e12513 **Publication Only**

The Breast Cancer Index Registry Study: Initial analysis of the first 1,000 patients.

Joyce O'Shaughnessy, Carlos A. Encarnacion, Brandon O'Neal, Jenna Wong, Natalia Siuliukina, Tara B. Sanft, Rachel Catherine Jankowitz, Mark D. Pegram, Kai Treuner, Jenny R. Fox; Baylor University Medical Center, Texas Oncology, US Oncology Network, Dallas, TX; Texas Oncology-Waco, US Oncology, Waco, TX; Biotheranostics, A Hologic Company, San Diego, CA; Yale School of Medicine, New Haven, CT; University of Pittsburgh Medical Center, Pittsburgh, PA; Stanford Women's Cancer Center, Stanford, CA; Rocky Mountain Cancer Center, Boulder, CO

Background: The Breast Cancer Index (BCI) is a gene expression-based biomarker that reports two results: BCI Predictive [BCI (H/I)], which predicts benefit from extended endocrine therapy (EET), and BCI Prognostic, which combines the Molecular Grade Index (MGI) with BCI (H/I) to provide individualized risk of both late (5-10 years) and overall (0-10 years) distant recurrence. The NCCN clinical practice guideline recommends use of BCI for prediction of benefit from EET in early stage, hormone receptor positive (HR+) breast cancer patients. **Methods:** The BCI Registry study was designed to prospectively evaluate the long-term clinical outcome, medication adherence and quality of life in HR+ early-stage breast cancer patients receiving BCI testing as part of routine clinical care. The BCI registry will enroll approximately 3,000 patients after completion of 4-7 years of primary adjuvant endocrine therapy. Patients will be followed for disease recurrence for at least 10 years from diagnosis. Patients extending endocrine therapy will be assessed annually for medication adherence. To evaluate the impact of BCI results on EET decision making, both the physician and patient will complete Decision Impact Questionnaires. Clinicopathological data are collected within the ClinCapture electronic data capture system. The BCI Registry Study is registered on ClinicalTrials.gov under NCT04875351. **Results:** The BCI Registry Study completed enrollment of the first 1,000 patients in January 2022. Clinical data were available for 942 patients (76.8% T1; 51.3% grade II; 75.4% N0). BCI test results were reported for 842 patients. 315 patients (37.4%) were classified as BCI (H/I)-High and 527 patients (62.6%) as BCI (H/I)-Low. Further, in node-negative (N0) patients, BCI classified 314 N0 patients (47.9%) with high risk for late distant recurrence and 342 patients (52.1%) with low risk. In node-positive (N1) patients, BCI classified 138 patients (74.2%) as high risk for late distant recurrence and 48 patients (25.8%) as low risk. The associated clinicopathological factors are shown in the table. **Conclusions:** The analysis of the first 1,000 BCI Registry patients confirms the expected distribution of clinicopathological factors. BCI by H/I status and prognostic risk groups are consistent with previous clinical validation studies. Clinical trial information: NCT04875351. Research Sponsor: Biotheranostics, Inc.

	All Patients (N=942)
Tumor size	
T1	723 (76.8%)
T2	201 (21.3%)
T3	13 (1.4%)
Unknown	5 (0.5%)
Tumor grade	
Well differentiated	268 (28.5%)
Moderately differentiated	483 (51.3%)
Poorly differentiated	188 (20.0%)
Unknown	3 (0.3%)
Nodal status	
N0	710 (75.4%)
N1	222 (23.6%)
Unknown	10 (1.1%)