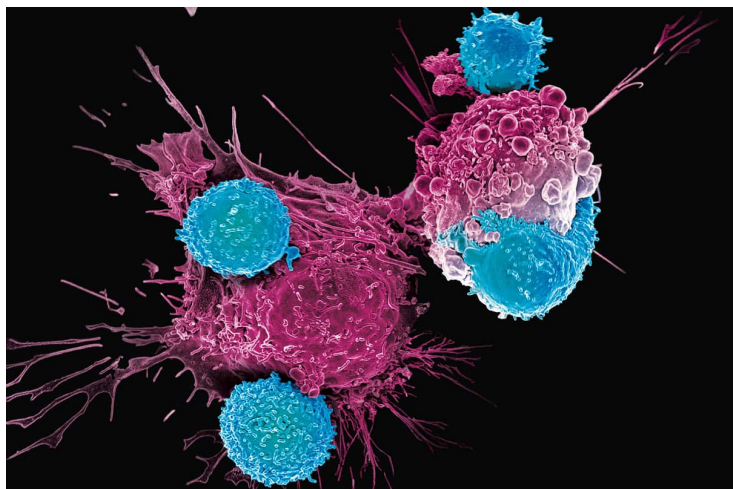


Tessa Therapeutics to launch first CAR-T therapy for Hodgkin's lymphoma (HL)

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TT11 will replace stem cell transplants as standard of care in Hodgkin's lymphoma, says GlobalData



Tessa Therapeutics TT11 has become the first CAR-T therapy to receive the Food and Drug Administration (FDA) regenerative medicine advanced therapy (RMAT) designation and is set to become the leading cell-based therapy in Hodgkin's lymphoma (HL), displacing the outdated stem cell transplants as the standard of care by 2024, says GlobalData, a leading data and analytics company.

Miguel Ferreira, MSc, Oncology and Hematology Analyst at GlobalData, comments: "TT11, being the first CAR-T therapy to emerge from the HL pipeline, will benefit from being the first to market and with no other CAR-T therapies closing in, GlobalData expects TT11 to comfortably take the lead as the sole cell-based treatment for HL. This is further supported by key opinion leaders (KOLs) interviewed by GlobalData, who have shown preference for CAR-T clinical trials for their patients when possible."

Tessa Therapeutics TT11 became the 47th drug to receive RMAT designation, making it an ideal candidate to emerge from the HL pipeline. The data leading to this designation demonstrated a significant complete response (CR) rate of 66.7% in patients who had failed multiple lines of treatment which is a highly encouraging result. The pivotal Phase II trial is planned to take place in Q4 2020 and to run for two years. GlobalData believes that Tessa Therapeutics will discuss surrogate endpoints with the FDA to apply for regulatory approval based on the RMAT designation.

Ferreira adds: "The current landscape of second-line treatment in HL is only partially set in stone. Salvage treatment and stem cell transplants are the standard of care, though the toxicity and impact in quality of life of patients labels this approach as outdated and highly toxic despite response benefit. A new treatment that can displace or replace stem cell transplants to improve the response, quality of life, as well as treatable population in HL second line, has been highly anticipated."