Invectys and CTMC announce FDA clearance of IND application for anti-HLA-G CAR-T cell therapy

FDA granted IND clearance for IVS-3001, Invectys's lead engineered anti-HLA-G CAR-T cell therapy, for the treatment of patients with solid tumors

HOUSTON, Texas, Dec 19, 2022 – Invectys, Inc. and CTMC, a joint venture between MD Anderson Cancer Center and National Resilience, Inc., today announced Food and Drug Administration (FDA) clearance of an Investigational New Drug (IND) application for a Phase 1/2a clinical study of IVS-3001, Invectys's lead engineered human leukocyte antigen A (HLA-G) targeting chimeric antigen receptor (CAR) T cell therapy for the treatment of solid tumors.

IVS-3001 has been developed in collaboration with CTMC as part of an agreement announced in 2022, and it will now move forward through an MD Anderson-sponsored trial led by principal investigator (PI) Aung Naing, M.D., professor of Investigational Cancer Therapeutics at MD Anderson and co-PI Samer Srour, M.D., assistant professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson. The planned first-in-human, single-arm, open-label, Phase 1/2a study will evaluate the safety, tolerability, pharmacokinetics, and clinical activity of IVS-3001 in patients with histologically or pathologically confirmed diagnosis of a locally advanced unresectable or metastatic HLA-G+ select solid tumor malignancy who failed or was intolerant to standard of care therapies known to confer clinical benefit per treating physician.

IVS-3001 may be administered to up to a total of 117 patients under approved protocol. Up to 24 may be treated in Phase 1 Dose Escalation and up to 93 may be treated in Phase 2a. All participants will be asked to enter the long-term follow up (LTFU) study as per FDA standard requirement for all gene and cell therapies. The IVS-3001 therapy for the Phase I trial will be manufactured by CTMC, which was launched to speed the development and manufacturing of innovative cell therapies for patients with cancer.

"CTMC was created to accelerate impactful cell therapies reaching patients," said Jason Bock, CEO of CTMC. "We are excited to partner with Invectys to move the HLA-G CAR-T from contract execution to IND safe-to-proceed, in less than a year."

"The FDA clearance of the IND application for IVS-3001 represents an important milestone for Invectys and our colleagues at CTMC, and it is the result of years of commitment to developing a novel class of engineered CAR-T therapy," said Praveen Tyle, Ph.D., CEO of Invectys. "We believe IVS-3001 therapy has the potential to significantly transform the treatment landscape for cancer patients and the potential to achieve improved clinical outcomes."

About IVS-3001

IVS-3001 is an HLA-G-targeting chimeric antigen receptor (CAR) T cell therapy. HLA-G is not only an immune checkpoint but also a tumor-specific antigen. The CAR construct consists of the HLA-G antigen-targeting domain fused to intracellular signaling domains. The CAR allows IVS-3001 to recognize and kill target cells which express HLA-G on the cell surface. Antigen-specific activation

of IVS-3001 results in CAR-T cell proliferation, cytokine secretion, and subsequent cytolytic killing of HLA-G-expressing cells.

IVS-3001 preclinical studies have generated adequate data to support efficacy and safety of the CAR-T therapy leading to IND clearance and initiation of First-in-Human clinical trial.

About Invectys

Invectys, transforming innovative immunotherapies to eradicate cancer, is a clinical stage immuno-oncology company spun-out of the world-renowned Pasteur Institute in Paris. Invectys has two wholly owned subsidiaries, Invectys, S.A. (Paris) which is focused on scientific research and innovation and Invectys USA, Inc. (Houston), whose lead product is the development of a first-in-human HLAG /CAR T initiative. Since 2010, Invectys has raised over $68 million in private funds to develop two innovative platforms of immunotherapy products which that target "universal" tumor antigens. Invectys has also received a grant of $14.2 million from the Cancer Prevention and Research Institute of Texas (Grant ID DP200034) to help fund it's HLA-G CAR T program.

About CTMC

CTMC – a joint venture between MD Anderson Cancer Center and Resilience – was created to accelerate the development and manufacturing of impactful cell therapies for patients with cancer. CTMC is uniquely positioned within the Texas Medical Center to provide therapies that begin and end with the patient. By leveraging the strengths of MD Anderson and Resilience we start clinical trials faster and provide a clear path to robust commercialization. Learn more at www.ctmc.com.

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