Assessment of the Acceptability and Swallowability of Darunavir-containing Fixed-dose Combination (FDC) Tablets in Adolescents Living with HIV-1, Using Matched Placebo Tablets

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INTRODUCTION
• Based on difference (90% CI) with reference or coadministration (COAB), has demonstrated high, durable virologic response, a high genetic barrier to resistance, and long-term safety in a broad range of patients,1,2 and is included in international HIV treatment guidelines.3–9
• DRV/COBI 50 mg/kg once daily, as a fixed-dose combination (FDC) tablet, combined with other antiretroviral therapy (ART) and the darunavir/coadministration/tenofovir alafenamide (DRV/COBI/TAF) fixed-dose combination (FDC) tablet in single and multiple tablet regimens (STR) are approved in the EU, US and Canada for adults living with HIV-1.

METHODS
Study Design
• TMC114FD2HTX1003 (NCT02993237): a Phase I, open-label, randomised, single-dose, 2x2 crossover study in adolescents living with HIV-1 aged ≥12–<18 years and weighing ≥40 kg. All participants were virologically suppressed on a stable ART regimen for 12 months.
• The study was performed using only matched placebo tablets as far as not to interfere with the participant’s active ART.
• Written informed consent was obtained from all participants/legal guardian before any study-related procedure. The study was performed in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki.

Patient Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Overall</th>
<th>(12–&lt;15) years</th>
<th>(≥15) years</th>
<th>(≥18) years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median, (\pm) IQR</td>
<td>14 (11–15)</td>
<td>14 (11–15)</td>
<td>14 (11–15)</td>
<td>14 (11–15)</td>
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<tr>
<td>Weight (kg), median, (\pm) IQR</td>
<td>58 (50–68)</td>
<td>55 (45–70)</td>
<td>66 (60–80)</td>
<td>66 (60–80)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), median, (\pm) IQR</td>
<td>21.1 (15.3–50.7)</td>
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<td>21.1 (15.3–50.7)</td>
<td>21.1 (15.3–50.7)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>14 (52)</td>
<td>12 (86)</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hispanic or Latino, n (%)</td>
<td>4 (15)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (15)</td>
</tr>
<tr>
<td>Not Hispanic or Latino, n (%)</td>
<td>23 (85)</td>
<td>13 (94)</td>
<td>9 (62)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>17 (63)</td>
<td>11 (81)</td>
<td>4 (26)</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Black or African American, n (%)</td>
<td>1 (4)</td>
<td>1 (8)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Asian, n (%)</td>
<td>4 (15)</td>
<td>3 (23)</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Current ART, n (%)</td>
<td>FDC</td>
<td>21 (78)</td>
<td>19 (136)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>FDC and single-tablet ARTs</td>
<td>6 (22)</td>
<td>0 (0)</td>
<td>4 (26)</td>
<td>2 (15)</td>
</tr>
</tbody>
</table>

RESULTS

Safety
• No adverse events were reported during this study.

CONCLUSION
• Both the DRV/COBI and the DRV/COBI FDC tablets are suitable to be administered to adolescents. Both tablets were considered to be acceptable for use over a longer period of time by almost all of the adolescent patients participating in this study.

REFERENCES

ACCOMMODATIONS AND ACKNOWLEDGMENTS
We thank the participants of this study, the Janssen study team and the site staff. The authors would also like to thank other Janssen staff members for their important contributions to the data collection and any presentation, in particular Paul Orkin for his review and input into the abstract.
All authors are full-time employees of Janssen and potential stockholders of Johnson & Johnson.

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Presented at the HIV Glasgow Drug Therapy Meeting, Glasgow, UK, 28–30 October 2018.