Background on FPA144

- FPA144, an antibody-drug conjugate, targets the FGFR2b receptor, selectively binds the kinase domain of FGFR2b.
- FPA144 therapy is designed to exert its antitumor effects through binding to FGFR2b and internalization and degradation of the receptor.
- Phase 1a clinical trial in 100 evaluable patients for FPA144 and concurrent chemotherapy (Roche, 2015).
- FGFR2b amplification (FISH) was also supported by external data (across 4 patients).

Clinical Study Design Overview (NCT 03318329)

- Complete clinicopathological data on 61 patients included in the phase 1 study (2013-2016).
- FGFR2b in 40 tissues tested by IHC.
- FGFR2b (FISH) and FGFR2b IHC data was evaluated separately.
- FGFR2b IHC data was also reanalyzed of external data (Fan et al., 2016).


Table 2: Most Common Treatment-Related (Across 4 Patients)

<table>
<thead>
<tr>
<th>Event</th>
<th>Frequency (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 2 ulcerative keratitis</td>
<td>11 (31.7%)</td>
</tr>
<tr>
<td>Decreased Weight</td>
<td>13 (31.7%)</td>
</tr>
<tr>
<td>Headache</td>
<td>5 (13.5%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>11 (31.7%)</td>
</tr>
<tr>
<td>constipation</td>
<td>8 (22.0%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>9 (24.3%)</td>
</tr>
<tr>
<td>Fatigue (with grade 3)</td>
<td>6 (16.4%)</td>
</tr>
</tbody>
</table>

Conclusions

- FPA144 was well tolerated in doses up to 10 mg/kg in patients with advanced solid tumors.
- No hypersensitivity reactions reported.
- 2 dose-limiting toxicities (DLT) were reported.
- No Grade 3 or 4 toxicities were observed (5 patients).
- No DLTs during dose escalation (3 cohorts).
- No toxicity data were available for 3 patients.
- FGFR2b inhibitor therapy delayed and was associated with lower toxicities (N = 10 patients, 16%, 18%, 19%).

References