

Tessa Therapeutics Doses First Patient in Phase 1b Clinical Trial Investigating TT11 in Combination with Nivolumab for the Treatment of Relapsed/Refractory Classical Hodgkin Lymphoma (cHL)

Phase 1b clinical trial (ACTION) designed to evaluate TT11 as a potential second-line therapy

TT11, Tessa's autologous CD30-CAR-T therapy, is also being investigated as a monotherapy in the treatment of relapsed/refractory cHL

SINGAPORE – Aug 17, 2022 – [Tessa Therapeutics Ltd. \(Tessa\)](#), a clinical-stage cell therapy company developing next-generation cancer treatments for hematological malignancies and solid tumors, today announced the dosing of the first patient in a Phase 1b clinical trial investigating TT11, the company's autologous CD30 chimeric antigen receptor T-cell (CAR-T) therapy, in combination with Bristol Myers Squibb's nivolumab as a potential second-line treatment for patients with relapsed or refractory CD30-positive classical Hodgkin lymphoma (cHL).

The Phase 1b open-label trial (ACTION; NCT05352828) will enroll up to 14 patients with CD30+ cHL with relapsed or refractory disease after front-line therapy combining PD-1 antibody and CAR-T therapy in a "sandwich" study design. Patients will initially receive two cycles of nivolumab dosed at four-week intervals followed by lymphocyte depleting treatment with fludarabine/bendamustine chemotherapy. Patients will then receive a single infusion of TT11, followed by two additional cycles of nivolumab. The primary endpoint of the trial is safety and tolerability of the combination regimen. Secondary endpoints will evaluate key efficacy indicators including overall response rate, duration of response, and progression-free survival.

"Initiation of this Phase 1b clinical trial marks an important milestone for our autologous CD30.CAR-T program as we now have the opportunity to evaluate TT11 in combination with nivolumab as a potential second-line treatment for relapsed or refractory classical Hodgkin lymphoma," **stated John Ng, CTO and Acting CEO of Tessa Therapeutics.** "Data from our ongoing clinical program investigating TT11 as a monotherapy treatment for later lines of classical Hodgkin lymphoma has demonstrated the CAR-T therapy to be safe with promising measures of efficacy. We now welcome the opportunity to capitalize on this clinical progress by investigating TT11 as a second-line combination therapy, which offers the opportunity to greatly increase the patient population who could potentially benefit from this course of care."

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, a well-validated lymphoma target. Clinical data from the pilot part of the ongoing Phase 2 CHARIOT trial of TT11 presented at ASH demonstrated a favorable safety profile and promising efficacy in 14 evaluable patients with relapsed or refractory classical Hodgkin lymphoma (cHL), with a complete response (CR) rate of 57.1 percent and an overall response rate (ORR) of 71.4 percent. Tessa expects to advance to the pivotal Phase 2 CHARIOT trial later this year.

Nivolumab is a human IgG4 monoclonal antibody that blocks PD-1. It has been approved by the U.S. Food and Drug Administration (FDA) as a treatment for numerous cancer indications, including classical Hodgkin lymphoma.

"The current standard of care for relapsed or refractory classical Hodgkin Lymphoma is associated with short-term toxicities and long-term morbidity, with particularly poor tolerability noted among elderly patients," said **Dr. Ivan Horak, Chief Medical Officer and Chief Scientific Officer of Tessa Therapeutics.** "TT11, Tessa's CD30 CAR-T therapy, has demonstrated



encouraging clinical results as monotherapy, and we believe the combination with nivolumab has the potential to further enhance efficacy and provide patients with a chemotherapy-sparing, second-line treatment option.”

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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