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The Addario Lung Cancer Medical Institute and Biocept Announce Collaboration and Initiation of Landmark ALCMI-009 Liquid Biopsy Clinical Trial in Lung Cancer

Large prospective multi-center clinical trial designed to evaluate the impact of cancer biomarker detection and serial monitoring using liquid biopsy to improve the outcomes of patients with lung cancer

Patient-founded research consortium of 25 global oncology centers to create large, well-annotated, uniformly collected biorepository of lung cancer patient blood samples

SAN CARLOS, Calif. and SAN DIEGO, May 10, 2017 /PRNewswire/ -- The Addario Lung Cancer Medical Institute (ALCMI), a non-profit, patient-centric, international research organization, and [Biocept, Inc.](#) (NASDAQ: BIOC), a leading commercial provider of clinically actionable liquid biopsy tests designed to improve the outcomes of cancer patients, announce a clinical collaboration and initiation of the landmark ALCMI-009 liquid biopsy clinical trial, which was developed and will be conducted by ALCMI and its consortium of leading U.S. and international oncology centers. In this large-scale study, which plans to enroll 400 patients, Biocept's Target Selector™ assay platform will be used to detect and assess cancer biomarkers found in both circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA) from the blood of patients with lung cancer.



Lung cancer is the leading cause of cancer-related deaths worldwide. New therapies are available and others are in development to provide improved treatment options by targeting specific lung cancer biomarkers. Identifying these biomarkers using tissue biopsy can be challenging for many reasons, including the difficulty in performing a biopsy due to tumor location, limited tumor material due to small biopsy sizes, tumor heterogeneity both within the tumor material and between multiple metastatic sites, and risk of complications. All of these reasons, in addition to the relatively high cost of tumor biopsy, have increased the interest in obtaining molecular information from a simple blood sample.

"We are pleased to join forces with major research institutions and cutting-edge molecular diagnostics companies such as Biocept to conduct a large-scale trial evaluating the use of liquid biopsy to detect and monitor key lung cancer biomarkers," said Steven Young, ALCMI's president & COO. Bonnie Addario, lung cancer survivor and the founder of both the Bonnie J. Addario Lung Cancer Foundation and ALCMI, added, "The collaborative research across these academic and community institutions will be transformative and will certainly benefit lung cancer patients."

The large prospective clinical trial, entitled "[ALCMI-009: Evaluation of Liquid Biopsies in Localized and Advanced Lung Cancer Patients](#)," will enroll 400 patients with advanced non-small cell lung cancer (NSCLC). Patients will have 4-6 blood samples drawn over the 12-month study duration period, for a cumulative total of 1,600 to 2,400 liquid biopsy data points. Blood samples will be shipped directly to Biocept's CLIA-certified, CAP-accredited laboratory for detection of key biomarkers including EGFR, BRAF, KRAS, ALK fusions, ROS1 fusions and PD-L1 expression. Facilitated by ALCMI and its global consortium of 25-member cancer institutions, the study's primary objective is to further validate the concordance of liquid biopsy to solid tissue biopsies at *de novo* presentation across the multicenter ALCMI research organization. This concordance will validate the use of a liquid biopsy sample when biopsy tissue is exhausted or difficult to obtain for biomarker stratification. The clinical trial will also seek to validate the utility of monitoring key biomarkers in lung cancer patients with a liquid biopsy, enumerating CTC counts, and quantifying ctDNA mutations, with the intent to:

- | illustrate drug response
- | predict treatment failure prior to progression observed using radiographic imaging; and
- | identify resistance mechanisms (e.g. EGFR T790M)

Due to different goals for the different histologies and stages of lung cancer, the trial plans to distinguish between advanced NSCLC patients with squamous cell and non-squamous cell carcinoma, and plans to evaluate the clinical utility of liquid biopsy in additional patients with early-stage NSCLC (stages I-III) as well as small cell lung cancer (SCLC). Collected data from this study will be centralized in a first-of-its-kind, large-scale database that will include uniform and complete patient demographic, pathology and clinical information. Principal investigators for the study are Erin M. Bertino, MD, Division of Medical Oncology, Department of Internal Medicine of Wexner Medical Center at The Ohio State University, and Luis E. Raez, MD, Memorial Cancer Institute/Memorial Health Care System, Florida International University (FIU).

"We have targeted several highly important objectives for this trial that could have a profound impact on the treatment of patients with lung cancer," said Dr. Raez. "Validating the concordance of liquid biopsy and tissue biopsy across the dozens of ALCMI member institutions could open new opportunities for using this approach when tissue biopsy material is exhausted or difficult to obtain." Dr. Bertino added, "Specifically, a better understanding of the role of serial blood based molecular markers in making treatment decisions for lung cancer patients is critical, and may also lead to the development of novel targeted therapies."

Michael W. Nall, Biocept's President and CEO, said, "The results of this large-scale study with renowned oncology centers could further validate the extremely high sensitivity and specificity that we have demonstrated with our Target Selector™ platform in past studies. We are excited to work with ALCMI on this groundbreaking clinical trial."

About ALCMI

The Addario Lung Cancer Medical Institute (ALCMI, voiced as "Alchemy"), founded in 2008 as a 501c(3) non-profit organization by lung cancer survivor Bonnie J Addario, is a patient-centric, international research consortium driving research otherwise not possible. Working in tandem with its "partner" foundation, the Bonnie J. Addario Lung Cancer Foundation, ALCMI powers collaborative initiatives in genetic (molecular) testing, therapeutic discoveries, targeted treatments and early detection. ALCMI overcomes barriers to collaboration via a world-class team of investigators from 25 member institutions in the USA, UK, and Europe, supported by dedicated, centralized research infrastructures such as standardized biorepositories and data systems. ALCMI directly facilitates research by combining scientific expertise found at leading academic institutions with patient access through its network of community cancer centers - accelerating novel research advancements to lung cancer patients. By providing access to critical masses of patient stakeholders, academic, community and industry researchers, ALCMI is making progress towards its goal of transforming lung cancer into a chronically managed disease by 2023.

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. 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 outcomes of cancer patients, the success of the [ALCMI-009: Evaluation of Liquid Biopsies in Localized and Advanced Lung Cancer Patients](#) clinical trial and its ability to meet its objectives, our ability to further validate our liquid biopsy technology and our ability to increase the clinical adoption of our testing services, 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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