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Biocept Comments on Reimbursement Provisions in CMS' Final PAMA Rule

Commends CMS for supporting innovation in diagnostics and transparency on future Medicare pricing

SAN DIEGO, June 29, 2016 /PRNewswire/ -- [Biocept, Inc.](#) (NASDAQ: BIOC), a molecular diagnostics company commercializing and developing liquid biopsies to profile and monitor patients diagnosed with cancer, provides the following statement regarding the Clinical Laboratory Fee Schedule (CLFS) provisions under [Protecting Access to Medicare Act](#) (PAMA) released by the Centers for Medicare and Medicaid Services (CMS). Among other provisions, the PAMA rule establishes guidelines by which Medicare will set reimbursement rates for advanced diagnostic laboratory tests beginning January 1, 2018.



"We commend CMS for its final PAMA rule that supports innovation in the diagnostics space and the timely market introduction of novel diagnostics products," said Michael Nall, Biocept's President and CEO. "Advances in diagnostics in recent years are positively impacting patient care and we applaud CMS for building provisions into the PAMA rule setting a timeframe that allows the industry to gather the necessary data to set appropriate reimbursement, while also encouraging continued development of new diagnostics."

"While we have yet to examine all implications of the PAMA rule, we now have greater transparency with regards to future Medicare reimbursement for our liquid biopsy tests that will help in our pricing decision making," added Mr. Nall. "We have a standing engagement with leading laboratory and diagnostics consultancy ADVI Health LLC (ADVI) and will be calling upon its extensive industry and policy expertise to guide us in developing our reimbursement strategy. ADVI has first-hand knowledge of the new provisions, having been instrumental in assisting political and industry leaders with formulating language within the new PAMA rule."

Michael Beebe, Senior Vice President at ADVI, commented, "Healthcare costs continue to be a topic of national discussion. Diagnostic companies such as Biocept offer potential solutions by helping to improve patient outcomes and helping to reduce patient and systemic costs. We look forward to working with Biocept in developing a reimbursement strategy that factors in the new PAMA provisions and highlights its unique technology and assays."

About ADVI Health LLC

ADVI is a healthcare consulting firm specializing in policy, strategy, and commercial development for lifescience and healthcare services companies and organizations. ADVI has offices in Austin, Texas; Chicago, Illinois; San Francisco, California; and Washington, DC. The ADVI team is a strong, cohesive and highly collaborative group proven at identifying, developing and realizing opportunities for transformational growth and managing crisis. ADVI's work in the personalized medicine and diagnostic space offers clients a unique combination of leadership, clinical, industry, and policy experience and time-worn relationships. Among others, ADVI's Dx Team includes former CMS Director of the Coverage and Analysis Group Dr. Louis Jacques; former Noridian Medical Officer Dr. Bernice Hecker, and former AMA Director, CPT Michael Beebe. ADVI expertise helps answer critical operational and strategic questions around public and private payer coverage, coding, and payment.

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers and melanoma. The company uses its proprietary liquid biopsy technology to provide physicians with information for treating and monitoring patients previously diagnosed with cancer. The company's patented Target Selector™ liquid biopsy technology platform captures and analyzes circulating tumor material in both CTCs and in plasma (ctDNA). After thousands of tests, the platform has shown effectiveness in identifying cancer mutations and alterations.

Biocept plans to introduce additional CLIA-validated tests in the near term. For additional information, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to have been correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this release are not strictly historical, including without limitation statements as to our ability to improve the diagnosis and treatment of cancer, Medicare setting reimbursement rates beginning January 1, 2018, the PAMA rules allowing companies to gather data to set appropriate reimbursement and encouraging development of new diagnostics, the new PAMA rules helping in our pricing decision making and developing a reimbursement strategy, our impact on reducing patient and systemic costs and planned future offerings, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risk factors as set forth in our Securities and Exchange Commission (SEC) filings. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC, which can be accessed over the Internet at the SEC's website located at www.sec.gov.

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