cohort provides prospective real-world data, focusing on virologic effectiveness, tolerability, and patient-reported outcomes.

- Here we present the 3-year data.

**Methods**

- **JUNGLE** is a non-interventional, prospective, 3-year, multi-centre cohort study in people living with HIV (PLHIV) on suppressive antiretroviral therapy (ART) switched to co-formulated DTG/RPV in accordance with the label.

- **Main Inclusion Criteria**
  - Adult PLHIV on suppressive ART for 26 months switched to DTG/RPV
  - No history of virologic failure
  - No INSTI or NNRTI resistance mutations
  - No hepatitis B coinfection
  - No contraindication based on the summary of product characteristics (SmPC)

- **Main Exclusion Criteria**
  - Non virologic-related reasons consistent with a sustained and significant improvement in treatment satisfaction in PLHIV remaining on DTG/RPV for 3 years.

- **Outcomes**
  - Viral suppression at year 3 was defined as HIV RNA <50 c/mL in the window 33 to 39 months or 50 to 50 c/mL with subsequent HIV RNA <50 c/mL (discontinuation = failure; excluding missing data/loss to follow-up).
  - Virologic failure is not defined within this study, but investigators may discontinue a patient at any time for “virologic reasons” at their discretion.
  - Persistence on study and/or DTG/RPV was estimated using Kaplan-Meier analysis.
  - Adverse drug reactions (ADRs) were coded using the Medical Dictionary for Regulatory Activities (MedDRA) system.

- **Tolerability**
  - Until data cut, 32 ADR events have been reported, yielding 37 ADRs using MedDRA coded terms (grades 1-2: n=16, grade 3: n=1). Grade 4 or higher ADRs included 3 grade 5 (n=1).
  - No serious ADRs were reported.

**Results**

- **Study Population**
  - 200 PLHIV were enrolled across 24 study centres in the JUNGLE cohort.
  - At data cut (April 2022), 176 participants were eligible for analysis (n=24 excluded due to missing follow-up data/year 3 visit window not yet reached).

- **Baseline Characteristics**
  - Table 1 shows baseline characteristics (Table 1).

- **Table 1. Baseline Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Median (IQR), mean [±]</td>
<td>45 (30–57)</td>
</tr>
<tr>
<td>Age ≥50 years, n (%)</td>
<td>82 (47)</td>
<td>176</td>
</tr>
<tr>
<td>BMI, median (IQR), kg/m²</td>
<td>24 (22–27)</td>
<td>149</td>
</tr>
<tr>
<td>Hyper tension, n (%)</td>
<td>55 (31)</td>
<td>176</td>
</tr>
<tr>
<td>Depression, n (%)</td>
<td>32 (18)</td>
<td>176</td>
</tr>
<tr>
<td>Lipid disorders, n (%)</td>
<td>29 (16)</td>
<td>176</td>
</tr>
<tr>
<td>Insomnia, n (%)</td>
<td>25 (14)</td>
<td>176</td>
</tr>
<tr>
<td>Chronic kidney disease, n (%)</td>
<td>23 (13)</td>
<td>176</td>
</tr>
</tbody>
</table>

- **ART Before Switch to DTG/RPV**
  - The median duration of the three ART regimens before DTG/RPV was 2.6 years (interquartile range [IQR]: 1.6–4.9 [n=165]).
  - Of 176 participants, 11% switched from first-line ART; 41% had a history of ≥3 treatment switches (Table 2A).
  - 88% of participants were switched from triple ART; 48% had been on a multi-drug regimen.

- **Table 2. (A) Treatment Switches Before DTG/RPV and (B) Last ART Before DTG/RPV (n=185)**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n (%)</th>
<th>(N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-line ART</td>
<td>11 (11)</td>
<td>100</td>
</tr>
<tr>
<td>1-2 switches</td>
<td>75 (43)</td>
<td>176</td>
</tr>
<tr>
<td>≥3 switches</td>
<td>73 (41)</td>
<td>176</td>
</tr>
<tr>
<td>Unknown</td>
<td>9 (5)</td>
<td>176</td>
</tr>
</tbody>
</table>

- **Reasons for Switching to DTG/RPV**
  - Primary reasons for switching to DTG/RPV were ‘side effects of previous ART’ (24%), ‘switch to a single-tablet regimen’ (24%), and ‘reduction in number of drugs’ (19%).
  - Persistence on study and/or DTG/RPV and discontinuation rates are shown in Table 3.

- **Figure 1. Persistence on Study and/or DTG/RPV (Kaplan-Meier Analysis)**

- **Prevalence of participants still on study and/or DTG/RPV and discontinuation rates are shown in Table 3.

- **Figure 2. Virologic Outcomes at Year 3**

- **Figure 3. Treatment Satisfaction (HIV-TSQs) and HIV Symptom Distress Module (HIV-SDM) in PLHIV Completing Questionnaires at Baseline and Year 3**

**Conclusions**

- In the prospective real-world setting of the JUNGLE cohort, DTG/RPV maintained viral suppression over 3 years with no discontinuations for virologic reasons.

- Discontinuations of DTG/RPV were mainly attributed to non-drug-related reasons consistent with a sustained and significant improvement in treatment satisfaction in PLHIV remaining on DTG/RPV for 3 years.

**Acknowledgements**

- Special thanks to the participants and investigators of the JUNGLE study cohort.

**References**