

## [CCTG Announces Initiation of IND.239](#)

Submitted by shawn on Thu, 08/13/2020 - 12:58 A Phase 2 Study of CFI-400945 and Durvalumab in Patients with Advanced/Metastatic Triple Negative Breast Cancer  
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The Canadian Cancer Trials Group (CCTG) has announced the commencement of a Phase II study of CFI-400945, an oral, first-in-class inhibitor of Polo-like Kinase 4 (PLK4) in combination with durvalumab, a PD-L1 checkpoint inhibitor, in patients with advanced or metastatic triple negative breast cancer (TNBC). “Immunotherapy in combination with chemotherapy has shown promise in this disease; however, non-chemotherapy combinations which avoid those toxicities and may have activity in the chemorefractory setting are of particular interest,” says Study Co-Chairs Dr. David Cescon, medical oncologist at Princess Margaret Cancer Centre (PMCC), and Dr. Andrew G. Robinson of the Department of Oncology, Queen’s University.

“This is the third phase 2 clinical study sponsored by CCTG involving Treadwell Therapeutics compounds. The others included patients with breast or prostate cancer. The phase 1 clinical trial of CFI-400945 demonstrated antitumor activity, while non-clinical studies conducted at the PMCC showed activity of CFI-400945 in TNBC models, which appears to be increased in immune competent models in combination with checkpoint blockade,” said Dr. Lesley Seymour, Director of CCTG’s Investigational New Drug Program and medical oncologist in the Department of Oncology at Queen’s University. The study is supported as part of the CCTG/AstraZeneca collaboration with CFI-400945 provided by Treadwell Therapeutics.

This multi-center, single-arm, open-label phase 2 trial is designed to assess the efficacy of CFI-400945 given with durvalumab in patients with treatment-resistant TNBC. The primary endpoint is objective response rate. Secondary endpoints include disease control rate, immune-related response rate, safety and tolerability, and correlative studies, including cfDNA analyses.

Initially, participating centers will include the PMCC, the Ottawa Hospital Research Institute, and Kingston Health Sciences Centre. For additional information about the study, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (search identifier NCT04176848).

## **About CFI-400945**

CFI-400945 is a first-in-class, oral selective and potent inhibitor of Polo-like Kinase 4 (PLK4), which regulates centriole duplication and thus mitotic progression. PLK4 is overexpressed in a variety of solid tumors and elevated expression is associated with poor clinical outcomes. Depletion of PLK4 expression in cancer cells by RNA interference leads to mitotic defects and cell death. PLK4 was identified as a drug target based on functional screening to identify vulnerabilities of genomically unstable breast cancers.

Anti-tumor activity of CFI-400945 has been shown in mice bearing human cancer xenografts, including robust tumor growth inhibition and durable tumor regression in primary tumor xenografts from breast cancer.

## **About Treadwell Therapeutics**

Treadwell Therapeutics is a clinical-stage oncology company exploiting cancer cells' vulnerabilities to develop first-in-class and best-in-class small molecules to address unmet needs in patients with cancer.

The Company's robust, internally developed pipeline includes a first-in-class PLK4 kinase inhibitor, CFI-400945 and a potentially best in class TTK inhibitor, CFI-402257 in Phase 2 studies, and CFI-402411, an oral immunomodulatory kinase inhibitor with activity toward HPK1, in Phase 1/2 studies. For more information, please visit [www.treadwelltx.com](http://www.treadwelltx.com).

## **About Canadian Cancer Trials Group (CCTG)**

Celebrating its 40th year, the Canadian Cancer Trials Group (CCTG) is a cancer clinical trials research cooperative that runs phase I-III trials to test anti-cancer and supportive therapies in over 80 institutions across Canada and internationally. From its operations centre at Queen's University, CCTG has led and participated in over 500 trials in over 40 countries aimed at improving survival and quality of life for all people with cancer. CCTG is a national program of the Canadian Cancer Society that provides core funding for the Group. To learn more about the CCTG, go to [www.ctg.queensu.ca](http://www.ctg.queensu.ca).