Aim: Immunotherapies such as ipilimumab, nivolumab and pembrolizumab alone and in combinations have provided durable benefits in metastatic melanoma, increasing five-year survival to around 20%. IMM-101, a systemic immunomodulator containing heat-killed Mycobacterium obuense, enhances the innate immune response and, in an animal model, increases the number of CD8+ cytotoxic lymphocytes. In a randomised Phase 2 study IMM-101, in combination with gemcitabine, increased overall survival in patients with metastatic pancreatic cancer compared to gemcitabine alone. Five year survival information is now available for patients with metastatic melanoma recruited to an earlier Phase 1 study.

Methods: Between March and July 2010, 18 patients with metastatic melanoma (12 stage IV, 3 stage IIIc and 3 stage IIIb) completed a first in human trial to evaluate the safety and tolerability of IMM-101. Three doses of IMM-101 (0.1mg, 0.5mg or 1.0mg), given by intradermal injection at 2-weekly intervals after an initial placebo dose, were each evaluated in sequential cohorts of 6 patients. Treatment with IMM-101 continued, initially on a named patient basis and then in an open label long term follow up study, which is ongoing. Here we report safety and 5 year survival information.

Results: Of the 18 patients who completed the original Phase 1 trial, 14 received subsequent treatment on a named patient basis and 10 of the 12 surviving enrolled in the follow up trial started in February 2012. On 26 August 2015, 6 remained on study, having received IMM-101 for over 5 years. IMM-101 was safe and well tolerated and local reactions at the injection site were the most frequently reported adverse events.

Conclusions: IMM-101 was well-tolerated when administered over 5 years to patients with metastatic melanoma. In this small uncontrolled study, it is notable that one third of the patients with stage III/IV melanoma originally enrolled in 2010 who were not lost to follow-up, remain alive and on study five years later. These data, together with those of the previously reported pancreatic cancer trial, indicate that IMM-101 may be effective in different tumour types.

Clinical trial identification: NCTC13365

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