ASCO GI Abstract # 336

Immodulon ASCO GI IMAGE 1 Press Release Jan 2015

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In IMAGE 1, a randomised controlled Phase II clinical trial, administration of IMM-101 with gemcitabine demonstrates significant survival advantage over gemcitabine alone

Poster Presentation Scheduled for Friday, 16th January at ASCO's Gastrointestinal Cancers Annual Symposium

LONDON, UK – (BUSINESS WIRE) – Jan. 12, 2015 – Immodulon Therapeutics Ltd today announced that in IMAGE 1, a randomised controlled Phase II clinical trial, IMM-101 (a bacterially derived systemic immunomodulator administered intradermally) in combination with gemcitabine, was associated with consistent and significant improvements in overall survival (OS) and progression free survival (PFS) in advanced pancreatic cancer patients.

In the predefined sub-group with metastatic disease (82 of the 110 patients randomised), a statistically significant and clinically meaningful 3.1 month or 70% improvement in overall survival compared to patients receiving gemcitabine alone (median of 7.5 vs 4.4 months) was demonstrated (HR 0.46, 95% CI 0.28-0.76, p=0.002).

In this study IMM-101 does not appear to confer an incremental safety burden beyond that associated with chemotherapy and the disease itself.

"There is a real need for treatments for pancreatic cancer which significantly improve survival without additional toxicity and these data suggest that immunomodulation with IMM-101 offers that hope" said Prof Angus Dalgleish, Chief Investigator of IMAGE 1.

Dr Kevin Bilyard, Immodulon CEO, commented "These results have surpassed expectations. Significant survival benefit in a randomised controlled clinical trial of this size is very encouraging and provides clear direction for the further development of IMM-101 in combination with chemotherapy as a first line treatment option for metastatic pancreatic cancer. We are now initiating discussions with regulatory authorities to determine a development pathway that will allow us to confirm these preliminary findings as quickly as possible. Although metastatic pancreatic

cancer is the lead indication for IMM-101, we expect it to be effective in other tumour types as well."

Further details of the study will be available at the Poster Presentation:

POSTER #336 PRESENTED AT ASCO GI FRIDAY 16th JANUARY 2015
General Poster Session B,
Cancer of the Pancreas, Small Bowel and Hepatobiliary Tract

Session times:
Friday 16th January 12.00-14.00 and 17.30-19.00

About IMAGE 1

In the IMAGE 1 (**I**mmune **M**odulation **A**nd **G**emcitabine **E**valuation 1) study, patients with advanced pancreatic cancer and a WHO score of 0-2 were assigned randomly to receive IMM-101 (0.1 mL intradermal injection of 10 mg/mL) plus Gemcitabine (Gem) (1000 mg/m^2 for 3 consecutive weeks out of 4) or Gem alone. Per protocol, this could be continued to a 12-cycle maximum. The primary efficacy endpoint was overall survival (OS); safety, tolerability and progression free survival (PFS) were also assessed.

A total of 110 patients were randomized, 75 to receive IMM-101 plus Gem and 35 Gem alone (ITT population). The PP population consisted of 63 and 35 patients, respectively, with 12 patients excluded relative to ITT for ineligibility or non-compliance with the protocol. Conclusions were similar and results of the ITT and PP analysis are presented in the poster. In the PP analysis median OS was increased significantly by 29% to 7.2 months in the IMM-101 plus Gem group compared to 5.6 months in the Gem group (p=0.022; HR 0.60, 95% CI 0.38-0.94). Median PFS was increased significantly by 83% to 4.4 months in the IMM-101 plus Gem group compared to 2.4 months in the Gem group (p=0.003; HR 0.51, 95% CI 0.32-0.81). In the pre-defined sub-group of patients with metastatic disease (n=82), median OS was increased significantly by over 3 months (70%) to 7.5 months in the IMM-101 plus Gem group (n=54) compared to 4.4 months in the Gem group (n=28) (p=0.002; HR 0.46, 95% CI 0.28-0.76). A highly significant 91% increase in median PFS from 2.3 months in the Gem group to 4.4 months in the IMM-101 plus Gem group was observed (p<0.001; HR 0.40, 95% CI 0.24-0.66). IMM-101 was well tolerated. The only adverse events of NCI CTC ≥Grade 3 occurring more frequently in the IMM-101 plus Gem group (absolute difference in frequency between the groups ≥5%) were asthenia 10.8%, abdominal pain 8.1%, and anaemia 8.1% (5.8%, 2.9% and 2.9% respectively in the Gem group). Longer survival and greater exposure to gemcitabine need to be considered when interpreting the safety data. Clinically meaningful increases in OS and PFS were demonstrated with IMM-101. No additional burden of adverse events above those relating to chemotherapy or the underlying disease was observed.

About Pancreatic Cancer

Pancreatic cancer is the most lethal cancer, and there is a need for new therapies to extend pancreatic cancer patients' lives. Pancreatic cancer is the fourth leading cause of cancer-related death in the US and the fifth in Europe, with a 5-year survival rate of less than 6%. Approximately 80% of patients are diagnosed with metastatic disease, for which the 5-year survival is 2%.

About IMM-101

IMM-101 is a suspension of heat-killed whole cell *Mycobacterium obuense* (NCTC13365) in borate-buffered saline which is administered intradermally.

IMM-101 has completed Phase II clinical development in metastatic pancreatic cancer and as such is not a licensed or approved product.

It is a systemic immunomodulator which induces protective CD8+ T cell responses and reduces metastatic burden in murine models of pancreatic cancer and which may have application across a variety of tumour types.

About Immodulon

Immodulon Therapeutics Ltd is a privately owned, UK-based biopharmaceutical company focused on developing systemic immunomodulators as potential adjunctive treatments for a range of cancers.

Source: Immodulon Therapeutics Ltd

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