Figure 2: Sustained BTK Inhibition in Peripheral Blood and Lymph Nodes

ALPINE KEY ELIGIBILITY CRITERIA

- **Key Inclusion Criteria**
  - CLL or SLL by iwCLL criteria requiring treatment
  - R-R to prior systemic therapy for CLL/SLL
  - Measurable lymphadenopathy by CT or MRI
  - Age ≥18 years
  - ECOG PS 0-2
  - Adequate BM function
  - Adequate organ function

- **Key Exclusion Criteria**
  - Known prolymphocytic leukemia
  - Current or past BTK inhibitor treatment
  - History of severe bleeding
  - Prior treatment with a BTK inhibitor
  - Known infection with HIV
  - Active HBV or HCV

**Table 1. Preliminary Efficacy of Zanubrutinib in CLL/SLL Patients From Phase 1b Study BGB-3111-AU-003 (NCT02343210)**

<table>
<thead>
<tr>
<th>Response</th>
<th>Treatment Naive (n=27)</th>
<th>Relapsed/Refractory (n=15)</th>
<th>Total (N=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up, median (range), mo</td>
<td>76 (37-116)</td>
<td>14.0 (2.2-2.68)</td>
<td>10.5 (2.2-2.68)</td>
</tr>
<tr>
<td>Best response</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORR</td>
<td>16 (100)</td>
<td>46 (92)</td>
<td>62 (94)</td>
</tr>
<tr>
<td>CR</td>
<td>1 (6)</td>
<td>1 (2)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>PR</td>
<td>13 (81)</td>
<td>41 (82)</td>
<td>54 (82)</td>
</tr>
<tr>
<td>PR-L</td>
<td>2 (13)</td>
<td>4 (8)</td>
<td>6 (9)</td>
</tr>
<tr>
<td>SD</td>
<td>0</td>
<td>3 (6)</td>
<td>3 (6)</td>
</tr>
<tr>
<td>PD</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>D/C before assessment</td>
<td>0</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

**Figure 3. ALPINE Study Design**

- **Primary objective of study is to compare efficacy of zanubrutinib versus ibritinib in ORR (PR or higher)**
- **Key Inclusion Criteria**
  - CLL or SLL by iwCLL criteria requiring treatment
  - R-R to prior systemic therapy for CLL/SLL
  - Measurable lymphadenopathy by CT or MRI
  - Age ≥18 years
  - ECOG PS 0-2
  - Adequate BM function
  - Adequate organ function

**ALPINE STUDY END POINTS**

- **PRIMARY**
  - ORR by independent review committee (IRC) per 2008 International Workshop on CLL (iwCLL) criteria with zanubrutinib
  - Progression-free survival (PFS) by IRC and investigator assessment (INV)
  - Duration of response by IRC and INV
  - Time to treatment failure
  - Rate of partial response by IRC and INV

- **SECONDARY**
  - Overall survival
  - European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLC-C30) and EuroQol 5-Dimension 5-level version (EQ-5D-5L) scores
  - Safety

**ALPINE STUDY STATUS**

- This study opened to accrual in November 2018 and will be recruiting patients from sites in 15 countries

**United States**

**Australia and New Zealand**

**Europe**

**China**

**Acknowledgments**

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