# Tessa Therapeutics Receives PRIME Designation from European Medicines Agency for CD30 CAR-T Therapy

**BEDMINSTER N.J. and SINGAPORE – DAY January 2021 – Tessa Therapeutics (Tessa)**, a clinical-stage cell therapy company developing next-generation cancer treatments for hematological malignancies and solid tumors, today announced that the European Medicines Agency (EMA) has granted PRiority MEdicines (PRIME) designation to the company's lead autologous CD30 CAR-T therapy for the treatment of relapsed or refractory classical Hodgkin Lymphoma (R/R cHL).

PRIME is a program launched by EMA to optimize development plans and speed up evaluation of medicines that demonstrate major therapeutic advantage over existing treatments, or otherwise benefit patients without treatment options. Through this program, EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency.

"We are very pleased that EMA has acknowledged the potential Tessa's CD30 CAR-T therapy holds for patients with Hodgkin Lymphoma" **said Jeffrey H. Buchalter, President and CEO of Tessa Therapeutics.** "Having received RMAT designation from FDA during 2020, we now hope to work closely with regulatory agencies in both the United States and Europe to expedite clinical development and the registration path for this therapy."

The PRIME designation was granted by EMA on the back of promising clinical data from two Phase I/II trials in R/R cHL conducted at Baylor College of Medicine and University of North Carolina Lineberger Comprehensive Cancer Center. These studies showed complete disappearance of tumor in ~60% of patients at the highest dose level with none of the serious toxicities that can be associated with several other CAR-T therapies. These results were published in Journal of Clinical Oncology (Ramos et al., 2020). Based on these data, Tessa plans to commence a multi-center pivotal study in the United States during 2021.

Europe accounts for approximately a quarter of the world's Hodgkin Lymphoma incidence. Tessa's pivotal trial will be recruiting patients from more than 20 cancer centers across the US and Europe including sites in Italy, Spain and Sweden. "CD30 CAR-Ts demonstrated excellent safety and efficacy data in heavily pre-treated R/R cHL patients. We look forward to collaborating with Tessa to further validate these impressive results in the pivotal trial." **said Dr. Pier Luigi Zinzani, Institute of Hematology "Seràgnoli" University of Bologna, Italy**.

**Ivan D. Horak, M.D., Chief Medical Officer and Chief Scientific Officer of Tessa Therapeutics said** "CD30 CAR-T therapy, with its promising efficacy and very limited toxicity, can meaningfully address current gaps that exist in the treatment of R/R cHL. We also are exploring the potential of this therapy in CD30 positive subtypes of Non-Hodgkin Lymphoma (NHL)." Tessa's Phase 1 clinical study for patients with relapsed / refractory CD30 positive NHL is open for enrollment in the United States.

**About Tessa Therapeutics**

Tessa Therapeutics is a clinical-stage biotechnology company developing a portfolio of next-generation cell therapies for cancer. It has a pipeline of therapies in clinical development for the treatment of hematological malignancies and solid tumors.

Tessa's lead autologous therapy is in late-stage clinical development for treatment of lymphomas. It has shown strong clinical responses in patients with relapsed/refractory classical Hodgkin Lymphoma, based on which it was granted the RMAT designation by the U.S. FDA and the PRIME designation by EMA.

Tessa is also developing a novel, differentiated, allogeneic "off-the shelf" cell therapy platform, to create more efficacious, reliable, and scalable therapies capable of targeting a broad range of cancers. A therapy using this platform is being evaluated in an ongoing clinical trial in United States.

For more information on Tessa, please visit www.tessacell.com.

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