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MD Anderson and Obsidian Therapeutics announce FDA clearance of IND application for novel TIL therapy OBX-115

FDA granted IND clearance for OBX-115, Obsidian's lead engineered TIL therapy, for the treatment of patients with solid tumors

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HOUSTON and CAMBRIDGE, Mass. — The University of Texas MD Anderson Cancer Center and Obsidian Therapeutics, Inc. today announced Food and Drug Administration (FDA) clearance of an Investigational New Drug (IND) application for an MD Anderson-sponsored Phase I clinical study of OBX-115, Obsidian's lead engineered tumor infiltrating lymphocyte (TIL) therapy candidate.

OBX-115 has been developed in collaboration with MD Anderson as part of an agreement announced in 2020. The planned first-in-human single-arm, open-label, Phase I study will evaluate the safety and preliminary efficacy of OBX-115 as monotherapy in adult patients with metastatic melanoma who are relapsed or refractory to prior therapeutic regimens containing anti-PD-1 antibodies.

"There is a significant opportunity to improve the standard of care in melanoma, especially in later line patients and those who have not responded well to immune checkpoint therapies," said Rodabe Amaria, M.D., associate professor of Melanoma Medical Oncology at MD Anderson and principal investigator of the OBX-115 study. "Preclinical studies suggest OBX-115 has the potential to show efficacy in these patients, and OBX-115 does not require patients to receive concomitant IL2 therapy. We look forward to continuing our collaboration with Obsidian to advance this novel therapy for our patients in need of new treatment options."

The OBX-115 therapy for the Phase I trial is planned to be manufactured by CTMC, a joint venture between MD Anderson and National Resilience, Inc. CTMC was launched to speed the development and manufacturing of innovative cell therapies for patients with cancer. CTMC researchers, formerly part of MD Anderson's Therapeutics Discovery division, contributed to the early development of OBX-115.

"The FDA clearance of the IND application for OBX-115 represents an important milestone for Obsidian and our colleagues at MD Anderson, and it is the result of years of commitment to developing a novel class of engineered TILs," said Paul Wotton, Ph.D., CEO of Obsidian Therapeutics. "We believe OBX-115 therapy has the potential to significantly transform the

treatment landscape for patients, bringing broader access to TILs with the elimination of concomitant IL2 therapy, and the potential to achieve improved clinical outcomes."

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Disclosure
MD Anderson is implementing an Institutional Conflict of Interest Management and Monitoring Plan for any research related to this relationship.

About Obsidian Therapeutics
Obsidian Therapeutics, Inc. is a clinical biotechnology company pioneering engineered cell and gene therapies to deliver transformative outcomes for patients with intractable diseases. Obsidian's proprietary cytoDRiVE® technology provides a way to precisely control the timing and level of protein function by using FDA-approved small molecules. Obsidian is headquartered in Cambridge, Mass. The Company has collaborations with Bristol Myers Squibb and Vertex Pharmaceuticals. For more information, please visit www.obsidiantx.com and follow us on LinkedIn and Twitter.

About MD Anderson
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 53 comprehensive cancer centers designated by the National Cancer Institute (NCI).
MD Anderson is No. 1 for cancer in U.S. News & World Report's "Best Hospitals" rankings. It has been named one of the nation's top two hospitals for cancer since the rankings began in 1990. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).