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Biocept Announces that Highmark Has Made a Positive Coverage Determination on Target Selector™ Liquid Biopsy

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Two-year evaluation in advanced lung cancers at Allegheny Health Network demonstrated improved access to optimal treatment while reducing healthcare costs

SAN DIEGO, Sept. 21, 2020 /PRNewswire/ -- [Biocept, Inc.](#) (Nasdaq: BIOC), a leading commercial provider of molecular technologies designed to provide physicians with clinically actionable information to improve the outcomes of patients with cancer, announces that [Highmark](#), America's fourth largest Blue Cross Blue Shield affiliate, has made a positive coverage determination that Biocept's Target Selector liquid biopsy assay has been accepted for medical coverage for use in the diagnosis and treatment of patients with non-small cell lung cancer (NSCLC). The coverage determination follows two years of evaluation performed by the [Allegheny Health Network Cancer Institute](#), of Biocept's liquid biopsy assay to more rapidly assess the molecular status of patients with NSCLC, enabling oncologists to select the most appropriate therapy while also reducing the overall cost of care.



Highmark's coverage determination includes testing with Biocept's assay in health insurances across the insurer's footprint, which includes Pennsylvania, Delaware and West Virginia, where it serves 5.6 million members. The evaluation was managed by [Highmark Health's VITAL Innovation Platform](#), which facilitates real-world testing of early-stage health innovations, producing evidence related to patient experience, care, and cost outcomes to support potential adoption within Highmark Health, as well as acceleration into the broader healthcare community. Highmark will be the first insurer in its footprint to provide coverage of the test. In addition, Allegheny Health Network is the first health system to offer the testing in Highmark's footprint, with others to follow.

"The diagnosis, treatment and care of patients with cancer is among Highmark Health's top priorities and a focus of the VITAL Innovation Platform," said [Anil C. Singh, MD, Allegheny Health Network](#) (AHN) System Director of Pulmonary/Critical Care/Allergy-Immunology and Sleep Medicine, and medical advisor to VITAL. "VITAL's evaluation clearly demonstrates the value of using Biocept's liquid biopsy test in making informed, first-line therapy decisions for patients with non-small cell lung cancer. Additionally, using a simple blood sample reduced the number of invasive tissue biopsies, which can be challenging in patients with advanced NSCLC."

The Biocept Target Selector platform was used to molecularly profile the liquid biopsies of newly diagnosed, treatment-naïve advanced NSCLC patients, as well as NSCLC patients who were progressing after initial therapy. These patients also received tissue biopsy as part of the evaluation.

"This project directly supports Highmark's and AHN's mission to provide members and patients with access to the best care that is available, freeing them to be their best," said [Gene G. Finley, MD](#), deputy director of Allegheny Health Network Medical Oncology and lead investigator on the project. "In order to realize the full potential of targeted therapies, oncologists require timely and accurate molecular characterization of a patient's cancer for selection of the best possible therapy. Our study indicated that results of Biocept's liquid biopsy provided clinicians with accurate knowledge about their patients' disease, allowing us to implement more effective and better targeted treatment strategies. This improves the patient experience and lowers healthcare costs."

"The positive results from our collaboration under the VITAL program further solidifies Biocept's role as a leader in the liquid biopsy field and represents an important movement towards improving care for cancer patients," said Michael Nall, Biocept's president and chief executive officer. "After several years of participating in the VITAL program, the fact that Highmark has made a positive coverage determination is a testament to the value we bring to patients with cancer and to the healthcare system."

Lung cancer is the leading cause of cancer death in the United States. The American Cancer Society estimates that approximately 135,720 Americans will die from lung cancer in 2020. The five-year survival rate for advanced NSCLC is less than 10%. However, 17–27% of NSCLC patients harbor molecular alterations that can be treated with specific FDA-approved targeted therapies.

Despite the advances of targeted therapies, a large percentage of patients may not undergo molecular profiling due to a number of practical constraints. Chief among these is the availability of tissue for molecular testing. Lung cancers are often difficult to biopsy because of their location within what is often diseased lung tissue of elderly patients. Needle biopsy is the most common technique but often does not yield enough tissue for molecular testing. Performing a second biopsy is a way of remedying this situation, but these procedures can add to risk and cost, making liquid biopsy (peripheral blood) a more feasible specimen type.

About Highmark Health

Highmark Health, a Pittsburgh, PA-based enterprise that employs more than 35,000 people who serve millions of Americans across the country, is the parent company of Highmark Inc., a hospital system, and other businesses. Highmark Inc. and its subsidiaries and affiliates provide health insurance to more than 5.6 million members in Pennsylvania, West Virginia, and Delaware as well as dental insurance, and related health products through a national network of diversified businesses. Highmark Health's other subsidiaries include an integrated delivery network comprised of eight hospitals, more than 2,500 affiliated physicians, ambulatory surgery centers, an employed physician organization, home and community-based health services, a research institute, a group purchasing organization, and health and wellness pavilions in western Pennsylvania; and an information technology business focused on meeting the information technology platform and other business needs of the Highmark Health enterprise as well as unaffiliated health insurance plans by providing proven business processes, expert knowledge, and integrated cloud-based platforms. To learn more, visit [www.highmarkhealth.org](#). For information specific to the VITAL Innovation Platform, please visit [www.vitalinnovation.com](#).

About Highmark

One of America's leading health insurance organizations and an independent licensee of the Blue Cross Blue Shield Association, Highmark Inc. (the Health Plan) and its affiliated health plans (collectively, the Health Plans) work passionately to deliver high-quality, accessible, understandable, and affordable experiences, outcomes, and solutions to customers. As the fourth-largest overall Blue Cross Blue Shield-affiliated organization, Highmark Inc. and its Blue-branded affiliates proudly cover the insurance needs of more than 5.6 million members in Pennsylvania, Delaware, and West Virginia. Its diversified businesses serve group customer and individual needs across the United States through dental insurance and other related businesses. For more information, visit [www.highmark.com](#).

About Allegheny Health Network

Allegheny Health Network is an integrated health care delivery system serving the greater Western Pennsylvania region. The network is composed of 12 hospitals, ambulatory surgery centers, Health + Wellness Pavilions, an employed physician organization, home- and community-based health services, a research institute, and a group purchasing organization. AHN provides patients with access to a complete spectrum of advanced medical services, including nationally recognized programs for primary and emergency care, cardiovascular disease, cancer care, orthopedic surgery, neurology and neurosurgery, women's health, diabetes and more. AHN employs approximately 21,000 people, has more than 2,500 physicians on its medical staff, and serves as a clinical campus for Drexel University College of Medicine, Temple University School of Medicine, and the Lake Erie College of Osteopathic Medicine. To learn more, visit [www.ahn.org](#).

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 clinically actionable information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. In addition, Biocept recently added COVID-19 testing to support efforts to fight the pandemic. 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 regarding the ability of our tests to provide clinically actionable information to oncologist and their patients and the ability of Biocept's platform to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options, 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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