Tessa Therapeutics Announces Three Abstracts Highlighting Data from Autologous and Allogeneic Cell Therapy Programs Accepted for Presentation at 64th ASH Annual Meeting and Exposition

New data from clinical trials of TT11 and TT11X to be featured in two oral podium presentations and a poster presentation

SINGAPORE – November 3, 2022 – Tessa Therapeutics Ltd. (Tessa), a clinical-stage cell therapy company developing next-generation cancer treatments for hematological malignancies and solid tumors, today announced that three abstracts reporting data from clinical trials investigating the company's autologous CD30.CAR-T therapy (TT11) and allogeneic CD30.CAR EBVST therapy (TT11X) have been accepted for presentation at the 64th American Society of Hematology Annual Meeting (ASH 2022) taking place December 10-13, 2022, at the Ernest N. Morial Convention Center in New Orleans.

TT11, Tessa's lead clinical asset, is an autologous CD30.CAR-T therapy currently being investigated as a potential treatment for relapsed or refractory classical Hodgkin lymphoma (r/r cHL) as both a monotherapy (Phase 2 CHARIOT) and combination therapy (Phase 1b). Two abstracts involving updated data from the CHARIOT clinical trial will be presented at ASH 2022, including an oral podium presentation demonstrating that circulating tumor DNA (ctDNA) analysis with Foresight Diagnostics PhasED-Seq technology provides a viable biomarker to monitor responses, rapidly stratify risk, and predict outcomes of r/r cHL patients treated with TT11.

TT11X, Tessa's allogeneic "off-the-shelf" cell therapy, is based on Tessa's proprietary CD30.CAR-modified Epstein-Barr virus-specific T-cell (EBVST) platform. An abstract highlighting updated data from the ongoing Phase 1/2 study of TT11X (BESTA) in CD30-positive lymphomas will be featured in an oral podium presentation at ASH 2022. The research demonstrates CD30.CAR EBVSTs (TT11X) to be a well-tolerated and preliminary efficacious treatment for CD30+ lymphomas.

"We are honored that ASH has accepted three abstracts involving Tessa's autologous and allogeneic CD30.CAR-T therapies, including two oral podium presentations, at its prestigious annual meeting," **stated Thomas Willemsen, President and CEO of Tessa Therapeutics**. "The data being presented at ASH 2022 from the ongoing clinical trials of TT11 and TT11X demonstrate the potential of these therapies to safely and effectively treat CD30 positive lymphomas, including relapsed or refractory classical Hodgkin lymphoma. ASH is an ideal venue for highlighting this important research, and we are grateful to the investigators at the Baylor College of Medicine, Stanford University and MD Anderson Cancer Center for leading their respective presentations."

Abstract Number: 167 (Podium)
Abstract Title: CD30.CAR-modified Epstein-Barr Virus-specific T-cells (CD30.CAR EBVST's) Provide a Safe and Effective Off-The-Shelf Therapy for Patients with CD30-Positive Lymphoma (BESTA)
Presenting Author: David H. Quach, PhD, Center for Cell and Gene Therapy, Baylor College of Medicine, Houston, TX
Session Date: Saturday, Dec. 10, 2022, at 1:00 PM CT; Ballroom AB

Commented [IDH1]: We should include ALL investigators contributing to these presentations.

Commented [RK2R1]: HI Ivan, as per your email, put MDA third in sequence post BCM and Stanford. Is that ok?

Alternatively, we can remove all institute names and keep the quote generic

Abstract Summary:
Off-the-shelf allogeneic T-cell therapies face a major challenge of graft-versus-host disease (GVHD) and graft rejection mediated by host and recipient alloreactive T-cells, respectively. Epstein-Barr-specific T cells (EBVSTs), which are virus-specific rather than allo-specific, offer the potential to mitigate GVHD, and data thus far from more than 300 allogeneic recipients have not produced GVHD. An analysis from an ongoing Phase 1/2 clinical trial of CD30.CAR EBVSTs in patients with CD30-positive lymphoma has demonstrated the therapy to be a well-tolerated and preliminary efficacious treatment for CD30+ lymphomas and may avert GVHD and immediate rejection even after multiple infusions.

Abstract Number: 3338 (Poster)
Abstract Title: Updated Results and Correlative Analysis of CHARIOT Trial: Autologous CD30.CAR-T-Cell Therapy in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma
Presenting Author: Sairah Ahmed, MD., Department of Lymphoma/Myeloma and Stem Cell Transplantation, MD Anderson Cancer Center, Houston, TX
Session Date: Sunday, Dec. 11, 6:00 PM-8:00 PM CT; Hall D
Abstract Summary:
Early results from the pilot segment of a Phase 2 trial of autologous CD30.CAR-T in patients with relapsed/refractory (r/r) classic Hodgkin Lymphoma (cHL) demonstrated a favorable safety profile and excellent anti-tumor responses of CD30.CAR-T. In an updated clinical and exploratory biomarker analysis, the therapy is shown to be well tolerated with no unexpected safety signal. Additionally, data suggest strong anti-tumor efficacy with an overall response rate of 73.3% in heavily pretreated r/r cHL patients, as well as good expansion and persistence after infusion.

Abstract Number: 984 (Podium)
Abstract Title: Ultrasensitive Circulating Tumor DNA (ctDNA) Dynamics after Autologous CD30.CAR-T-Cell Therapy for Relapsed or Refractory (r/r) Classical Hodgkin Lymphoma (CHARIOT Trial)
Presenting Author: David M. Kurtz, MD, Ph.D., Stanford University, Stanford, CA.
Session Date: Monday, Dec. 12, 2022, 5:45 PM CT; Hall E
Abstract Summary:
CHARIOT, a Phase 2 single-arm, multicenter study, is designed to investigate the safety and efficacy of CD30.CAR-T cells in cHL patients experiencing progression after at least 3 lines of therapy. In the pilot part of the study, ctDNA was analyzed as an exploratory biomarker using Foresight Diagnostics PhasED-Seq MRD assay at multiple time points, including at baseline (pre-treatment), Day 42 post-CD30.CAR-T infusion (D42), and upon progressive disease (PD). Based on ctDNA successfully genotyped directly from pre-treatment plasma in 12 patients, it was determined that ctDNA responses largely mirrored radiographic responses, suggesting that pre-treatment ctDNA levels could have predictive value on patient response to CAR-T therapy. From this, the researchers concluded that PhasED-Seq ctDNA analysis is a viable biomarker to monitor responses, rapidly risk stratify, and predict outcomes of patients with r/r cHL treated with CD30.CAR-T therapy.

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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