

## **Tessa Therapeutics Announces Positive Data from Phase 2 Trial of Autologous CD30-CAR-T Therapy (TT11) in Relapsed or Refractory Classical Hodgkin Lymphoma at 2021 ASH Annual Meeting**

*Oral poster highlights data from 14 heavily pre-treated patients enrolled in pilot stage of multicenter, open-label, single arm CHARIOT study to evaluate safety and efficacy of TT11*

*TT11 demonstrated compelling anti-tumor activity with complete disappearance of tumor observed in 8 of 14 patients*

*Therapy well tolerated with no instances of neurotoxicity or Grade 3 CRS*

**SINGAPORE – December 14, 2021 – [Tessa Therapeutics Ltd. \(Tessa\)](#), a clinical-stage cell therapy company developing next-generation cancer treatments for hematological malignancies and solid tumors, today announced 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. The results demonstrated a favorable safety profile and promising efficacy in relapsed or refractory CD30-positive classical Hodgkin lymphoma (cHL) patients, with a complete response (CR) rate of 57.1 percent and an overall response rate (ORR) of 71.4 percent. The data was presented in an oral poster presentation at the 63<sup>rd</sup> Annual Meeting of the American Society of Hematology (ASH) and follows a poster presented on December 11 reporting favorable safety and efficacy data in a Phase 1 trial of Tessa's "off-the-shelf" CD30-CAR EBVST cell therapy in relapsed or refractory CD30-positive lymphomas.**

The ASH poster, entitled, "Safety and Efficacy Profile of Autologous CD30.CAR-T-Cell Therapy in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma (CHARIOT Trial)," reported data demonstrating compelling signs of anti-tumor response in 14 heavily pretreated patients with advanced cHL treated with TT11 at a median dose of  $2.4 \times 10^8$  cells/m<sup>2</sup> after lymphodepletion. Disease control was observed in 11 patients overall, including eight complete responses, two partial responses and one patient with stable disease.

As of the data cutoff, TT11's CD30-CAR-T cells, initially detected three hours post infusion, had persisted for more than 42 days post-infusion. The cells showed strong expansion that peaked seven to 14 days after treatment. TT11 remained well tolerated with no reports of neurotoxicity or grade 3 or higher CRS (cytokine release syndrome). One patient experienced a Grade 1 CRS which resolved within five days.

"These data demonstrate the promise of CD30-CAR-T cell therapy for patients with relapsed or refractory classical Hodgkin lymphoma who have limited treatment alternatives. The therapy demonstrated excellent efficacy in heavily pre-treated patients who had undergone a median of six and as many as 18 previous lines of therapy," stated **Sairah Ahmed, M.D., principal investigator, lead presentation author, and Associate Professor, The University of Texas MD Anderson Cancer Center**. "The persistence of the CD30-CAR-T cells, which can play a major role in anti-tumor activity, was also encouraging. We look forward to further clinical development of this therapeutic approach for Hodgkin lymphoma patients."

The data released in the ASH poster further validates results from two previous independent Phase 1/2 studies conducted by Tessa collaborators at Baylor College of Medicine and the University of North Carolina Lineberger Comprehensive Cancer Center and published last year in

the [Journal of Clinical Oncology](#)<sup>1</sup>. Tessa expects to initiate the second, pivotal stage of the CHARIOT trial in 2022.

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 a chimeric antigen receptor T-cell therapy, also known as CAR-T, which harvests a patient's own T-cells and modifies them by introducing a chimeric antigen receptor (CAR) to target and kill cancer cells that express the CD30 protein.

"The ASH poster presentation marks a critical milestone in the development of Tessa's CD30-CAR-T cell therapy and provides a strong data foundation for us to build on as we gear up to commence the pivotal stage of the CHARIOT trial next year," said **Ivan Horak, M.D., Chief Medical Officer and Chief Scientific Officer of Tessa Therapeutics**. "We believe that Tessa's CD30-CAR-T cell therapy, with its promising efficacy and excellent safety profile, has the potential to address clear unmet need in the treatment of cHL."

**Dr. Horak continued**, "The current standard of care for relapsed or refractory classical Hodgkin lymphoma can cause high toxicity and long-term morbidity, with particularly poor tolerability noted among elderly patients. Thus far, TT11 has proven to be well tolerated by patients, while demonstrating strong clinical results as a third- and fourth-line monotherapy. We look forward to progressing this trial further and also exploring the use of TT11 in combination with other therapeutic modalities in earlier lines of therapy where there is higher patient need."

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).

The ASH Annual Meeting is taking place December 11-14, 2021. The poster can be viewed via the conference's virtual platform.

### **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 targeting CAR-T therapy currently being investigated as a potential treatment for relapsed or refractory classical Hodgkin lymphoma (Phase 2). TT11 has been granted RMAT designation by the FDA and PRIME designation 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 technology to prevent graft rejection. A therapy using this platform is currently the subject of a Phase 1 clinical trial in CD30-positive lymphoma. A third clinical asset evaluates novel combination therapy of HER2-CAR-T cells and binary oncolytic virus in HER2 positive solid tumors. 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](http://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.

<sup>1</sup>Ramos et al. “Anti-CD30 CAR-T Cell Therapy in Relapsed and Refractory Hodgkin Lymphoma” J Clin Oncol (2020)

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