ARTISTRY-2 Lay Summary

Study title

A Phase 1/2 Study of ALKS 4230 Administered Subcutaneously as Monotherapy and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors (ARTISTRY-2)

Who carried out the research? (including details of sponsor, funding and any competing interests)

The study was sponsored and funded by Alkermes, Inc. (now Mural Oncology, Inc.).

Where and when the study took place

The study took place in the USA, Canada, South Korea, Spain, and Taiwan from March 2019 to March 2023.

Why was the research needed?

The study was conducted to determine the safety, tolerability, and recommended dose of ALKS 4230 (administered subcutaneously, under the skin) alone or in combination with pembrolizumab in subjects with advanced solid tumors.

What were the main questions studied?

The main questions studied were:

- What were the types and frequency of adverse events, and
- How did ALKS 4230 alone or in combination with pembrolizumab affect the participant's disease?

Who participated in the study?

One hundred and sixteen (116) adults with solid tumors (including specific tumors of the stomach, ovary, lung, head and neck) participated in the study.

What treatments or interventions did the participants take/receive?

Participants received ALKS 4230 or ALKS 4230 in combination with pembrolizumab.

What medical problems (adverse reactions) did the participants have?

The most common adverse reactions were fever, chills, injection site redness, fatigue, injection site reaction, and nausea.

What happened during the study?

The study was conducted in two phases. Phase 1 studied multiple doses of ALKS 4230 administered subcutaneously followed by treatment in combination with pembrolizumab in order to find the recommended Phase 2 dose (RP2D). Phase 2 of the study was a dose-expansion phase with subcutaneous ALKS 4230 administered at the recommended Phase 2 dose (determined from Phase 1) in combination with pembrolizumab.

Phase 2 enrolled participants into different groups based on each participant's specific tumor type (stomach, ovarian, lung, head and neck).

What were the results of the study?

Overall, ALKS 4230 and ALKS 4230 in combination with pembrolizumab was well tolerated and showed limited activity in reducing participant's tumors.

Details of any further research planned

ALKS 4230 is currently being studied in three ongoing clinical trials, one in melanoma, one in ovarian cancer, and one looking at a different dosing schedule administering the drug intravenously.

Where can I learn more about this study?

If you have questions about the results of this study, please speak with the doctor or staff at your study site. For more details on the study protocol, please visit www.clinicaltrials.gov (use study identifier NCT03861793).