BACKGROUND

- Immunotherapy may produce durable responses in some cancers.
- There is an urgent need for pancreatic cancer treatments that improve survival without adversely affecting safety and quality of life.
- IMM-101 is a systemic immunomodulator that induces protective CD8+ T cell responses and reduces metastatic burden in murine models of pancreatic cancer (Elia et al., 2013).
- IMM-101 is a suspension of heat-killed whole cell Mycobacterium tuberculosis (NCTC13365) in borate-buffered saline, administered intradermally.

METHODS

- Proof of concept Phase 2 study (NCT01303172) to direct future development of IMM-101 in pancreatic cancer.
- Patients were randomly assigned in a 2:1 ratio to receive IMM-101 (0.1mL intradermal injection of 10mg/mL) + Gemcitabine (Gem, 1000mg/m²) (IMM-101 treated group) or Gem alone (Control group).
- Per protocol this could be continued to a 12-cycle maximum.
- Efficacy was assessed with Kaplan-Meier curves and the log rank test. All statistical testing was at 2-sided 5% significance level. Hazard ratios and p values are from Cox regression models. Survival probabilities are calculated using life tables.

RESULTS

- Survival data for the sub study with a cut-off date of April 25, 2015.
- Safety and tolerability endpoints analyzed using the Safety Set. Efficacy endpoint of primary interest was overall survival (OS).

CONCLUSIONS

- The overall shape of the IMM-101 Kaplan-Meier curves is characteristic of immunotherapy agents (McDermott et al., 2014).
- The continued separation of the Kaplan-Meier curves to 24 months and the survival probabilities at 12, 18 and 24 months are indicative of a durable response in some patients.
- The separation in the tail of the Kaplan-Meier curves previously reported at 12 months is amplified at 18 and 24 months. The IMM-101 treated curve then reaches a plateau, suggesting there are more durable responses in a small proportion of patients, consistent with observations of the effects of immunotherapy for other cancers, but not predicted in advanced pancreatic cancer.

REFERENCES

Elia A et al., 2013, J Immunother Cancer 1: Sup 1, P215
Dalgleish A G et al., ASCO meeting library, Gastrointestinal Cancers Symposium, 2015
McDermott et al., Cancer Treatment Reviews 40 (2014) 1056-1064

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Survival extensions, durable responses and a favourable safety profile mean this proof of concept study has exceeded its objectives.