### Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time

**FID-MC-HGJ Acute Phase**

<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>Olz(1) (Total=1336)</th>
<th>Hal(2) (Total=660)</th>
<th>--- p-Value #1 ---</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n (%)</td>
<td>N</td>
</tr>
<tr>
<td>Lab Test: <strong>HEMATOCRIT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1288</td>
<td>37 (2.9)</td>
<td>621</td>
</tr>
<tr>
<td>HIGH</td>
<td>1276</td>
<td>23 (1.8)</td>
<td>617</td>
</tr>
<tr>
<td>Lab Test: <strong>HEMOGLOBIN</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1286</td>
<td>22 (1.7)</td>
<td>629</td>
</tr>
<tr>
<td>HIGH</td>
<td>1281</td>
<td>12 (0.9)</td>
<td>617</td>
</tr>
<tr>
<td>Lab Test: <strong>ERYTHROCYTE COUNT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1292</td>
<td>33 (2.6)</td>
<td>628</td>
</tr>
<tr>
<td>HIGH</td>
<td>1295</td>
<td>6 (0.5)</td>
<td>625</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges

Reporting SI Units

Patients with Baseline Abnormality are Excluded

RNP.F1DPR.JCLLIB(SSAFE6J)

RNP.F1DPR.SASMCEQ(SSAFE6)

* Frequencies are analyzed using a Chi-Square test.

Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.

N = Total number of at risk patients with the lab test.

n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
<table>
<thead>
<tr>
<th>Lab Test: MEAN CELL HEMOGLOBIN CONCENTRATION (MCHC)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
</tr>
<tr>
<td>1271</td>
<td>610</td>
</tr>
<tr>
<td>1273</td>
<td>619</td>
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</table>

<table>
<thead>
<tr>
<th>Lab Test: MEAN CELL HEMOGLOBIN (MCH)</th>
<th></th>
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<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
</tr>
<tr>
<td>1288</td>
<td>626</td>
</tr>
<tr>
<td>1277</td>
<td>628</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Test: LEUCOCYTE COUNT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>HIGH</td>
</tr>
<tr>
<td>1293</td>
<td>594</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RMP.F1DP.JCLLIBI(SSAFE6J)
RMP.F1DP.SASMACRO(SSAFE6G)
* Frequencies are analyzed using a Chi-Square test.
Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at risk patients with the lab test.
n = Total number of at risk patients with the specific lab result (e.g. HIGH).
<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>Olz(1) (Total=1536)</th>
<th>Hal(2) (Total=660)</th>
<th>--- p-Value #1 ---</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n</td>
<td>(%)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1301</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Lab Test: BANDS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1207</td>
<td>29</td>
<td>2.3</td>
</tr>
<tr>
<td>HIGH</td>
<td>1206</td>
<td>101</td>
<td>8.4</td>
</tr>
<tr>
<td>Lab Test: NEUTROPHILS, SEGMENTED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1273</td>
<td>31</td>
<td>2.4</td>
</tr>
<tr>
<td>HIGH</td>
<td>1285</td>
<td>25</td>
<td>1.9</td>
</tr>
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</table>

Using Lilly Reference Ranges

Reporting SI Units

Patients with Baseline Abnormality are Excluded
RMP.F1DP.JC8LIBISSAFE6j
RMP.F1DP.SASMACHISSAFE6j

* Frequencies are analyzed using a Chi-Square test.

Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at risk patients with the lab test.
n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
## Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time

**F10-MC-HSAJ Acute Phase**

### Incidence

<table>
<thead>
<tr>
<th>Group</th>
<th>Olz(1) (Total=1336)</th>
<th>Hal(2) (Total=660)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n (%)</td>
<td>N</td>
</tr>
<tr>
<td>HIGH</td>
<td>1203</td>
<td>103 (8.6)</td>
<td>587</td>
</tr>
<tr>
<td>LOW</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Lab Test: MONOCYTES

- **HIGH**: 1203, 103 (8.6%)
- **LOW**:
- **OTHER**:

### Lab Test: EOSINOPHILS

- **HIGH**: 1272, 62 (4.9%)
- **LOW**:
- **OTHER**:

### Lab Test: BASOPHILS

- **HIGH**: 1286, 35 (2.7%)
- **LOW**:
- **OTHER**:

--- **p-Value = 1** ---

### Using Lilly Reference Ranges

- Reporting SI Units
- Patients with Baseline Abnormality are Excluded
- RMP.F10P.JCLLIB(SSsafe6)
- RMP.F10P.SASMCRS(SSsafe6)

* Frequencies are analyzed using a Chi-Square test.

**Note:**
- Total = Total number of patients in the treatment group having both baseline and endpoint visits.
- N = Total number of at risk patients with the lab test.
- n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
<table>
<thead>
<tr>
<th>Lab Test: MEAN CELL VOLUME (MCV)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1274</td>
<td>5 (0.2)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1274</td>
<td>31 (2.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Test: PLATELET COUNT</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1293</td>
<td>12 (0.9)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1271</td>
<td>23 (1.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Test: LYMPHOCYTES, ATYPICAL</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>1300</td>
<td>1 (0.1)</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RMP.F1DP.JICLLEB(SSAFE6J)
RMP.F1DP.SASMACRO(SSAFE6J)
* Frequencies are analyzed using a Chi-Square test.
Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at risk patients with the lab test.
n = Total number of at risk patients with the specific lab result (e.g. HIGH).
### Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time

**F10-NC-HEAJ Acute Phase**

**Incidence**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>n</th>
<th>(%)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1336</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Olg(1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1199</td>
<td>120</td>
<td>10.0</td>
<td>.906</td>
</tr>
<tr>
<td>HIGH</td>
<td>1292</td>
<td>4</td>
<td>0.3</td>
<td>.564</td>
</tr>
</tbody>
</table>

**Hal(2)**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>n</th>
<th>(%)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>660</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Olg(1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>506</td>
<td>62</td>
<td>10.6</td>
<td></td>
</tr>
<tr>
<td>HIGH</td>
<td>628</td>
<td>1</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

--- p-Value = 1 ---

**Lab Test: UA-SPECIFIC GRAVITY**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>n</th>
<th>(%)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1199</td>
<td>120</td>
<td>10.0</td>
<td>.906</td>
</tr>
<tr>
<td>HIGH</td>
<td>1292</td>
<td>4</td>
<td>0.3</td>
<td>.564</td>
</tr>
</tbody>
</table>

**Lab Test: UA-PH**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>n</th>
<th>(%)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>1290</td>
<td>3</td>
<td>0.2</td>
<td>.226</td>
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</tbody>
</table>

**Lab Test: AST/SGOT**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>n</th>
<th>(%)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1283</td>
<td>25</td>
<td>1.9</td>
<td>.286</td>
</tr>
<tr>
<td>HIGH</td>
<td>1299</td>
<td>57</td>
<td>4.4</td>
<td>.001</td>
</tr>
</tbody>
</table>

--- p-Value = 1 ---

**Using Lilly Reference Ranges**

**Reporting SI Units**

**Patients with Baseline Abnormality are Excluded**

RMP.F10P.JCLLIB(SSSAFE6J)

Frequencies are analyzed using a Chi-Square test.

**Note:** Total = Total number of patients in the treatment group having both baseline and endpoint visits.

N = Total number of at risk patients with the lab test.

n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLSAS0004
<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>O1 (1) (Total=1336)</th>
<th>O2 (2) (Total=660)</th>
<th>--- p-Value #1 ---</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Test: ALT/SGPT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1281 13 (1.0)</td>
<td>630 9 (1.4)</td>
<td>.425</td>
</tr>
<tr>
<td>HIGH</td>
<td>1289 102 (7.9)</td>
<td>629 7 (1.1)</td>
<td>.000</td>
</tr>
<tr>
<td>Lab Test: CREATINE PHOSPHOKINASE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1295 2 (0.2)</td>
<td>654 2 (0.3)</td>
<td>.465</td>
</tr>
<tr>
<td>HIGH</td>
<td>1244 87 (7.0)</td>
<td>603 33 (5.5)</td>
<td>.214</td>
</tr>
<tr>
<td>Lab Test: ALKALINE PHOSPHATASE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1291 4 (0.3)</td>
<td>634 5 (0.8)</td>
<td>.148</td>
</tr>
<tr>
<td>HIGH</td>
<td>1287 15 (1.2)</td>
<td>630 2 (0.3)</td>
<td>.063</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RHP.FIDP.JCELLIB(SSFAC6J)
RHP.FIDP.SAMMACR(SSFAC6J)
* Frequencies are analyzed using a Chi-Square test.
Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at risk patients with the lab test.
n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>Olz(1) (Total=1336)</th>
<th>Hal(2) (Total=660)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Lab Test: GGT(GPL/SGPT/ALT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1294</td>
<td>3</td>
<td>(0.2)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1292</td>
<td>15</td>
<td>(1.2)</td>
</tr>
<tr>
<td>Lab Test: UREA NITROGEN</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1201</td>
<td>115</td>
<td>(9.6)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1291</td>
<td>16</td>
<td>(1.2)</td>
</tr>
<tr>
<td>Lab Test: CREATININE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1296</td>
<td>7</td>
<td>(0.5)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1285</td>
<td>14</td>
<td>(1.1)</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RMP.F1DP.JCLLIB1SSAF60
RMP.F1DP.SASMACROSSAF6E6
* Frequencies are analyzed using a Chi-Square test.
Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at-risk patients with the lab test.
n = Total number of at-risk patients with the specific lab result (e.g. HIGH).

XLAS00004
### PRODUCTION DATA - PRODUCTION MODE

Appendix HGAJ.7.207.01
Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time
FID-MC-HGAJ Acute Phase

<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>G1 N</th>
<th>N (%)</th>
<th>G2 N</th>
<th>n (%)</th>
<th>Overall</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lab Test:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CALCIUM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1283</td>
<td>43 (3.4)</td>
<td>629</td>
<td>13 (2.1)</td>
<td></td>
<td>.117</td>
</tr>
<tr>
<td>HIGH</td>
<td>1290</td>
<td>6 (0.5)</td>
<td>634</td>
<td>4 (0.6)</td>
<td></td>
<td>.635</td>
</tr>
<tr>
<td><strong>PHOSPHORUS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1267</td>
<td>46 (3.6)</td>
<td>619</td>
<td>10 (1.6)</td>
<td></td>
<td>.015</td>
</tr>
<tr>
<td>HIGH</td>
<td>1269</td>
<td>64 (5.0)</td>
<td>626</td>
<td>19 (3.0)</td>
<td></td>
<td>.046</td>
</tr>
<tr>
<td><strong>SODIUM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1237</td>
<td>73 (5.9)</td>
<td>588</td>
<td>41 (7.0)</td>
<td></td>
<td>.377</td>
</tr>
<tr>
<td>HIGH</td>
<td>1294</td>
<td>7 (0.5)</td>
<td>629</td>
<td>2 (0.3)</td>
<td></td>
<td>.501</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RMP.FIDP.JOLLIB(SSFEE6J)
RMP.PIDP.SASMACRJ(SSFEE6J)
* Frequencies are analyzed using a Chi-Square test.
Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
N = Total number of at risk patients with the lab test.
n = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
PRODUCTION DATA - PRODUCTION MODE

Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time
FID-MC-HGAM Acute Phase

<table>
<thead>
<tr>
<th>Incidence</th>
<th>( 0.1 \times 1 )</th>
<th>( 1.0 \times 1 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>( N )</td>
<td>( n )</td>
</tr>
<tr>
<td>LOW</td>
<td>1289</td>
<td>20 (1.6)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1287</td>
<td>14 (1.1)</td>
</tr>
</tbody>
</table>

Lab Test: POTASSIUM

<table>
<thead>
<tr>
<th>Incidence</th>
<th>( 0.1 \times 1 )</th>
<th>( 1.0 \times 1 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>( N )</td>
<td>( n )</td>
</tr>
<tr>
<td>LOW</td>
<td>1268</td>
<td>30 (2.4)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1288</td>
<td>29 (2.3)</td>
</tr>
</tbody>
</table>

Lab Test: CHLORIDE

<table>
<thead>
<tr>
<th>Incidence</th>
<th>( 0.1 \times 1 )</th>
<th>( 1.0 \times 1 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>( N )</td>
<td>( n )</td>
</tr>
<tr>
<td>LOW</td>
<td>1283</td>
<td>42 (3.3)</td>
</tr>
<tr>
<td>HIGH</td>
<td>1269</td>
<td>17 (1.3)</td>
</tr>
</tbody>
</table>

Using Lilly Reference Ranges
Reporting SI Units
Patients with Baseline Abnormality are Excluded
RMP.FIDP.JDL8N(SSAFE6J)
RMP.FIDP.SASMACRO(SSAFE6)
* Frequencies are analyzed using a Chi-Square test.
  Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.
  \( N \) = Total number of at risk patients with the lab test.
  \( n \) = Total number of at risk patients with the specific lab result (e.g. HIGH).

XLAS0004
### PRODUCTION DATA - PRODUCTION MODE

**Appendix HGAJ.7.207.01**

Treatment-Emergent Abnormal, High, or Low Laboratory Values at Any Time

FID-MC-HGAJ Acute Phase

<table>
<thead>
<tr>
<th>Incidence Group</th>
<th>Olz(1)</th>
<th>Hal(2)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n (%)</td>
<td>N</td>
</tr>
<tr>
<td><strong>Lab Test: ALBUMIN</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td>1275</td>
<td>80 (6.3)</td>
<td>624</td>
</tr>
<tr>
<td>HIGH</td>
<td>1291</td>
<td>3 (0.2)</td>
<td>629</td>
</tr>
</tbody>
</table>

| **Lab Test: GLUCOSE, NON-FASTING** |       |        |         |        |                   |
| LOW              | 1251  | 96 (7.7) | 611     | 38 (6.2) | .254 |
| HIGH             | 1294  | 34 (2.6)  | 625     | 7 (1.1)  | .031 |

| **Lab Test: URIC ACID** |       |        |         |        |                   |
| LOW              | 1292  | 4 (0.3)  | 626     | 9 (1.4)  | .005 |
| HIGH             | 1285  | 24 (1.9) | 627     | 9 (1.4)  | .496 |

Using Lilly Reference Ranges

Reporting SI Units

Patients with Baseline Abnormality are Excluded

RMP.F1DP.JOLLIB(SSAFE6J)

RMP.F1DP.SASMACRO(SSAFE6J)

* Frequencies are analyzed using a Chi-Square test.

Note: Total = Total number of patients in the treatment group having both baseline and endpoint visits.

N = Total number of at risk patients with the lab test.

n = Total number of at risk patients with the specific lab result (e.g. HIGH).