

Treadwell Therapeutics Announces a Presentation at the 2023 ASH Annual Meeting and Advisory Board Meeting

Description

TORONTO and SAN MATEO, Calif., Dec. 15, 2023 (GLOBE NEWSWIRE) — Treadwell Therapeutics, a clinical-stage biotechnology company developing novel first-in-class medicines for unmet needs in cancer, today announced a presentation for the Company's lead program, CFI-400945, a first-in-class inhibitor of Polo-like Kinase 4 (PLK4) being advanced in relapsed/refractory AML, at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition being held from December 9-12, 2023. Treadwell also conducted a clinical advisory board meeting on December 10th at ASH with experienced experts in the treatment of AML and in clinical trials of novel agents, which included current investigators and thought leaders new to the program.

"CFI-400945 is demonstrating complete remissions as a single agent and in combination with azacitidine in relapsed, adverse risk AML, including those with *TP53* mutant disease. As we optimize dose and schedule, we are encouraged by the data with this oral dosing regimen," said Principal Investigator and Advisory Board Co-Chair Dr. Gautam Borthakur, MD, Professor, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. "The advisory board confirmed the enthusiasm about the data to date in the relapsed AML setting, in particular with *TP53* mutant disease and look forward to working with Treadwell to advance and shape this program."

"CFI-400945, our lead program and first-in-class PLK4 inhibitor, represents an opportunity to address a substantial unmet in relapsed/refractory AML, including *TP53* mutant AML," said Roger Sidhu, MD, Acting CEO at Treadwell Therapeutics. "We look forward to advancing the program into key dose expansion studies in monotherapy and in combination in 2024 with a view to initiating pivotal studies in 2025."

2023 ASH Poster Presentations and Details:

Title: Preliminary Results from a Phase 1b/2 Open-Label, Multicenter, Dose Optimization Clinical Study of the Safety, Tolerability, and Pharmacokinetic (PK) and Pharmacodynamic (PD) Profiles of CFI-400945 As a Single Agent or in Combination with Azacitidine in Patients (Pts) with Acute Myeloid Leukemia, Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia (TWT-202)

Session Name: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster III

Publication Number: 4294

Session Date: Monday, December 11, 2023

Presentation Time: 6:00 PM – 8:00 PM

Location: San Diego Convention Center, Halls G-H

CFI-400945 has been generally well tolerated in this difficult to treat patient population, including patients whose disease has progressed on or following venetoclax based therapies?.

Three of 6 evaluable patients with AML achieved a response (MLFS=2, CRi=1 with MRD+) at the 96mg dose?. After this data cut, one additional MLFS response (end of cycle 1) and two additional CRs (end of cycle 2) were seen in two patients treated with 80 mg + azacitidine combination

cohort and became transplant eligible (*PI communication*)?. PK characteristics support daily dosing of CFI-400945 and PD studies are ongoing?. Dose expansions are planned and enrollment continues?.

About Treadwell Therapeutics

Treadwell Therapeutics is a clinical-stage oncology company developing novel medicines to address unmet needs in patients with cancer. The Company's robust, internally developed clinical pipeline includes CFI-400945 (PLK4 inhibitor), CFI-402257 (TTK/Mps1 inhibitor) and CFI-402411 (HPK1 inhibitor). Treadwell also has a broad pre-clinical pipeline with multiple biologic and next generation TCR based autologous cell therapy programs. For more information, please visit www.treadwelltx.com.

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