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US FDA Warns Of Car-T Therapy Hospitalization, Deaths

US FOOD AND DRUG ADMINISTRATION

The US Food and Drug Administration says it has warned manufacturers of autologous chimeric antigen receptor T-cell (CAR-T-cell) immunotherapies of risks, including deaths.

In its January 23, 2024 'FDA Roundup' the FDA said that on January 19, it "issued safety labeling change notification letters to all manufacturers of licenced BCMA-directed and CD19-directed genetically modified autologous CAR T-cell immunotherapies requiring a revision to the package insert due to risk of T-cell malignancies, with serious outcomes, including hospitalization and death".

Biotech Daily counted 12 Australian companies and organizations which previously said they were developing CAR-T-cell therapies.

In 2022, the Walter and Eliza Hall Institute for Medical Research said that it had developed a way to potentially reduce the toxic side-effects of Car-T-cell immunotherapy treatments (BD: Jun 21, 2022).

In 2018, Cynata said it had filed an Australian patent application to cover its Cymerus technology for Car-T therapy side effects (BD: Apr 20, 2018).

In its January 23, 2024 'FDA Roundup' the FDA said it "considers the serious risk of T-cell malignancy to be applicable to all BCMA and CD19-directed genetically modified autologous T-cell immunotherapies".

“The letters notify manufacturers of each such licenced product to update the package insert to include available information related to the risks and to update the Medication Guide for these products to identify the possibility of the increased risk of getting cancers, including certain types of cancers of the immune system,” the US regulator said.

The FDA said that in November 2023 it “posted a safety communication to provide information related to the receipt of reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA or CD19-directed autologous CAR T cell immunotherapies”.

“Reports were received from clinical trials and/or post-marketing adverse event data sources,” the Administration said.

“Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA continues to investigate the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death,” the FDA said.

“Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies,” the FDA said.

“In the event that a new malignancy occurs following treatment with these products, clinicians are encouraged to contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the chimeric antigen receptor transgene,” the FDA said.