11-1-2022

Phase 1 study of fianlimab, a human lymphocyte activation gene-3 (LAG-3) monoclonal antibody, plus cemiplimab in advanced melanoma

O. Hamid

Amy Weise
Henry Ford Health, aweise3@hfhs.org

T. M. Kim

M. McKean

N. J. Lakhani

See next page for additional authors

Authors

O. Hamid, Amy Weise, T. M. Kim, M. McKean, N. J. Lakhani, J. Kaczmar, K. P. Papadopoulos, S. Chen, J. Mani, V. Jankovic, G. Kroog, T. Sims, I. Lowy, and G. Gullo

lowing treatment end (90 days for serious AEs). The primary end point is objective response rate. Secondary end points are progression-free survival, duration of response, overall survival, and safety.

Results: LEAP-009 is enrolling patients in North America, Europe, Asia, and Australia. Recruitment is currently underway.

Conclusion: Results of LEAP-009 will provide clarification on the efficacy and safety of Lenvatinib with or without pembrolizumab vs chemotherapy for patients with R/M HNSCC upon progression after platinum and immunotherapy.

Clinical trial registration: NCT04428151

205 | Phase 1 study of fianlimab, a human lymphocyte activation gene-3 (LAG-3) monoclonal antibody, plus cemiplimab in advanced melanoma

Omid Hamid[1], Amy Weise[2], Tae Min Kim[3], Meredith McKean[4], Nehal J. Lakhani[5], John Kaczmar[6], Kyriakos P. Papadopoulos[7], Shuquan Chen[8], Jayakumar Mani[8], Vladimir Jankovic[8], Glenn Kroog[8], Tasha Sims[8], Israel Lowy[8], Giuseppe Gullo[8]

[1]*The Angeles Clinical and Research Institute, a Cedars-Sinai Affiliate, Los Angeles, CA, USA*

[2]*Henry Ford Hospital, Detroit, MI, USA*

[3]*Seoul National University Hospital, Seoul, South Korea*

[4]*Sarah Cannon Research Institute/Tennessee Oncology PLLC, Nashville, TN, USA*

[5]*START Midwest, Grand Rapids, MI, USA*

[6]*MUSC Hollings Cancer Center, North Charleston, SC, USA*

[7]*START San Antonio, San Antonio, TX, USA*

[8]*Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA*

Background: Concurrent LAG-3 blockade may enhance efficacy of anti–program cell death-1 (PD-1) therapies such as cemiplimab. We present updated safety and clinical activity data from patients with advanced melanoma treated concurrently with cemiplimab and fianlimab (NCT03005782).

Methods: Patients were included with unresectable or metastatic melanoma (excluding uveal melanoma) who were anti–PD-ligand (L) 1 treatment naive (expansion cohort [EC] 6) or anti–PD-(L)1 experienced within 3 months of screening (EC7). Patients received fianlimab 1600 mg + cemiplimab 350 mg intravenously every 3 weeks for 12 months (optional extra 12 months if clinically indicated). Tumours were measured every 6 weeks for 24 weeks, then every 9 weeks. In EC6 ($n = 40$) and EC7 ($n = 15$), respectively (data cutoff 9th February 2022), median age was 69.5 and 59.0 years, and median treatment duration was 37.1 and 9.0 weeks.

Results: In EC6 and EC7, respectively, incidence of Grade ≥3 treatment-emergent adverse events (TEAEs) were 38% and 47%, incidence of serious TEAEs was 33% and 33%, and 18% and 13% of patients discontinued treatment due to a TEAE. Adrenal insufficiency rate was 13% and 7% in EC6 and EC7, respectively; no instances led to treatment discontinuation. Investigator-assessed objective response rate was 63% (six complete responses; 19 partial responses) in EC6 and 13% (two partial responses) in EC7. Kaplan-Meier estimate of median progression-free survival was 14.2 (95% CI: 5.6–not estimated) months in EC6 and 1.4 (95% CI: 1.3–7.7) months in EC7. Median duration of response was not reached in EC6 or EC7.

Conclusion: Fianlimab plus cemiplimab in advanced melanoma had a similar safety profile to anti–PD-1 monotherapies. Clinical activity in anti–PD-(L)1–naive patients appeared higher than previously reported for anti–PD-1 monotherapy or anti–LAG-3 plus anti–PD-1. A Phase 3 trial (NCT05352672) investigating fianlimab plus cemiplimab in advanced melanoma is ongoing.

206 | Efficacy and tolerability of docetaxel chemotherapy in 'real-world' patients with metastatic hormone-sensitive prostate cancer (mHSPC)

May Tun Hla Maw[1], Laeeq Malik[1]

[1]*Department of Medical Oncology, The Canberra Hospital, Garran, ACT, Australia*

Background: Recent clinical trials have demonstrated improved survival of young and fit patients with metastatic hormone sensitive prostate cancer treated with upfront docetaxel chemotherapy. Prostate cancer patients in 'real world' are elderly with multiple comorbidities. The efficacy and tolerability of docetaxel in these patients is unknown.

Methodology: We conducted a retrospective observational study of patients with newly diagnosed hormone-sensitive de novo or recurrent (metastatic) prostate cancer (mHSPC) who were treated with upfront docetaxel within three months of starting androgen deprivation therapy at Canberra Region Cancer Centre. We collected demographic and the relevant medical information from the medical records.

Results: There were 38 patients in our study with a median age of 65 years (range 46–77 years). The median PSA at the start of chemotherapy was 63.5. The sites of metastases included bone (82% of patients), lymph nodes (79%) lung (21%) and liver (8%). 26 patients had de novo disease, 10 patients had recurrent disease, and two patients had missing data.

After a median follow up of 28 months, 24 patients were still alive. The 12-month and 24-month survival rates were 84% and 66%, respectively. About five patients (13%) experienced grade ≥3 toxicities including fatigue, peripheral neuropathy, mucositis, infusion reaction, and palmar plantar erythrodysesthesia.

Conclusion: In this small retrospective study with a short follow up, we found that docetaxel was tolerable in 'real world' patients with mHSPC with a low grade ≥3 toxicity rate. Longer follow-up is needed to assess efficacy outcomes.

207 | Immunotherapy efficacy and concomitant antibiotic use in advanced cancers: Retrospective analysis in a regional centre

Saw Htut[1], Megan Lyle[2], James Flectcher[3]