2018 Annual AACR Meeting
Session: Clinical Research; Liquid Biopsy 5
Abstract 5597, Poster Board 29

TargetSelector™ CTC technology demonstrates clinical utility in monitoring treatment response in germ cell tumors (testicular cancer)

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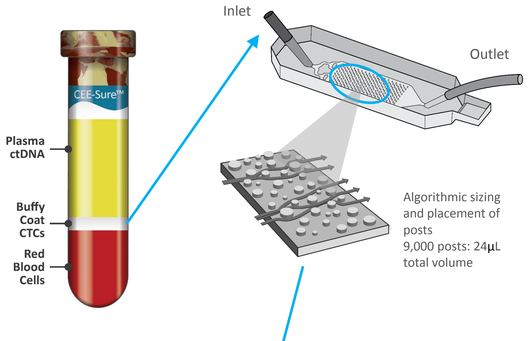
Background

Liquid biopsy has recently emerged as a minimally invasive and cost effective means to assess for disease burden and cancer biomarkers. Using a simple blood draw, circulating tumor cell (CTC) analysis is capable of providing information with implications for diagnosis, prognosis, and aid in treatment decisions of various cancers. Serial CTC measurements can aid in monitoring disease progression or response to therapy. Biocept's proprietary TargetSelector™ technology captures CTCs and provides assessment of enumeration, gene amplifications or translocations via FISH, and protein expression by immunofluorescence. There is limited data on clinical utility of CTCs in germ cell tumors (GCT). We are studying correlation of clinical responses with CTCs in patients with refractory GCT in an ongoing clinical trial of brentuximab vedontin and bevacizumab in refractory CD 30+ GCT (NCT02988843). CTC enumeration is being done at baseline, prior to cycle 3 of treatment, and at progression to monitor treatment response in blood from patients with refractory GCT, to supplement clinical response data.

Methods

Peripheral whole blood samples from refractory testicular cancer patients are collected into Biocept CEE-Sure™ blood collection tubes that are validated to preserve CTCs for up to 96 hours. Biocept's TargetSelector™ platform utilizes a proprietary antibody capture cocktail and microfluidic channel enabling enrichment, enumeration, and CTC biomarker analyses which were performed at Biocept's CLIA-certified and CAP accredited laboratory.

Target Selector™ CTC Analysis Workflow



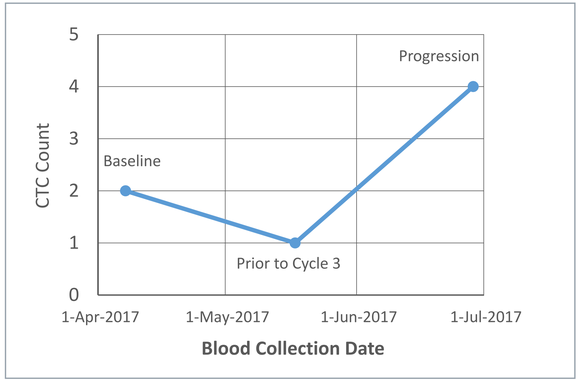
IF = Immunofluorescence
FISH = fluorescence in situ hybridization

Results

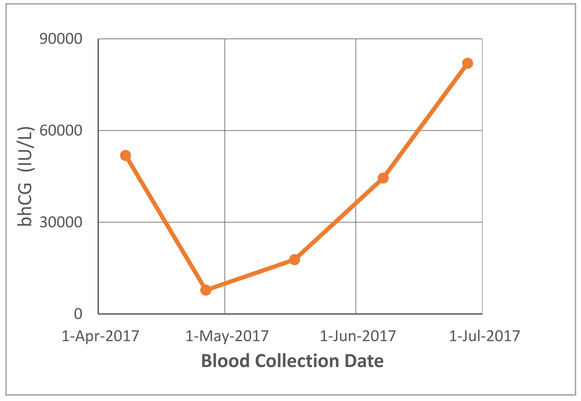
Serial blood collections from a heavily pretreated refractory testicular cancer patient were obtained for CTC analyses at:

- Baseline
- Prior to Cycle 3 (approximately six week interval)
- Progression (after cycle 4)

CTC Enumeration



Tumor Marker
Beta-Human Chorionic Gonadotrophin



CTC Count During Course of Therapy

CTC enumeration by the TargetSelector™ CTC platform reflects correlation with clinical response and progression:

- Decreased CTC count prior to treatment Cycle 3 corresponded to beta human chorionic gonadotrophin (bhCG) tumor marker response and CT scan showing stable disease.
- Increased CTC count at progression after Cycle 4 corresponded to increase in bhCG tumor marker data and progression on CT scan.

Conclusions

- Clinical application of Biocept's TargetSelector™ CTC technology enables the sensitive detection of CTCs in GCT, a rare disease with limited data related to the role of CTCs.
- Longitudinal CTC assessment implemented in the clinical setting can be used to assess response to treatment in GCT, a rare disease, as well as other cancers.
- The TargetSelector™ liquid biopsy platform provides an economical, non-invasive, and reliable means to arm physicians with valuable information for disease management and patient care.
- Ongoing collection of blood samples and data analysis from patients being enrolled on the study will provide a better understanding of the potential clinical use of this novel technology in GCT patients.

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