CITY OF HOPE AND CYTOIMMUNE ANNOUNCE STUDY DEMONSTRATING NOVEL OFF-THE-SHELF CHIMERIC ANTIGEN RECEPTOR (CAR) NATURAL KILLER (NK) CELL-BASED THERAPY AGAINST PANCREATIC CANCER

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- **Gastroenterology study demonstrates therapeutic efficacy of off-the-shelf CAR NK cell-based therapy targeting prostate stem cell antigen in human metastatic pancreatic cancer models**
- **Treatment showed no signs of systematic toxicity**
- **Research supports start of a clinical trial in 2022**

DUARTE, Calif. & TOA BAJA, Puerto Rico--(BUSINESS WIRE)--City of Hope, a world-renowned cancer research and treatment organization, and CytoImmune Therapeutics, a clinical-stage immunotherapy company that is developing a novel class of natural killer (NK) cell-based cancer therapies, today announced a study published in the high-impact journal Gastroenterology that demonstrates off-the-shelf anti-prostate stem cell antigen (PSCA) chimeric antigen receptor (CAR) NK cells significantly suppressed pancreatic cancer in vitro and in vivo using a method known as freeze-thaw.

The therapy — PSCA CAR_s15 NK cells, also known as CYTO NK-203 — persisted more than 90 days after infusion and significantly prolonged the survival of mice with pancreatic cancer, showing that the freeze-thaw method works. For the study, PSCA CAR_s15 NK cells were produced and then frozen. The cells were then thawed and used in preclinical studies at City of Hope.

“Our patients need additional ways to attack their pancreatic cancer. The work presented by City of Hope’s team is distinctive and promising for two reasons: First of all, it is based on a precision medicine approach that is a special target in the patient's pancreatic cancer — PSCA. Secondly, it is an immunologic approach, using human natural killer cells, which are specifically engineered to attack the patient's cancer. These findings should be accelerated to a clinical trial as rapidly as possible,” said Daniel D. Von Hoff, M.D., a distinguished professor in the Molecular Medicine Division of the Translational Genomics Research Institute (TGen), an affiliate of City of Hope. He also is senior consultant-clinical investigator at City of Hope and is one of the nation’s leading authorities on the treatment and care of pancreatic cancer patients.

“City of Hope is committed to finding more effective and innovative treatments for difficult-to-treat solid cancers, and pancreatic cancer is clearly one of them,” said Saul Priceman, Ph.D., assistant professor in the Department of Hematology & Hematopoietic Cell Transplantation at City of Hope and a study author. “These new PSCA CAR_s15 NK cell preclinical studies provide tremendous support for the anticipated upcoming clinical trials to evaluate efficacy and safety of this novel CAR-engineered NK cell therapy in patients with pancreatic cancer, which is a promising expansion of our existing clinical programs that target PSCA in solid cancers using CAR-engineered T cell therapy.”

Pancreatic cancer is the third leading cause of cancer-related death in the United States with a

five-year survival rate of approximately 10%. The cancer is typically detected when it is at a late stage and incurable. Chemotherapy or other therapies provide modest benefit. Therefore, the development of new therapies for pancreatic cancer is crucial. The therapy can also be used for other PSCA+ cancers, such as stomach and prostate.

NK cell technology works by using natural killer cells from a patient or donor. NK cells are then engineered so they express a receptor — a CAR — that is specific for a protein expressed by cancerous cells, along with the secretion of IL-15, which sustains the survival of the NK cells.

Christina Coughlin, M.D., CEO of CytoImmune Therapeutics, said, "We are excited to share this data on our CAR NK candidate for pancreatic cancer. This foundational data supports robust anti-tumor activity with CYTO NK-203, making us confident our innovative and off-the-shelf NK cell therapy approach has the potential to deliver more accessible, safe and effective cell-based treatment options to cancer patients. We are encouraged by these findings and look forward to continuing our work with City of Hope in order to move this initiative to the clinic."

This immunotherapy is revolutionizing the treatment of some blood cancers; however, its use in the treatment of solid tumors has been limited, in part because most of the proteins currently used to target CAR cells to solid tumors are present in low levels on other normal tissues, leading to toxic side effects.

Based on research by Michael Caligiuri, M.D., president of City of Hope National Medical Center and the Deana and Steve Campbell Physician-in-Chief Distinguished Chair, and Jianhua Yu, Ph.D., professor and director of the Natural Killer Cell Biology Research Program, who have nearly 55 years of collective laboratory investigation of NK cells, CytoImmune is developing an NK cell platform designed to overcome the limitations and challenges of current technologies for engineering NK cells. The platform is designed to generate an abundant supply of CAR NK cells from a single umbilical cord donor, engineered with the CAR for effective recognition of tumor targets, and secreting IL-15 to improve the persistence of CAR NK cells for sustained activity in the body. The process enables scientists to freeze, transport and store engineered CAR NK cells for off-the-shelf use for the treatment of cancer.

The study titled “Off-the-shelf PSCA-directed chimeric antigen receptor natural killer cell therapy to treat pancreatic cancer” can be found here.

About City of Hope

City of Hope is an independent biomedical research and treatment center for cancer, diabetes and other life-threatening diseases. Founded in 1913, City of Hope is a leader in bone marrow transplantation and immunotherapy such as CAR T cell therapy. City of Hope’s translational research and personalized treatment protocols advance care throughout the world. Human synthetic insulin, monoclonal antibodies and numerous breakthrough cancer drugs are based on technology developed at the institution. A National Cancer Institute-designated comprehensive cancer center and a founding member of the National Comprehensive Cancer Network, City of Hope is ranked among the nation’s “Best Hospitals” in cancer by U.S. News & World Report. Its main campus is located near Los Angeles, with additional locations throughout Southern California and in Arizona. Translational Genomics Research Institute (TGen) became a part of City of Hope in 2016. AccessHopeTM, a subsidiary launched in 2019, serves employers and their health care partners by providing access to NCI-designated cancer center expertise. For more information about City of Hope, follow us on Facebook, Twitter, YouTube or Instagram.

About CYTO NK 203

CYTO NK-203 is an off-the-shelf allogeneic CAR NK cell therapy derived from umbilical cord blood, expressing a CAR against prostate stem cell antigen and soluble IL-15 and engineered with proprietary features designed to improve the safety and efficacy of NK cells as a potential therapy.

About CytoImmune Therapeutics Inc.

Founded in 2017, CytoImmune Therapeutics is a clinical-stage biotechnology company, focused on developing an innovative and differentiated pipeline of NK cell therapies, using proprietary, robust and well characterized NK cell expansion and engineering technologies pioneered by Michael Caligiuri, M.D., and Jianhua Yu, Ph.D. The pipeline includes cytokine induced NK (CI-NK) for lung cancer, FLT3 CAR-NK for acute myeloid leukemia, PSCA CAR-NK cells for solid tumors and GPRC5D BiKE secreting BCMA CAR-NK cells for multiple myeloma. CytoImmune's lead product, CYTO-102 (CI-NK) cell therapy, aims to enter the clinic in combination with atezolizumab (anti-PD-L1 monoclonal antibody) for nonsmall cell lung cancer in 2022.

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