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Tessa Therapeutics CD30 CAR-T cell therapy attains USFDA RMAT designation

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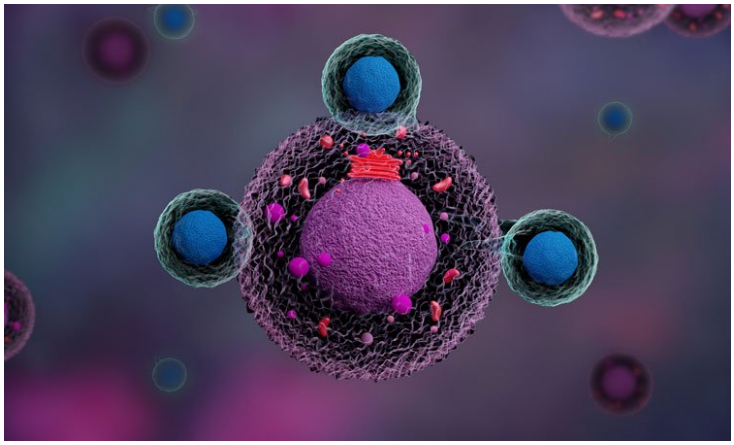
The designation includes early interactions with the FDA to facilitate development and discuss the potential for expedited review for the Treatment of Relapsed or Refractory CD30-positive Classical Hodgkin Lymphoma



Singapore based Tessa Therapeutics (Tessa), a clinical-stage cell therapy company developing next-generation cancer treatments, has announced that the Company's investigational CD30-directed autologous chimeric antigen receptor T cell (CD30 CAR-T) therapy has been granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with relapsed or refractory CD30positive classical Hodgkin lymphoma (cHL). Tessa expects to initiate its pivotal Phase II multi-site trial in the fourth quarter of 2020.

"The RMAT designation speaks to the strength of the data in two independent Phase I/II trials, which show promising efficacy and a strong safety profile of the therapy in Hodgkin lymphoma patients whose disease had failed to respond to other available therapies," said Ivan D. Horak, M.D., President of Research and Development at Tessa Therapeutics. "We look forward to working closely with the FDA as we advance our trial at multiple sites in North America and work to bring this potentially transformative treatment option to patients."

The RMAT designation is supported by clinical data from two independent CD30 CAR-T Phase I/II studies in patients with relapsed or refractory CD30-positive classical Hodgkin lymphoma conducted by Baylor College of Medicine (NCT02917083) and the University of North Carolina Lineberger Comprehensive Cancer Center (NCT02690545). Both studies demonstrated objective response rates of more than 70%, with 18 patients achieving complete response out of 27 patients treated with CD 30 CAR- T with lymphodepleting chemotherapy as of November 2019.

Dr Horak added: "As part of our longer-term R&D program, we are also developing an allogeneic CD30-CAR Epstein-Bar Virus-Specific T cell (CD30-CAR EBVST) therapy product that combines the unique properties of VSTs and CD30 CARs, in an effort to develop off-the-shelf cell therapies intended to treat a range of hematologic malignancies and solid tumors."

RMAT designation is designed to facilitate development and expedite review of cell therapies and other qualifying regenerative medicines intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. Advantages include all the benefits of the FDA's Fast Track and Breakthrough Therapy Designation programs, such as early interactions with the FDA that may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval and satisfy

post-approval requirements.