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WindMIL Therapeutics Announces FDA Clearance of Investigational New Drug (IND) Application for Phase 2 Study of Marrow Infiltrating Lymphocytes (MILs™) in Non-Small Cell Lung Cancer

June 25, 2019

BALTIMORE, MD AND PHILADELPHIA, PA – June 25, 2019 – WindMIL Therapeutics, a clinical-stage company developing marrow-infiltrating lymphocytes (MILs™) for cancer immunotherapy, announced today that it has been cleared by the U.S. Food and Drug Administration (FDA) to proceed with its Phase 2 study of MILs as a potential treatment for patients with non-small cell lung cancer (NSCLC) who have progressed on an anti-PD-1 containing regimen. The clearance was received following WindMIL's submission of an investigational new drug (IND) application for this program.

"The FDA's clearance of this IND application is an important milestone for WindMIL, as it allows us to move directly into a Phase 2 study in a key solid tumor indication," said Donald Hayden, Jr., chairman and chief executive officer of WindMIL. "We believe that MILs have broad therapeutic potential in the solid tumor setting and we are excited to initiate those efforts in NSCLC, where significant unmet medical need exists for patients who were refractory to, or have relapsed on, an anti-PD-1 containing regimen."

Lung cancer is the leading cause of cancer death in the United States, with more people dying annually of lung cancer than of colon, breast and prostate cancers combined. Moreover, approximately 80-85% of lung cancer diagnoses are NSCLC.

WindMIL's study will examine the safety and efficacy of MILs combined with a PD-1 inhibitor in patients with advanced unresectable and metastatic NSCLC who were refractory to, or have relapsed on, an anti-PD-1 containing regimen. The trial's primary endpoint is overall response rate (ORR). WindMIL plans to expand the study if sufficient activity is achieved, as well as open additional cohorts of patients. WindMIL intends to initiate the clinical study at several leading medical centers in the fourth quarter of 2019.

The bone marrow is a unique niche in the immune system to which antigen-experienced memory cells traffic and are then maintained. WindMIL has developed a proprietary process to select, activate and expand these memory T cells into MILs. Because memory T cells in bone marrow occur as a result of the immune system's recognition of tumor antigens, MILs are specifically suited for adoptive cellular immunotherapy and are able to directly eradicate or facilitate eradication of each patient's unique cancer.

The planned Phase 2 study of MILs in NSCLC builds on clinical results already observed in high-risk multiple myeloma (MM). A 25-patient Phase 1 study of MILs in high-risk MM produced a 59% overall response rate, with 32% of patients experiencing a complete response, and found MILs to have a favorable safety profile. A 90-patient randomized multi-center Phase 2 trial in high-risk MM is also now fully enrolled.

In addition, WindMIL is initiating collaborations with multiple academic centers to explore the feasibility of activating and expanding MILs in patients with other solid tumors, and eventually studying safety and efficacy of MILs in those indications.

About WindMIL Therapeutics
WindMIL Therapeutics is a clinical-stage company developing a novel class of autologous cell therapies based on marrow infiltrating lymphocytes (MILs™) for

cancer immunotherapy. As the leader in cellular therapeutics emanating from bone marrow, WindMIL translates novel insights in bone marrow immunology into potentially life-saving cancer immunotherapeutics for patients. WindMIL believes that Cell Source Matters™ and the company's proprietary process to extract, activate and expand these cells offers unique immunotherapeutic advantages, including inherent poly-antigen specificity, high cytotoxic potential, and long persistence. For more information, please visit: https://windmiltherapeutics.com.

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