Treadwell Therapeutics Announces US FDA Clearance of IND Application for Phase 2 Study of TTK inhibitor, CFI-402257

Description

New York and Hong Kong â?? November 30th, 2021 â?? Treadwell Therapeutics, a clinical stage biotechnology company developing novel therapeutics for highly aggressive cancers, today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application to evaluate CFI-402257, an oral, first-in-class inhibitor of Threonine Tyrosine Kinase (TTK, also as MPS1) in advanced solid tumors and breast cancer.

â??TTK is a critical component of the Spindle Assembly Checkpoint and potentially represents a tumor specific vulnerability. Pharmacologic inhibition of TTK using CFI-402257 causes tumor cells to prematurely exit mitosis, leading to increased genomic instability and cell death,â?• said Dr. Mark Bray, Treadwell Chief Scientific Officer and Co-Founder. â??CFI-402257 was developed from concept to clinic by our world class team. Preclinical studies and emerging clinical evidence support the use of CFI-402257 in the context of CDK4/6 inhibitor failure in ER+/Her2- breast cancer, a segment where there is a strong unmet need. We are excited by the promise of the molecule in advanced breast cancer and beyondâ?• added Dr. Michael Tusche, Treadwell co-Chief Executive Officer.

Under this IND, Treadwell intends to initiate a Phase 2 clinical trial of CFI-402257 in the first quarter of 2022. This clinical trial is designed to confirm previously efficacious doses and to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of CFI-402257 as a single agent in advanced solid tumors, and in combination with fulvestrant in patients with ER+/HER2- advanced breast cancer after disease progression on prior CDK4/6 inhibitor and endocrine therapy. Start-up activities are currently underway.

CFI-402257 is a highly bioavailable, potent and selective inhibitor of TTK. Preclinical studies showed robust inhibition of tumor growth in a wide variety of xenograft models. CFI-402257 also demonstrated durable activity and a manageable safety profile as a single agent and in combination with fulvestrant in advanced ER+ breast cancer in studies conducted at select Canadian sites.

About Treadwell Therapeutics

Treadwell Therapeutics is a science driven, clinical-stage, multi-modality biotechnology company spun out of the University Health Network (UHN) in Toronto. The company is developing first-in-class and best-in-class medicines to address unmet needs in patients with cancer. Founded by a cadre of pre-eminent scientific luminaries, including Dr. Tak W. Mak, the Companyâ??s robust, internally developed clinical pipeline includes CFI-400945 (PLK4 inhibitor), 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 cell therapy programs. For more information, please visit www.treadwelltx.com.

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