**IMAGE 1 (Immune Modulation and Gemcitabine Evaluation), a Randomised, Open-label Phase II Trial Comparing Gemcitabine with and without IMM-101 in Advanced Pancreatic Cancer**

(INCLUDING RESULTS FROM THE LONG-TERM FOLLOW-UP SUB-STUDY)

Angus G Dalgleish and the IMAGE 1 Trial Investigators

St Georges. University of London

1 See Acknowledgements

**Survival in advanced pancreatic cancer**

- The introduction of nab-paclitaxel/gemcitabine and FOLFIRINOX has improved median survival for patients with metastatic disease and good performance status (PS, ECOG 0-1) (8.7 months) and 11.1 months respectively compared to gemcitabine (GEM) monotherapy typically 5-7.6 months and 4.5 months on median survival.
- Patients with lower PS (ECOG 2) and/or a comorbidty profile precluding more aggressive regimes have fewer options with Gem modulation recommended, both as first and second line treatment.
- Long-term survival remains elusive – 4-6% at 36 months for patients treated with nab-paclitaxel/GEM in the phase 3 MPACT study with only 1% patients in the ‘at risk’ category at 36 months in the FOLFIRINOX arm of the phase 3 PRODIGE 4/ACCORD trial.
- Five-year survival rates for subjects diagnosed with disease late remain low at 3%.
- Toxicity to treatment limits exposure time: 22% of patients withdrew from the nab-paclitaxel/GEM arm of the MPACT trial due to unacceptable treatment-related toxicity and neutropenia a grade 3 occurred in 38% of patients treated with nab-paclitaxel/GEM and 46% treated with FOLFIRINOX.

**The IMAGE 1 Trial**

- **Open-label phase 2 study** (NCT01303172) comparing safety and efficacy of IMM-101 with and without GEM in subjects with advanced (unresectable stage 3 or stage 4) pancreatic cancer.
- Patients randomised 2:1 to IMM-101 (0.1L, Intradermal injection of 10mg/m^2 suspension) +/- GEM (1000mg/m^2) or GEM alone.
- Study treatment could be continued to a maximum of 12 cycles of IMM-101 in the Main Study.
- Patients from both treatment groups who completed the Main Study were eligible to participate in a long-term follow up (Sub-Study) where all received IMM-101 and, at the Investigator’s discretion, adjunctive chemotherapy.

**The Investigation Product: IMM-101**

- An investigational product with an innate immune system activator, enhancing antigen presentation.
- Which chemotherapies did patients in the Sub-Study receive?
  - 46% treated with FOLFIRINOX (2 patients) and combinations or sole use of gemcitabine alone (2 patients).

**Safety and Tolerability**

<table>
<thead>
<tr>
<th>Overall Exposure to IMM-101 (months)</th>
<th>IM/MM-101 + GEM</th>
<th>GEM alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 46</td>
<td>10 (9-11)</td>
<td>12 (11-13)</td>
</tr>
<tr>
<td>Median</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Range</td>
<td>0-23</td>
<td>0-48</td>
</tr>
</tbody>
</table>

**Conclusions from the completed IMM-1 Sub-Study:**

- The IMAGE 1 Sub-Study identified long-term survivors from the Main Study and showed IMM-101 to be well tolerated over an extended period, with a maximum exposure of 46.5 months.
- The survival probability at 24, 36 and 60 months indicated the long-term benefits of the previously reported study and, in some cases, with a variety of other anti-cancer treatments, especially at 60 months.
- No additional safety signals were identifiable from the Sub-Study.

**Future Directions:**

- Image 1 demonstrated promising efficacy and tolerability of IMM-101 + GEM with the possibility of long term use and survival benefits. There is potential for use in metastatic pancreatic cancer as:
  - First line treatment in patients who are unsuitable for more aggressive regimes
  - Second line/maintenance therapy

**Acknowledgements**

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**References**

6. Cancer facts and figures, American Cancer Soc., 2019