

Biocept

Completing the Answer™

Highmark Health's VITAL Innovation Program testing benefits of Biocept's liquid biopsy platform for improving outcomes and lowering costs of treatment for patients with non-small cell lung cancer

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Allegheny Health Network's Cancer Institute spearheading the evaluation

PITTSBURGH and SAN DIEGO, Aug. 23, 2018 /PRNewswire/ -- Highmark Health announced today that through its VITAL Innovation Program, it is testing Biocept, Inc.'s Target Selector™ liquid biopsy platform designed to help oncologists improve the diagnosis and treatment of patients with non-small cell lung cancer (NSCLC). The goals of the collaboration are to improve health outcomes by using liquid biopsy to more rapidly assess a patient's molecular status and select appropriate therapy, while reducing the overall cost of care.



A test-and-learn platform, the unique VITAL program leverages Highmark Health's position as the nation's second largest integrated delivery and financing system. VITAL facilitates real-world testing of early-stage health innovations, producing evidence related to patient experience, and care and cost outcomes. The evidence may accelerate an innovation's coverage and utilization by health plans and care delivery systems, fast-tracking the solution to patients and supporting swifter marketplace adoption.

More than 100 patients of Highmark Health-affiliated Allegheny Health Network (AHN) Cancer Institute will participate in the evaluation of the Biocept (NASDAQ: BIOC) platform as a method of improving the molecular profiling rate of advanced NSCLC. During the evaluation, the Biocept platform will molecularly profile the liquid biopsies of newly diagnosed, treatment-naïve advanced NSCLC patients and NSCLC patients progressing after initial therapy. These patients will also receive tissue biopsy as part of the evaluation.

Lung cancer is the leading cause of cancer death for both men and women in the United States, with an estimated 155,870 deaths in 2017.¹ The median overall survival for patients with advanced NSCLC is approximately one year, with the five-year survival rate for metastatic lung cancer at 5%.² However, 17–27% of NSCLC patients harbor molecular alterations that can be treated with specific FDA-approved targeted therapies. In order to realize the full potential of these targeted therapies, oncologists require timely and accurate molecular characterization of a patient's cancer for selection of the best possible therapy, with some of the treatment regimens extending median patient survival times from one to two and one-half years.³⁻⁷

Despite these advances, 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. The VITAL test will study the opportunity for Biocept's liquid biopsy from a simple blood draw to provide an effective solution that can lower cost, provide additional information to help oncologists precisely target therapies, and achieve better outcomes.

"The diagnosis, treatment and care of cancer patients is among Highmark Health's chief priorities and a focus of the VITAL Innovation Program," said Sarah Ahmad, senior vice president of innovation and transformation strategy for Highmark Health. "We look forward to evaluating the ways in which Biocept's technology could help transform the care of patients challenged by lung cancer."

"This project directly supports the Allegheny Health Network Cancer Institute's mission to advance best practices, including diagnosis and treatment of all cancers, and to help remove any barriers to patients' access to the best care that's available," said Gene Finley, MD, deputy director of Allegheny Health Network Medical Oncology and lead investigator on this project. "We believe that implementing Biocept liquid biopsies could provide AHN clinicians with more accurate knowledge about their patients' disease, allowing us to implement more effective and better targeted treatment strategies."

"This collaboration with the VITAL Innovation Program and Allegheny Health Network reflects 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. "We hope to further build the body of evidence supporting our Target Selector™ platform's ability to help physicians rapidly obtain the actionable information they need to design personalized treatment plans for their patients."

VITAL's evaluation of Biocept's Target Selector™ liquid biopsy platform will occur for a period of 12 months, concluding in August of 2019.

About Highmark Health

Highmark Health, a Pittsburgh, PA-based company, that, together with its subsidiaries and affiliates collectively employ more than 40,000 people and serve millions of Americans across the country, is the second largest integrated health care delivery and financing network in the nation based on revenue. Highmark Health is the parent company of Highmark Inc., Allegheny Health Network, and HM Health Solutions. Highmark Inc. and its subsidiaries and affiliates provide health insurance to nearly 5 million members in Pennsylvania, West Virginia, and Delaware as well as dental insurance, vision care and related health products through a national network of diversified businesses that include United Concordia Companies, HM Insurance Group, and Visionworks. Allegheny Health Network is the parent company of an integrated delivery network that includes eight hospitals, more than 2,400 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. HM Health Solutions focuses 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, please visit www.highmarkhealth.org. For information specific to the VITAL Innovation Program, please visit www.vitalinnovation.com.

About Allegheny Health Network

Allegheny Health Network, a Highmark Health company, is an integrated healthcare delivery system serving the greater Western Pennsylvania region. The Network is composed of eight hospitals, including Allegheny General Hospital, its flagship academic medical center in Pittsburgh, Allegheny Valley Hospital in Natrona Heights, Canonsburg Hospital in Canonsburg, Forbes Hospital in Monroeville, Jefferson Hospital in Jefferson Hills, Saint Vincent Hospital in Erie, West Penn Hospital in Pittsburgh and Westfield Memorial Hospital in Westfield, NY. The Network 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. It also is home to a comprehensive research institute: Health + Wellness Pavilions; an employed physician organization, home and community based health services and a group purchasing organization. The Network employs approximately 19,000 people, has more than 2,400 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, please visit www.AHN.org.

About Biocept

Biocept, Inc. (NASDAQ: BIOC) is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company leverages its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. Biocept'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. For additional information, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This news release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although Biocept believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, Biocept can give no assurance that such expectations and assumptions will prove to be 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 news release are not strictly historical, including, without limitation, statements as to Biocept's ability to improve the outcomes of cancer patients, the utility and cost effectiveness of Biocept's tests, and Biocept's ability to further validate its liquid biopsy technology, 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 Biocept's 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 news release. Biocept does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

References:

[1] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2017. *CA Cancer J Clin.* 2017 Jan;67(1):7-30.

[2] Kim TE, Murren JR. Therapy for stage IIIB and stage IV non-small cell lung cancer. *Clin Chest Med.* 2002 Mar; 23(1):209-224.

- [3] Sequist LV, et al. Phase III study of afatinib or cisplatin plus pemetrexed in patients with metastatic lung adenocarcinoma with EGFR mutations. *J Clin Oncol*. 2013 Sep 20; 31(27):3327-3334.
- [4] Fukuoka M, et al. Biomarker analyses and final overall survival results from a phase III, randomized, open-label, first-line study of gefitinib versus carboplatin/paclitaxel in clinically selected patients with advanced non-small-cell lung cancer in Asia (IPASS). *J Clin Oncol*. 2011 Jul 20; 29(21):2866-2874.
- [5] Rosell R, et al. Erlotinib versus standard chemotherapy as first-line treatment for European patients with advanced EGFR mutation-positive non-small-cell lung cancer (EURTAC): a multicentre, open-label, randomised phase 3 trial. *Lancet Oncol*. 2012 Mar; 13(3):239-246.
- [6] Maemondo M, et al. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. *N Engl J Med*. 2010 Jun 24; 362(25):2380-2388.
- [7] Chih-Hsin Yang J et al Afatinib versus cisplatin based chemotherapy for EGFR mutation positive lung adenocarcinoma (LUX-Lung 3 and LUX-Lung 6): analysis of overall survival from two randomized phase 3 trials *Lancet Oncology* 2015;16 141-151

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