**Effect of Dose Modifications on Response to Duvelisib in Patients With Relapsed/Refractory CLL/SLL in the DUO Trial**

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**Results**

**Exposure and AEIS**

- Among 158 DUV-treated patients, the median duration of DUV exposure was 11.6 months (range, 0.2-36.8 months).
- The median overall DUV dose intensity (total dose taken/total expected dose) was 300 mg/m² (range, 24-1573).
- DUV dose intensity was highest during the first 3 months and then decreased slightly during months 3-6 (first 3 months, 102 [range, 65-102]) and months 7-12 (30 [range, 3-105]).
- Median time to onset across AEs after starting DUV ranged from 2.2-4.3 months (Figure 4). The median time to onset for DI was 4 months (range, 10 days to 18 months).

**TeAEs**

- AEs of special interest (AESIs) were defined as groupings of infections, diarrhea, colitis, neutropenia, cutaneous reactions, anemia, and transaminase elevation.

**Response**

- The median duration of DUV treatment was 22.1 months (range, 15.1-28.3 months). The mPFS for DUV was 17.8 months (range, 16.3-24.3 months).

**Impact of DI and DR on PFS**

- Of the 43 patients with DIs, 13 of 25 patients who had a DR after the first CR had a median mPFS of 7 months (range, 0.2-36.8 months).

**References**


**Table 3. AEIS Resulting in DI or DR**

<table>
<thead>
<tr>
<th>DI</th>
<th>DR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duvamycin</td>
<td>4 (32)</td>
</tr>
<tr>
<td>Colitis</td>
<td>4 (32)</td>
</tr>
<tr>
<td>Infections</td>
<td>10 (8)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>6 (4)</td>
</tr>
<tr>
<td>Cutaneous reactions</td>
<td>13 (10)</td>
</tr>
<tr>
<td>Hepatotoxicity (transaminase elevation)</td>
<td>9 (7)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>8 (6)</td>
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<tr>
<td>MedDRA ontology term</td>
<td>13 (10)</td>
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</tbody>
</table>

**Figure 4. Rates of First AESI After DUV**

- No DIs > 1 week.
- DR typically coincided with time to onset of AESI.
- DI typically coincided with time to onset of AESI.
- Among DUV-treated patients, DI occurred more frequently than DR (80% vs 27%).
- Patients with DI or DR had ≥ 1 DI or DR, respectively.
- 13% of patients who had a DI before CR had a median mPFS of 7 months (range, 0.2-36.8 months).

**Conclusion**

- Duvamycin is a new, oral treatment option for patients with R/R CLL/SLL that has the potential for durable responses and good tolerability over time.
- Response to DUV was rapid, occurring prior to first DI or DR in most patients.

- DUV was associated with a high rate of discontinuation due to adverse drug reactions (52% for DI and 30% for DR).