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Supplemental Appendix for:
Attrition of Patients on a Precision Oncology Trial: Analysis of the I-PREDICT Experience
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SUPPLEMENTAL: MATERIALS AND METHODS

I-PREDICT Trial

The I-PREDICT trial is a prospective navigational trial that included subgroups with metastatic or locally advanced unresectable disease that were treatment naïve, albeit with lethal cancers, and patients who had exhausted treatment in the metastatic or unresectable setting.

Participants

To be eligible for the I-PREDICT trial, pertinent inclusion criteria included: (a) age ≥18 years; (b) incurable malignancy that was treatment naïve and with ≥50% 2-year mortality, or previously treated metastatic disease that had failed standard therapies or had no standard therapy; (c) measurable disease on cross-sectional imaging; (d) Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 [S1] and New York Heart Association Functional Class of I-II [S2]; (e) adequate end-organ (including bone marrow, liver and kidney) function; (f) able to swallow; (g) a negative pregnancy test for fertile women; and (h) no severe or uncontrolled medical disorder, for example, uncontrolled infection, diabetes, lung disease, psychiatric disorder, or kidney disease. The database was locked on September 26, 2017.

Molecular Profiling

Next-generation sequencing was performed using Foundation Medicine on blood and/or tissue (FoundationOne™, FoundationOne Heme™ and FoundationACT, Cambridge,

Massachusetts, http://www.foundationmedicine.com) (clinical-grade, Clinical Laboratory Improvement Amendments (CLIA)-certified). The FoundationOne™ tissue assay interrogates 236 to 405 genes. All 4 classes of genomic alterations (base substitutions, deletions and insertions, rearrangements, and copy number alterations) are recognized. FoundationACT is a blood-derived circulating tumor DNA assay that identifies 62 clinically pertinent genomic alterations.

Data Analysis

Comparisons of characteristics between groups were made by using the two-sample Pearson's chi-square test, Student's *t*-test, and Aspin-Welch *t*-test. Univariable and multivariable analyses with binary logistic regression modelling evaluated patient characteristics as independent predictors of inevaluable status. The subgroup of evaluable patients with previously treated metastatic or advanced cancers from the two study sites has been published [10]. The current analysis examines inevaluable patients derived from all consecutively enrolled patients in both the treatment-naïve and previously treated cohorts at the UC San Diego Moores Cancer Center.

Definition of Inevaluable Patients

Patients were considered "inevaluable treated" for the following reasons: (a) treated but early lost to follow-up ($\leq$10 days post therapy initiation); (b) received an oral drug daily for $\leq$10 days; (c) received less than 2 doses of an intravenous drug; (d) on trial for $\leq$10 days before death; (e) received inconsistent/intermittent treatment; (f) signed consent but then failed eligibility criteria for treatment upon protocol work up (but received a therapy of some type); (g) therapy was initiated over 6 months after consent; and (h) molecular profiling failed but the

patient received a treatment of some type. Patients were considered "inevaluable untreated" for the following reasons: (a) never received any treatment after signing consent and over 6 months had elapsed from consent, if they were still alive; (b) died without receiving treatment; and (c) patient refused treatment after initially consenting to the study. Patients who were not yet treated and for whom 6 months had not yet elapsed since consent were classified as "awaiting treatment." Patients awaiting treatment were not included in the analysis of inevaluable patients.

Supplemental References

S1. Oken MM, Creech RH, Tormey DC et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol 1982;5:649-655.

S2. NHFA CSANZ Heart Failure Guidelines Working Group, Atherton JJ, Sindone A et al. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand: Guidelines for prevention, detection, and management of heart failure in Australia 2018. Heart Lung Circ 2018;27:1123-1208.