

# Treadwell Therapeutics Announces Fast Track Designation Granted by the FDA to CFI-400945 for the Treatment of Acute Myeloid Leukemia

## Description

NEW YORK and HONG KONG, April 26, 2022 /PRNewswire/ — Treadwell Therapeutics, a clinical-stage biotechnology company developing novel medicines for unmet needs in cancer, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to CFI-400945, a first in class inhibitor of Polo-like kinase 4 (PLK4), for the treatment of adult patients with relapsed or refractory Acute Myeloid Leukemia (AML).

“Although several exciting new classes of medicines have emerged in the past decade for patients with AML, there still remains an unmet need for certain patient segments, where survival rates remain low,” said Dr. Michael Tusche, Treadwell co-CEO. “CFI-400945, has shown encouraging signs of monotherapy activity in AML patients with adverse cytogenetics. We are grateful for the Fast Track Designation for this exciting program, and look forward to frequent interactions with the FDA to chart our regulatory path forward, as we continue the development of ‘945 in leukemia.”

Fast Track designation seeks to streamline the development and accelerate the review of new agents with potential to treat serious or life-threatening diseases and that potentially address an unmet medical need. Drugs that are granted this designation can have more frequent interactions with the FDA, as well as potential pathways for expedited approval.

## About AML

AML is a disease characterized by uncontrolled proliferation of malignant clonal hematopoietic stem cells which can lead to anemia, neutropenia, and thrombocytopenia. If left untreated, AML can lead to death within weeks. In the US, an estimated 19,940 new cases of AML were expected to be diagnosed and approximately 11,180 deaths attributed to AML, nearly all in adults. AML is generally a disease of the elderly with an average age of 68 years at the time of diagnosis and is more common in men than women. For adults 65 years of age.

## About Treadwell Therapeutics

Treadwell Therapeutics is a clinical-stage multi-modality oncology company developing novel medicines to address unmet needs in patients with cancer. The Company’s robust, internally developed clinical pipeline includes CFI-400945, CFI-402257 (TTK inhibitor) and CFI-402411 (HPK1 inhibitor). Treadwell also has a robust pre-clinical pipeline with multiple biologic and next generation TCR based autologous cell therapy programs. For more information, please visit [www.treadwelltx.com](http://www.treadwelltx.com).

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