Two cancer drug trials put on hold after patients died, companies say

By Brenda Goodman, CNN
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Cancer: The facts

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CNN —
Two clinical trials have been paused within the past two days because six participants – including one child – have died, according to reports by the drug companies.

The two trials were unrelated: They were in different stages and testing therapies. But both were testing new cancer treatments. One was testing a treatment for a blood cancer called acute myeloid leukemia, or AML, and the other was testing a new agent for ovarian cancer.

Deaths in clinical trials are thought to be rare. A study published in 2019, which looked at deaths in studies testing breast cancer drugs over a decade in Germany, found that out of more than 23,000 patients treated in 32 trials, 88 of them (0.4%) died on their therapies. Of those 88 deaths, only 27% were determined to be related to the treatments themselves.

More than 90% of large US cancer centers report shortage of life-saving chemo drugs in new survey

The AML trial was a phase one safety study being conducted by the Cambridge, Massachusetts-based biotech company 2seventy bio in conjunction with Seattle Children's Hospital.

Seattle Children's has paused the study while the death is investigated, according to Dr. Rebecca Gardner, interim chief medical officer at the hospital. The participant who died was the first to take a higher dose of the study therapy, which combines CAR T-cells that are turned on by the anti-cancer drug rapamycin.

"Our thoughts and hearts go out to this family and what happened to their child," she said.

"The field of pediatric oncology is a small field, and we go into it to figure out ways that we can cure patients of their childhood cancers, and that's what we're all dedicated to doing. So anytime something like this happens, it's devastating for the family and for the team," Gardner said.

Gardner said the death was a recent event. Three other patients have been given a lower dosage of the therapy.

“The safety of every patient who participates in our studies or is treated with our therapies is the utmost priority for us, and we are in communication with FDA while we assess the data surrounding this SAE [serious adverse event], and the potential next steps for the study,” said Dr. Steve Bernstein, chief medical officer 2seventy bio, in a news release.

The second study, on ovarian cancer, was in phase three – typically the final stage before a company presents a drug for FDA approval. The drug company Mersana, also based in Cambridge, Massachusetts, is testing upifitamab rilsodotin, or UpRi, which attaches cancer-killing medications to antibodies that target tumor cells.

Mersana said Thursday that the FDA had issued a partial clinical hold after five study participants had fatal bleeding events, a rate that was higher than would have been expected. About 560 people have taken the study drug to date, the company said.

The FDA is pausing further enrollment while the bleeding events in the study, which included an unspecified number of low-grade events as well as the deaths, are being investigated, according to a news release. Participants who are enrolled in the trial will continue to receive the investigational treatment.

Mersana said it expects that the FDA will ask for a comprehensive assessment of safety data related to the study drug. It also said it expects to announce more safety and efficacy information from the trial in August.

“Patient safety is always at the forefront for us, and work is now underway to compile further analyses that may inform FDA,” said Anna Protopapas, president and chief executive officer of Mersana Therapeutics, in a news release.

The FDA has not responded to a request for comment on the trials.

https://www.cnn.com/2023/06/16/health/cancer-drug-trials-patient-deaths/index.html