Here we present results from CLL patients enrolled in an ongoing Phase 1 study of TG-1701 alone and in combination with Ublituximab and Umbralisib (U2) inhibited tumor growth in BTK-resistant cell lines.

**Patient Disposition - CLL**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose-Escalation Phase</th>
<th>Dose-Expansion Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td>TG-1701</td>
<td>100 – 400 mg</td>
<td>100 – 300 mg – 900 mg</td>
</tr>
<tr>
<td>TG-1701 + U2</td>
<td>100 – 300 mg</td>
<td>100 – 300 mg – 900 mg</td>
</tr>
</tbody>
</table>

**Patient Demographics and Disease Characteristics – CLL Patients**

- **Sex**: Male (50), Female (50)
- **Age**: Median age 65 years
- **ECOG**: 0 (10), 1 (40), 2 (50)
- **Pts discontinued treatment, N(%)**: 1 (5)
- **Dose reduction (any agent), N(%)**: 2 (10), 4 (20)
- **Dose discontinued treatment, N(%)**: 1 (5)
- **Reason for treatment discontinuation, N(%)**: Progression by IWCLL criteria (30), Other (20)

**Efficacy**

- **ORR – Monotherapy**: 100% (19/19)
- **SD**: 1 (5)
- **PR**: 83% (5/6)
- **CR**: 100% (3/3)

**Safety**

- **Toxicity**: Common AE (50%) includes anemia, neutropenia, contusion, hypertension, atrial fibrillation, and other
- **Median follow up**: 100 – 125 months

**Results**

- **Median follow up**: 200 – 250 months
- **Median follow up**: 300 – 350 months
- **Median follow up**: 400 – 450 months

**Conclusion**

- **TG-1701 exhibits an encouraging safety and efficacy profile in patients with CLL**
- **TG-1701 shows promising activity and a manageable tolerability profile as monotherapy and in combination with U2**
- **The MTD has not been achieved in the monotherapy arm (up to 400 mg QD)**
- **The study is on-going and continuous enrollment and future registration trials are being planned**

**Acknowledgements**

- Thank you to the patients and their families for their participation.

**For questions:** Chen.Cha@health.msw.edu.au

**REFERENCES**

- **Background and Methods**
  - Deep remissions with BTK monotherapy in CLL are rare
  - The triple combination of TG-1701 with umbralisib and umbralisib (U2) inhibited tumor growth in BTK-resistant xenograft models

**Patient Disposition - CLL**

- **Sex**: Male (50), Female (50)
- **Age**: Median age 65 years
- **ECOG**: 0 (10), 1 (40), 2 (50)
- **Pts discontinued treatment, N(%)**: 1 (5)
- **Dose reduction (any agent), N(%)**: 2 (10), 4 (20)
- **Dose discontinued treatment, N(%)**: 1 (5)
- **Reason for treatment discontinuation, N(%)**: Progression by IWCLL criteria (30), Other (20)

**Efficacy**

- **ORR – Monotherapy**: 100% (19/19)
- **SD**: 1 (5)
- **PR**: 83% (5/6)
- **CR**: 100% (3/3)

**Safety**

- **Toxicity**: Common AE (50%) includes anemia, neutropenia, contusion, hypertension, atrial fibrillation, and other
- **Median follow up**: 100 – 125 months
- **Median follow up**: 200 – 250 months
- **Median follow up**: 300 – 350 months
- **Median follow up**: 400 – 450 months

**Conclusion**

- **TG-1701 exhibits an encouraging safety and efficacy profile in patients with CLL**
- **TG-1701 shows promising activity and a manageable tolerability profile as monotherapy and in combination with U2**
- **The MTD has not been achieved in the monotherapy arm (up to 400 mg QD)**
- **The study is on-going and continuous enrollment and future registration trials are being planned**

**Acknowledgements**

- Thank you to the patients and their families for their participation.

**For questions:** Chen.Cha@health.msw.edu.au

**REFERENCES**