

Tessa Therapeutics Announces Updated Safety, Efficacy and Biomarker Data from Phase 2 Trial of Autologous CD30.CAR-T Therapy (TT11) in Relapsed or Refractory Classical Hodgkin Lymphoma

Updated Results from CHARIOT Phase 2 trial presented at the 2022 ASH Annual Meeting indicate a 73.3% overall response rate and 60% complete response rate from 15 heavily pre-treated patients dosed with TT11

Research presented in an oral podium presentation during the 2022 ASH Annual Meeting demonstrates potential of circulating tumor DNA (ctDNA) as a biomarker to predict outcomes of patients with r/r classical Hodgkin lymphoma (cHL) treated with CD30.CAR-T therapy

SINGAPORE – December 12, 2022 – [Tessa Therapeutics Ltd. \(Tessa\)](#), a clinical-stage cell therapy company developing next-generation cancer treatments for hematological malignancies and solid tumors, today announced updated clinical data from the pilot stage of the ongoing Phase 2 CHARIOT trial ([NCT04268706](#)) of TT11, the Company’s autologous CD30 chimeric antigen receptor T-cell (CAR-T) therapy, were presented in a poster and oral podium presentation at the 64rd Annual Meeting of the American Society of Hematology (ASH). The results demonstrated TT11 to be well-tolerated with promising efficacy in relapsed or refractory (r/r) CD30-positive classical Hodgkin lymphoma (cHL). Moreover, research identified circulating tumor DNA (ctDNA) analysis as a potential measure of response in cHL after CD30 targeted CAR T-cell therapy.

The ASH poster, titled, “Updated Results and Correlative Analysis: Autologous CD30.CAR-T Cell Therapy in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma (CHARIOT Trial),” reported expanded data from the pilot segment of a Phase 2 trial of autologous CD30.CAR-T in patients with r/r cHL. The CD30.CAR-T cell therapy was demonstrated to be well tolerated with no unexpected safety signals. An ORR of 73.3% and a CR of 60% was observed in 15 heavily pre-treated r/r cHL patients, suggesting strong anti-tumor responses. Additionally, CD30.CAR-T expansion and persistence was observed after CD30.CAR-T infusion.

In an oral podium presentation on December 12, titled, “Ultrasensitive ctDNA Dynamics after Autologous CD30.CAR-T Cell Therapy for Relapsed or Refractory (r/r) Classical Hodgkin Lymphoma (CHARIOT Trial),” research examining the potential of ctDNA as a biomarker in r/r cHL after CD30 CAR-T therapy were reported. Foresight Diagnostics’ PhasED-Seq MRD assay was used to measure ctDNA at multiple timepoints throughout therapy. Data showed that ctDNA responses mirrored radiographic responses, suggesting that ctDNA levels could be predictive of patient response to CAR-T therapy. Researchers also determined that PhasED-Seq ctDNA analysis is a viable biomarker to monitor responses and predict outcomes in patients with r/r cHL treated with CD30.CAR-T Cell Therapy.

“The data presented at ASH 2022 continue to demonstrate the CD30.CAR-T cell therapy to be well tolerated with excellent anti-tumor responses in patients with relapsed or refractory classical Hodgkin lymphoma. This includes an overall response rate of 73.3% in heavily pretreated patients, as well as good expansion and persistence after infusion,” stated **Sairah Ahmed, M.D., principal investigator, lead presentation author, and Associate Professor, The University of Texas MD Anderson Cancer Center.**

“We are pleased to present research demonstrating the potential of minimally invasive ctDNA analysis as a viable method to monitor responses, rapidly risk stratify, and predict outcomes of

patients with r/r cHL treated with CD30.CAR-T therapy,” stated **David M. Kurtz, M.D., Ph.D., lead presenter and Assistant Professor, Department of Medicine (Oncology), Stanford University.**

CD30 is a well validated lymphoma target with homogeneous expression in 98% of cHL and a significant proportion of subsets of non-Hodgkin lymphoma (NHL). TT11 is an autologous CD30 chimeric antigen receptor T-cell (CAR-T) therapy that harvests the patient’s own T-cells and modifies them to target cancer cells expressing the CD30 protein.

“We continue to be intrigued by the data being generated from our ongoing Phase 2 CHARIOT trial of TT11, which show the therapy to be safe and well tolerated, along with clear signals of efficacy, in patients with relapsed or refractory CD30-positive classical Hodgkin lymphoma,” said **Ivan Horak, M.D., Chief Medical Officer and Chief Scientific Officer of Tessa Therapeutics.**

TT11 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA) and PRiority MEDicines (PRIME) designation by the European Medicines Agency (EMA).

About Tessa Therapeutics

Tessa Therapeutics is a clinical-stage biotechnology company developing next-generation cell therapies for the treatment of hematological cancers and solid tumors. Tessa’s lead clinical asset, TT11, is an autologous CD30-CAR-T therapy currently being investigated as a potential treatment for relapsed or refractory classical Hodgkin lymphoma as both a monotherapy (Phase 2) and combination therapy (Phase 1b). TT11 has been granted RMAT designation by the FDA and access to the PRIME scheme by European Medicine Agency. Tessa is also advancing an allogeneic “off-the- shelf” cell therapy platform targeting a broad range of cancers in which Epstein Barr Virus Specific T Cells (EBVSTs) are augmented with CD30-CAR. A therapy using this platform is currently the subject of a Phase 1 clinical trial in CD30-positive lymphomas. Tessa has its global headquarters in Singapore, where the company has built a state of the art, commercial cell therapy manufacturing facility. For more information on Tessa, visit www.tessacell.com.

Cautionary Note on Forward Looking Statements

This press release contains forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995, to the fullest extent applicable) including, without limitation, with respect to various regulatory filings or clinical study developments of the Company. You can identify these statements by the fact that they use words such as “anticipate,” “estimate”, “expect”, “project”, “intend”, “plan”, “believe”, “target”, “may”, “assume” or similar expressions. Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the Company’s financial results, the ability to raise capital, dependence on strategic partnerships and licensees, the applicability of patents and proprietary technology, the timing for completion of the clinical trials of its product candidates, whether and when, if at all, the Company’s product candidates will receive marketing approval, and competition from other biopharmaceutical companies. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made, and disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be

based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. The Company's products are expressly for investigational use pursuant to a relevant investigational device exemption granted by the U.S. Food & Drug Administration, or equivalent competent body.

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