A Phase I/II, open-label, two-part study of GSK3359609 in combination with tremelimumab in participants with selected, advanced solid tumors

A study sponsored by GlaxoSmithKline (GSK).

Study Number: 207871

Why was this study done?

Researchers wanted to know if a combination of GSK3359609 and tremelimumab is safe and tolerable and to see if these medicines might help people with relapsed/refractory head and neck squamous cell carcinomas survive longer. They designed a two-part study. Part 1 looked at different doses in participants with solid tumors, and Part 2 would focus on people with relapsed/refractory head and neck squamous cell carcinomas.

What did the researchers do and find?

In Part 1, researchers tested three doses of GSK3359609 (8 mg, 24 mg, and 80 mg) and two doses of tremelimumab (75 mg and 225 mg). Adults with advanced, selected solid tumors that had relapsed or were refractory to standard therapies could join the study.

A total of 26 participants received at least one dose of the study medicines.

The study started in November 2018 and ended in September 2021. More than half of the participants were male (65%). Participants ranged in age from 36 to 83 years old.

Less than 25% of participants experienced dose limiting toxicities (DLTs). This was considered by researchers to be an acceptable number.

All participants reported at least one adverse event. Four participants stopped taking the study medicines because of adverse events.

Nineteen of 26 participants (73%) experienced at least one adverse event that the study doctors thought was related to the study medicines (side effect). The two most frequent side effects were diarrhoea and tiredness.

Seventeen of 26 participants (65%) died during the study due to their underlying disease. Most of the deaths (15 of 17 participants) happened more than 30 days from the last dose of the study medicines.

What do these findings mean?

The researchers concluded that GSK3359609 and tremelimumab in combination was similar in terms of safety to each medicine individually.

Since the results of Part 1 did not show enough evidence that the study medicine combination improved the outcome for patients with cancer, Part 2 of the study was not started.

We would like to thank the participants who contributed to this study. The results of this study will help answer scientific questions about cancer treatment.

The content for this document was finalized by GSK on 20 December 2021. The information in this summary does not include additional information available after this date.