Results

- There were no DLTs, and the TGR1202 recommended phase 2 dose (RP2D) for both CLL and MCL is 800 mg daily

<table>
<thead>
<tr>
<th>Patient Characteristics (n=27)</th>
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<tbody>
<tr>
<td><strong>Histology</strong></td>
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<tr>
<td>Median age at enrollment</td>
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<tr>
<td>Median # prior therapies</td>
</tr>
<tr>
<td>Median age at diagnosis</td>
</tr>
</tbody>
</table>

**CLL (n=17)**

- **Hematologic toxicity:**
  - Neutropenia (30%, 10% Gr 3-4)
  - Thrombocytopenia (24%, all Gr 1)
  - Anemia (35%, all Gr 1/2)

- **All grade non-hematologic toxicities:**
  - Diarrhea (41%, 35% Gr 1, 6% Gr 2)
  - Nausea (35%, all Gr 1)

- **SAEs:** None led to discontinuation

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<th>MCL (n=10)</th>
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| **Hematologic toxicity:**
  - Neutropenia (30%, 10% Gr 3-4)
  - Thrombocytopenia (40%, 10% Gr 3)
  - Anemia (30%, 10% Gr 1/2)

- **All grade non-hematologic toxicities:**
  - Diarrhea (60%, 50% Gr 1, 10% Gr 2)
  - Fatigue (50%, all Gr 1/2)
  - Neutropenia (30%, all Gr 1/2)
  - CNS infection, dizziness, hypocalcemia (30% each, all Gr 1)

- **SAEs:** None led to discontinuation

**Efficacy Analysis (n=21)**

- **Best %decrease in disease burden:**
  - CR (BM MRD+): 75%

- **Response evaluations:**
  - after cycles 2, 5, 8, 12, and q6 mo. thereafter

**Conclusions**

- The toxicities of TGR1202 + ibrutinib are manageable and comparable to the additive toxicity profiles of the two agents given individually
- The preliminary efficacy results suggest a high response rate in both diseases, with a CLL patient achieving CR at 1 yr and several others approaching CR radiographically
- Acral continues to this ongoing study

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Corresponding Author: Matthew_Davids@dfci.harvard.edu

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