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## **Biocept and Clariant Announce Collaboration on First Test for Circulating Tumor Cells and HER2 status in Breast Cancer Patients**

San Diego, California: Biocept, Inc., a privately-held CLIA-certified laboratory testing company, focused on the detection and analysis of circulating tumor cells (CTCs) in cancer patients, and Clariant, Inc. (a GE Healthcare Company) today announced a collaboration on the commercialization of a proprietary blood test for CTCs in breast cancer patients, which includes the determination of HER2 status. Clariant and Biocept will market and sell Biocept's new OncoCEE<sup>®</sup>BR<sup>™</sup> CTC test to community hospitals, pathologists and medical oncologists. Biocept will perform the test in its laboratories, and results will be interpreted by Clariant's highly respected pathology group (Clariant Pathology Services, Inc). The test includes CTC enumeration and HER2 status of the detected CTCs by fluorescence in situ hybridization (FISH); it is the first commercially available CTC test to include analysis of a specific treatment-associated biomarker.

David Hale, Executive Chairman of Biocept, said, "We are very excited about this collaboration with Clariant, and feel there is real synergy between our two companies. We believe the combination of the technical advantages of the OncoCEE<sup>®</sup>BR<sup>™</sup> test and Clariant's highly regarded marketing and pathology capabilities, will enable the rapid education of the physician community about the benefits of CTC analysis for patients with breast cancer." He continued, "We think a blood-based, CTC-directed HER2 test, which can be performed when a treatment decision arises, has high potential, and expect that it will be used to support other laboratory and clinical information to provide physicians with the most current information on a tumor to help select the most appropriate course of therapy."

The OncoCEE<sup>®</sup>BR<sup>™</sup> test includes enumeration of CTCs as well as the determination of HER2 status by FISH. Biocept intends to add ER/PR status determination to the test, and potentially other biomarkers, in the future. OncoCEE<sup>®</sup>BR<sup>™</sup> is the only commercially available CTC test that combines enumeration and cytogenetic characterization.

Ron Andrews, CEO of Clariant, said, "Establishing the ability to perform molecular characterization of peripheral cancer cells from a blood sample takes us one step closer to making cancer a chronic disease. Biocept's OncoCEE<sup>™</sup> platform supports our mission of personalized medicine and care for cancer patients."

Biocept's OncoCEE<sup>®</sup>BR<sup>™</sup> test is expected to have application in several clinical settings, including:

- At the time of recurrence, and especially in cases where a biopsy may be difficult to obtain, to determine if the patient's HER2 status has changed from the original diagnosis or surgery.
- Confirmation of HER2 status at the time of original diagnosis or surgery, where tumor tissue analysis was negative for HER2 amplification. Biocept has demonstrated detection of HER2-amplified CTCs in patients with HER2 negative primary tumors, a finding reported by other groups in the scientific literature. This suggests that the pathologist may have examined a part of the tumor that was not HER2 amplified for a variety of reasons including tumor heterogeneity, and that treatment with HER2-targeted agents may be justified. This could be a life-changing event for a breast cancer patient.