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Bexmarilimab, a novel macrophage re-programmer shows promising anti-tumour activity in phase I/II trial in several last line solid tumour types

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Background

Bexmarilimab (FP-1305) is a novel humanized anti-CLEVER-1 IgG4-antibody capable of inducing a phenotypic M2 to M1 immune switch of tumor-associated macrophages.

Methods

MATINS (Macrophage Antibody To INhibit immune Suppression) trial is a three-part, first-in-human phase I/II study (NCT03733990) to assess safety and preliminary efficacy of Bexmarilimab in patients with advanced solid tumours. The Part I was recently completed (Bono et al., ESMO 2020). In Part II, 10 distinct solid tumour types were enrolled to assess tolerability, safety and preliminary efficacy (overall survival (OS), progression free survival (PFS), and disease control rate (DCR; PR+SD)).

Results

Between Dec 2018 and Jul 2021, 159 patients were enrolled into Part I (n=30; 0.1 - 10 mg/kg), and into Part II (n=129; 0.3 – 3.0 mg/kg), and received 1-12 doses (median 3) of Bexmarilimab every three weeks (q3w). Median follow-up was 2.1 months (range, 0.5 to 8.2). Total of 185 serious Treatment Emergent Adverse Events (TEAEs; 17.7% of all TEAEs) were reported. 13 were related to the study drug. The most common TEAEs were fatigue (31% of patients), abdominal pain (23%) and anaemia (21%). Part I and Part II fully enrolled 11 cancer cohorts (n=138 for tumor and survival analysis), the median PFS was 59 days (95% CI 58 - 61) and the median OS was 151 days (95% CI 118 - 190) at the data cut. DCR for Part II was 17.3% (19/110) at cycle 4 of treatment (by RECIST v.1.1). Six-month survival rate (based on the current Kaplan-Meier estimates) was 82.5% for DCR patients compared to 27.1% for non-DCR patients, with a similar length of prior therapy in both groups. Notably, 34% DCR at cycle 4 was seen in cutaneous melanoma (3/10), gastric cancer (3/10), cholangiocarcinoma (3/10), breast cancer (4/10) and hepatocellular cancer (4/10).

Conclusions

This phase I/II study with Bexmarilimab in patients with advanced solid tumours demonstrates good initial safety and tolerability, and promising anti-tumour activity as a monotherapy in several refractory metastatic solid tumours. Further expansion of the study will investigate optimal dosing, biomarkers of efficacy and Bexmarilimab's potential for combination with earlier lines of therapy.

Legal entity responsible for the study

Faron Pharmaceuticals.

Funding

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Disclosure

P. Bono: Financial Interests, Personal, Advisory Role: Faron Pharmaceuticals; Financial Interests, Personal, Stocks/Shares: TILT Biotherapeutics; Financial Interests, Personal, Advisory Board: MSD; Financial Interests, Personal, Advisory Board: Oncorena; Financial Interests, Personal, Advisory Board: Herantis Pharma; Financial Interests, Personal, Advisory Board: BMS; Financial Interests, Personal, Advisory Board: Ipsen; Financial Interests, Personal, Stocks/Shares: Terveystalo. S. Shetty: Financial Interests, Personal, Advisory Board: Faron Pharmaceuticals. S. Jalkanen: Financial Interests, Personal, Ownership Interest: Faron Pharmaceuticals. M. Hollmen: Financial Interests, Personal, Ownership Interest: Faron Pharmacuticals. J. Mandelin: Financial Interests, Personal, Stocks/Shares: Faron Pharmaceuticals. M.K. Karvonen: Financial Interests, Personal, Stocks/Shares: Faron Pharmaceuticals. J.P. Koivunen: Financial Interests, Personal, Advisory Board: Faron Pharmaceuticals. All other authors have declared no conflicts of interest.