Trial in progress: a Phase I, open-label study of GSK1795091 administered in combination with immunotherapies in participants with advanced solid tumours (NCT03447314)

Introduction

Context
The 'tumour immunity cycle' is a series of steps by which the immune system recognises and kills tumour cells, which is counterbalanced by tumour and host factors that inhibit antitumour immune responses.

Hypothesis
Combining GSK1795091 with Immunotherapies acting at complementary steps in the immune cycle is hypothesised to elicit greater antitumour activity compared with monotherapy approaches.

Study aims
To evaluate safety and tolerability, PK and PD of escalating doses of GSK1795091 in combination with fixed dose of pembrolizumab (CT05), GSK3359609 (ICOS), or pembrolizumab (PD-1), and to identify recommended dose(s) of GSK1795091 for further evaluation.

This trial design is a: 1. Phase I - Open-label - Non-randomised - Multi-centre study

The study will be conducted in two parts:

1. Dose escalation

Objective:
To assess safety and tolerability, PK and PD of escalating doses of GSK1795091 in combination with fixed dose of pembrolizumab (CT05), GSK3359609 (ICOS), or pembrolizumab (PD-1), and to identify recommended dose(s) of GSK1795091 for further evaluation.

Study population
Advanced solid tumours (NS72)

Study treatment
The IV mode of administration for GSK1795091 potentially enables the targeting of tumours not amenable to IT injection.

Endpoints
Primary
• Safety and tolerability

Secondary
• Antitumour activity

Exploratory
• PD, including effect on genes associated with immune cells and tumour function

Biomarker strategy
Target engagement and mechanism of action

Study population
Main inclusion criteria

• Patients presenting with at least 1 measurable lesion per RECIST version 1.1
• Life expectancy of at least 12 weeks
• Archival tumour tissue available if not feasible to obtain fresh biopsy
• Other malignant disease than the disease under study, or disease-free for <2 years

Main exclusion criteria

• Known human immunodeficiency virus infection
• Other malignant disease than the disease under study, or disease-free for <2 years
• Prior systemic or IT therapy with TLR agonist, OX40 and ICOS agonist at any time
• Other malignant disease than the disease under study, or disease-free for <2 years
• Prior systemic or IT therapy with TLR agonist, OX40 and ICOS agonist at any time

Current status

As of August 2018
10 patients have been enrolled into the 3 dose cohorts

In August 2018
4 patients have been enrolled into the first dose level of each of the arms

Acknowledgements

Authors

Informed Consent: all participants provided written informed consent.

Study registration: NCT03447314

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Conflict of interest: see 'Disclosures' section.

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Disclosure

Disclosures

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References


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