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MD Anderson Cancer Center and Biocept, Inc. Study Reveals HER2+ CTCs and DTCs in Patients with HER2- Tumors by Tissue Analysis

San Diego, California – Biocept, Inc., a privately-held, CLIA certified laboratory testing company focused on detection and analysis of circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA) in cancer patients, reported the publication in the journal *Cancer Medicine* of a paper entitled “Discordance in HER2 gene amplification in circulating and disseminated tumor cells in patients with operable breast cancer” on research performed with collaborators from the University of Texas MD Anderson Cancer Center. One of the key findings of the research was the demonstration that greater than 20% of studied patients classified as HER2- by analysis of their tumors by standard methods were shown to have HER2+ CTCs in blood and/or disseminated tumor cells (DTCs) in bone marrow as determined by fluorescence in situ hybridization (FISH).

In this study, peripheral blood and bone marrow samples were collected prospectively from patients who were candidates for surgery with clinical stage I-IV breast cancer. Samples were processed and analyzed using Biocept's proprietary Cell Enrichment and Extraction (CEETM) microfluidic platform. CTCs and DTCs were captured using an antibody capture “cocktail” that targeted cells expressing EpCAM as well as other tumor- associated antigens. FISH was performed on all captured cells, focusing on those that were negative for staining with anti-CD45 antibodies, to eliminate nucleated immune cells from the analysis. As a consequence, CTCs identified in blood were either cytokeratin positive (CK+)/CD45-, or CK-/CD45- and HER2+.

Farideh Bischoff, Ph.D., Vice President of Translational Research at Biocept and an author on the paper, said, “This study was interesting because it involved a large number of early stage breast cancer patients, and looked at matched blood and bone marrow samples in comparison to tumor tissue. We demonstrated what has been suggested in other studies, that there can be discordance of HER2 status between tumor tissue and CTCs or DTCs in the same patient, and even discordance between CTCs and DTCs when samples are taken at the same time. The relatively high number of HER2+ CTC or DTC determinations for patients classified as HER2- was surprising. One conclusion is that a more comprehensive analysis, involving several sample types, may be necessary to appropriately characterize breast cancer patients, and enable selection of therapies most suited to their particular cancer. Regardless of the tissue source, cells with an amplified HER2 gene need to be considered carefully.”