Bemarituzumab

**Methods (continued)**

### Phase 1 Patient Population

**Key Inclusion Criteria**

- Adult with incurable GI cancer for whom mFOLFOX6 is appropriate
- Key Exclusion Criteria
  - Prior treatment with selective inhibitor of FGFR-FGFR pathway
  - Known HER2
  - Known mutations in FGFR2b
- **Evaluative disease by RECIST v1.1**
- Distinct from the Phase 3 FIGHT Study Population: Phase 1 was:
  - Not restricted to gastric/GEJ cancer
  - Not selected for FGFR2b status
  - Not limited to patients without prior chemo for advanced disease

### Definition of Dose Limiting Toxicities

Attributed to bema within the first 28 days after starting treatment

- **Any Grade 5 AE:**
  - Grade 4 oropharyngeal AE or Grade 2-3 ophthalmic AE that does not resolve in 7 days
  - Grade 3 oropharyngeal adverse event Grade 3 or higher except nausea, vomiting and diarrhea
  - Grade 4 nausea, vomiting, or diarrhea
  - Fabric Neutropenia or ANC < 0.5 x 10^9/L greater than 5 days in duration

### Phase 1 Dose Levels

<table>
<thead>
<tr>
<th>Cycle 1</th>
<th>Cycle 2 and beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>6 mg/kg Q2W</td>
</tr>
<tr>
<td>Day 8</td>
<td>15 mg/kg Q2W</td>
</tr>
<tr>
<td>Day 1</td>
<td>6 mg/kg Q2W</td>
</tr>
<tr>
<td>Day 8</td>
<td>15 mg/kg Q2W + 7.5 mg/kg D8</td>
</tr>
</tbody>
</table>

### Results

#### Phase 1 Patient Characteristics

- **Number of Patients:** 14
- **Number of Treatment Cycles:** 14

#### Status of Enrolled Patients in Phase 1

- **Percentage of Patients:**
  - With at least 1 evaluable lesion: 92%
  - With 2 lesions: 92%
  - With 3 lesions or more: 92%

#### Treatment Emergent Adverse Events

At completion of OLT evaluation period for Phase 1:

- **No DLTs**
- **No Grade ≥ 4 AEs, no deaths**
- **1 Grade 4 Adverse Event**
  - Dyspnea due to pulmonary involvement of GI malignancy (summarized to bema)

### Conclusion

**Patient 13: Complete Metabolic Response on PET**

**Target Bema C_{uv} was Achieved by All Patients in Cohort 2**

**PK Profile of Bemarituzumab is Not Affected by Addition of mFOLFOX6**

**Bema in combination with mFOLFOX6 had acceptable toxicity in previously-treated patients with GI malignancies in Phase 1 safety run-in**

- **Bema 15 mg/kg Q2W + 7.5 mg/kg D8 has been selected to combine with mFOLFOX6 in the Global Phase 3 study**
- **PK results support 15 mg/kg Q2W + 7.5 mg/kg D8**
- **Bema exposure was not affected by combination with mFOLFOX6**
- **Additional GI bema dose achieved larger C_{uv}, C_{ss} in all patients treated with bema 15 mg/kg Q2W by D15**
- **Bema continuous IV administration with weekly or biweekly dosing demonstrated GI safety and efficacy in Phase 2 studies**

**For more information please visit:**

[stomachcancertrial.com](http://stomachcancertrial.com)