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Circulating Tumor DNA (Ct DNA) as a Biomarker in High-Grade Gastroenteropancreatic Neuroendocrine Tumor

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BACKGROUND: In the last few decades, the incidence of high-grade gastroenteropancreatic neuroendocrine tumors (GEP-NET) has increased. Patients with high-grade GEP-NETs are generally treated with cytotoxic chemotherapy with a poor prognosis. This emphasizes the need for identifying biomarkers that predict response to treatment. Over the past few years, circulating tumor DNA (Ct DNA) has emerged as an important diagnostic and predictive tool in different solid tumors. Our primary objective is to investigate if Ct DNA can be used as a predictive biomarker for treatment response in high-grade GEP-NET patients.

METHODS: Patients will be recruited from a non-randomized, single-arm, phase 2 clinical trial evaluating the efficacy of nanoliposomal irinotecan with fluorouracil and folinic acid in refractory advanced high-grade GEP-NETs. Our planned enrollment is 37 patients over 2 years. Blood will be collected from each patient at three different time points: at baseline, after the first cycle of combination chemotherapy, and at 6 months or at disease progression, whichever occurs first. Collected blood will be sent for FoundationOne Liquid assay for Ct DNA assessment. The liquid assay identifies base substitutions, indels copy number alterations, and rearrangements in 70 commonly altered oncogenes. Ct DNA will be measured by quantification of Mutant Allele Fraction (MAF). To compare MAF pre- and post-therapy, a paired t-test will be used.

A multivariate Cox proportional hazards regression analysis will be performed to correlate changes in MAF with progression-free survival and overall survival. All tests are two-sided and will be performed at a nominal significance level of 0.05.

RESULTS: As of June 25, 2020, four patients have been enrolled.

CONCLUSION: ClinicalTrials.gov Identifier: NCT03736720.

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