LymphomaHub

FDA safety concerns halt ACTR087 B cell non-Hodgkin lymphoma clinical trial

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The U.S. Food and Drug Administration has decided to place on hold clinical trial ATTCK-20-2 investigating an experimental T-cell therapy ACTR087 in combination with rituximab following lymphodepleting chemotherapy with fludarabine and cyclophosphamide in relapsed/refractory (R/R) CD20+ B-cell NHL (NCT02776813).

ACTR087, an autologous T lymphocytes expressing antibody coupled T-cell receptors (CD16V-41BB-CD3ζ), is also in clinical development in combination with SEA-BCMA in multiple myeloma (NCT03266692).

The FDA decision was brought by a recent report of serious adverse events including grade 3 neurotoxicity, cytomegalovirus infection, and grade 4 respiratory distress in one patient in the safety expansion cohort of the trial.

It is the second time that this phase I trial has been put on clinical hold due to the safety concerns. Previously, one patient died after suffering neurotoxicity related to ACTR087 events and another two patients suffered cytokine release syndrome before dying of sepsis. Before re-starting the trial changes were made to the protocol and dosing to reduce the incidence of adverse events.

References

1. UNUM Therapeutics announces regulatory update from phase 1 trial with ACTR087 https://investors.unumrx.com/news-releases/news-release-details/unum-therapeutics-announces-regulatory-update-phase-1-trial. [Accessed 04/07/2019]