**INTRODUCTION**

Mechanism of BI 754091 Activity

- **Tumors may achieve immune evasion by expressing PD ligand (PD-L1) to bind to PD-1 expressed on activated T-cells, resulting in the absence of effector T-cell responses within the microenvironment.**
- **Pharmacokinetic and target activity can be restored when this interaction is blocked by therapeutic PD-1 or PD-L1 inhibition.**
- **BI 754091 is a monoclonal IgG4-Pro antibody that restores PD-1 ligand (PD-L1) target activity in vivo.**
- Here we present the preliminary results of the Phase I study evaluating BI 754091 in patients with advanced solid tumors.

**KEY ELIGIBILITY**

- **Inclusion Criteria**: Advanced, metastatic, or solid metastatic tumors
- **Eligibility**: Any tumor type
- **Exclusion**: PD-1+ non-small cell lung cancer (NSCLC), bladder cancer, prostate cancer, triple-negative breast cancer (TNBC), and renal cell carcinoma (RCC)
- **Dose escalation according to RECIST 1.1 and IRRECIST**
- **Exhausted standard treatment options**

**STUDY DESIGN**

- **Cycle 1 (N=3)**: 240 mg or 400 mg BI 754091 to cancer patients (linear scale).
- **Source data**: Study No. 1381.1, exploratory PK results

**PHARMACOKINETICS**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cohort 1 (N=3)</th>
<th>Cohort 2 (N=3)</th>
<th>Cohort 3 (N=3)</th>
<th>Expansion (N=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nadir</strong></td>
<td>4460000 (28.0)</td>
<td>3880000 (28.0)</td>
<td>2730000 (28.0)</td>
<td>3210000 (27.1)</td>
</tr>
<tr>
<td><strong>Max</strong></td>
<td>1430000 (19.6)</td>
<td>597000 (16.6)</td>
<td>307 (8.60)</td>
<td>3210000 (27.1)</td>
</tr>
<tr>
<td><strong>AUC</strong></td>
<td>3400000 (34.4)</td>
<td>473000 (34.4)</td>
<td>361 (37.7)</td>
<td>3905000 (31.8)</td>
</tr>
<tr>
<td><strong>Cmax</strong></td>
<td>250000 (37.7)</td>
<td>737000 (9.80)</td>
<td>737000 (9.80)</td>
<td>13600000 (27.1)</td>
</tr>
<tr>
<td><strong>t1/2</strong></td>
<td>3.52 (1.50-4.00)</td>
<td>1.50 (1.50-2.00)</td>
<td>1.52 (1.40-2.00)</td>
<td>1.52 (1.40-2.00)</td>
</tr>
</tbody>
</table>

**DOSE-LIMITING TOXICITY AND SERIOUS ADVERSE EVENTS**

- **There were no dose-limiting toxicities**
- **There were no treatment-related serious adverse events**
- **1 patient in the dose expansion discontinued treatment due to an unrelated AE of abdominal pain in the context of disease progression with intestinal obstruction**

**RESPONSE ASSESSMENT**

<table>
<thead>
<tr>
<th>Best overall response, n (%)</th>
<th>Cohort 1</th>
<th>Cohort 2</th>
<th>Expansion</th>
<th>All Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial response</td>
<td>0</td>
<td>1 (33)</td>
<td>0</td>
<td>1 (33)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>2 (67)</td>
<td>2 (67)</td>
<td>4 (36)</td>
<td>8 (10)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>0 (0)</td>
<td>1 (33)</td>
<td>0 (0)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>Not evaluable</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Complete response/partial response</td>
<td>1 (33)</td>
<td>1 (33)</td>
<td>2 (18)</td>
<td>4 (50)</td>
</tr>
</tbody>
</table>

**ACKNOWLEDGMENTS**

The authors are fully responsible for all content and editorial decisions, were involved at all stages of poster development and have approved the final copy of the poster.

**REFERENCES**


**CONCLUSIONS**

- **BI 754091 is safe and well-tolerated across all dose levels tested in advanced solid tumors, with preliminary evidence of anti-tumor activity.**
- **Adverse events were mild and included fatigue, decreased appetite, rash, and arthralgia.**
- **A dose of 240 mg q3w was selected for dose expansion cohorts.**

**DOSE-RESPONSE CURVE**

Dose-response curve of BI 754091 in patients with advanced solid tumors (N=13).

**RESPONSE RATE**

Best overall response rates for BI 754091 in the dose expansion cohort.

**ACKNOWLEDGMENTS**