Treadwell Therapeutics Announces Fast Track Designation Granted by the FDA to CFI-402257 for the Treatment of ER+/HER2- Breast Cancer

Description

NEW YORK, Jan. 10, 2023 /PRNewswire/ — Treadwell Therapeutics, a clinical-stage biotechnology company, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to CFI-402257, a best in class inhibitor of Threonine Tyrosine Kinase (TTK, also known as Mps1), for the treatment of adult patients with ER+/HER2- advanced breast cancer after disease progression on prior CDK4/6 inhibitors and endocrine therapy, both as a monotherapy and in combination with fulvestrant.

“There is an urgent need for new, safe and efficacious therapies to treat ER+/HER2- breast cancer, particularly when standard of care regimens fail,” said Dr. Mark Bray, Treadwell CSO and Co-founder. “CFI-402257 has shown early signs of durable activity with a manageable safety profile, as a monotherapy and in combination with fulvestrant in ER+/HER2- breast cancer patients that have failed CDK4/6 inhibitors. We are thankful for the Fast Track Designation granted by the FDA and look forward to the continued development of CFI-402257 in ER+/HER2- breast cancer.”

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 ER+/Her2- Breast Cancer

Globally, breast cancer is the world’s most prevalent cancer and the 2nd leading cause of cancer death in women in many countries. The ER+/HER2- subtype is the most common subtype of breast cancer, accounting for 68% of all breast cancer types, with nearly 1.2 million women living with the disease in the US alone. Standard of care for ER+ patients is CDK4/6 inhibitors in combination with endocrine therapies, which have been very successful in prolonging survival for this patient population. However, resistance to this treatment occurs within a median of 2 years. As a result, the ER+ population resistant to this standard of care is growing and is an unmet medical need requiring new treatment options.

About Treadwell Therapeutics

Treadwell Therapeutics is a science driven, clinical-stage, multi-modality biotechnology company developing first-in-class and best-in-class medicines to address unmet needs in patients with cancer. The Company’s internally developed clinical pipeline includes CFI-400945, CFI-402257 (TTK inhibitor) and CFI-402411 (HPK1 inhibitor). The company is also advancing a pre-clinical pipeline of first-in-class antibody and TCR-based cell therapy assets. For more information, please visit www.treadwelltx.com.

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