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VisionGate's Cell-CT™ Platform Uses 3D Cell Morphometry and Artificial Intelligence to Detect an Immunotherapy Predictive Biomarker and Cancer-Associated Cells (CACs) that have undergone Malignancy Associated Change (MAC) from Liquid Biopsy

Breakthrough Research to be Presented at the 2018 World Conference on Lung Cancer

SEATTLE, WA (September 24, 2018) – VisionGate, a clinical stage oncology pharmaceutical and diagnostics company announces two peer-reviewed poster presentations at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC), 23-26 September in Toronto, Canada. These studies demonstrate important new morphometric detection findings of the Cell-CT™ platform and the LuCED® lung test. These findings promote new disease interception capability for the detection of early stage lung cancer and assessment of personalized immunotherapy efficacy in lung cancer.

Previous research has demonstrated that the LuCED lung test, a non-invasive liquid biopsy sputum assay, has potential to address critical unmet medical needs to advance the lung cancer interception and management in three areas: 1) accurate diagnosis of small and early stage tumors and pulmonary nodules; 2) detection and treatment of pre-cancerous dysplasia; and 3) detection of critical lung cancer driver mutations.

The results of these two feasibility studies demonstrate exciting new potential applications and new methods to utilize cellular level *optical computed tomography* (CT) and *artificial intelligence* (AI) of VisionGate's 3D single cell imaging Cell-CT platform to obtain lung cancer diagnostic and biomarker information from a sputum liquid biopsy.

The first study demonstrates the feasibility of using the Cell-CT® platform for morphometric detection of mismatch repair protein deficiency (MMR-D) which is proving to be a predictive biomarker for the efficacy of immunotherapy and potential for correlation to the Tumor Mutational Burden (TMB) level. TMB has emerged as a quantitative marker that can help predict potential responses to immunotherapies across different cancers including lung cancer.

While multiple molecular tests are available for the detection of MMR-D, they require invasive biopsy and are often not applicable for early stage disease. Published studies have demonstrated that MMR-D results in histological and morphological changes. This study reports the development of morphology phenotype-based classifiers for lung cancer cell-lines that have been engineered to exhibit MMR-D by knockdown of MLH1 expression. The 3D cell morphometric artificial intelligence classifiers were able to distinguish cells of parental cell lines from those of MMR-D lines and demonstrate promise as a means of identifying MMR-D in malignant cells from patient specimens.

The second study involving the Cell-CT™ platform demonstrates the detection of malignancy associated change (MAC) in cancer-associated cells (CACs), without the need to detect actual cancer cells in patients with lung cancer. This study presents promising research demonstrating that the Cell-CT™ platform can detect subtle changes in the cellular and nuclear morphology of CACs as a likely result of the cancer field effect. These non-cancerous cells may have been

affected by the presence of neighboring cancer cells that have undergone structural changes which include alterations in nuclear chromatin compaction – a phenomenon also known as Malignancy Associated Change (MAC).

This is the second study report[i] showing that VisionGate's Cell-CT platform, using 3D optical computed tomography, can detect these changes in non-cancerous cells that are presumably influenced by the tumor microenvironment. The capability of the Cell-CT platform to detect MAC has the potential to further enhance the already impressive sensitivity and specificity demonstrated by the LuCED lung test thereby enabling the detection of lung cancer at its earliest, most treatable stage.

A spectrum of change in the cellular composition is typical in patients with cancer such that malignant, pre-malignant and atypical cells are observed in biopsy specimens. Cell diagnosis pathology is typically based on microscopic evaluation of cells on slides in two dimensions (2D). However, this 2D process is compromised by obscuration due to cell overlap and fundamentally limited by the nature of 2D imaging. For many cells the changes imparted to them through the tumor field are so subtle that they fall beneath the threshold of human perception and are thus understood, incorrectly, to be within normal limits. The Cell-CT platform computes the third dimension through *optical computed tomography* with 200nm resolution that is isotropic. The system characterizes the cells analytically and repeatably allowing measurement of cellular morphometric biosignatures that extend well beyond the ability of human review.

With this study, VisionGate has demonstrated:

- The Cell-CT platform improves upon cytology, can detect cell changes beyond human visual perception and, aided by artificial intelligence, can provide detailed insights into subtle morphological alterations that are beyond the capabilities of human visual perception.
- The study confirms the presence of the MAC phenomenon in lung cancer but, more importantly, shows that through Cell-CT platform imaging, MAC can be reliably detected.

"We are entering an era where technological advances like the Cell-CT platform coupled with Artificial Intelligence and big data are allowing us to detect lung cancer cells and cancer associated cells in sputum liquid biopsy, and these two feasibility studies are extending that impactful capability further toward early interception and biomarker development for targeted therapies", said Alan C. Nelson, PhD, Chairman and CEO.

Detection of MAC could be used to alert cytology staff of likely abnormal conditions – a feature that may be especially important in detecting early stage cancers with exceedingly high sensitivity", added Dr. Nelson.

"Importantly, this capability could further boost LuCED lung test's accuracy, reducing the potential for false positive tests", Dr. Nelson added.

Moreover, MAC detection may enable detection of minor, but significant changes in cancer progression and therapy response that are not perceivable by human review. VisionGate envisions broader potential applications based on additional liquid biopsy specimens for detection of other cancers.

The abstract details are:

Title: **3D Morphometric Detection of Mismatch Repair Deficiency in Human Lung Adenocarcinoma Cell Lines using the Cell-CT® Platform**
Presentation Number: Abstract #14118
Session: P3.03-16 - Biology
Date and Time: Wednesday, September 26, 2018, 12:00 pm – 1:30 pm
Location: Poster Board 16

Title: **Malignancy Associated Change and the LuCED® Test for Detection of Early Stage Lung Cancer**
Presentation Number: Abstract #14044
Session: P2.11-14 - Screening and Early Detection
Date and Time: Tuesday, September 25, 4:45 pm - 6:00 pm
Location: Poster Board 14

Full session details and data presentation listings for WCLC 2018 can be found at: https://www.iaslc.org

For more information on VisionGate, please visit http://www.visiongate3d.com.

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About VisionGate, Inc.

VisionGate is a clinical stage oncology pharmaceutical and diagnostics company focused on the early detection and prevention of cancer. Our lead investigative pharmaceutical drug is oral iloprost, with clinical development planning ongoing for the treatment of pre-cancerous bronchial dysplasia and the prevention of lung cancer following a successful Phase 2 clinical trial. We intend to develop the LuCED® lung test as a companion diagnostic for oral iloprost. VisionGate's proprietary LuCED lung test is a non-invasive liquid biopsy diagnostic test in development for detection of early-stage lung cancer, demonstrating exquisite sensitivity and specificity in blinded clinical studies. This non-invasive sputum test is processed on the world's first automated 3D single cell imaging and analysis technology, the Cell-CT™ platform, named aptly because it is similar in principle to taking a CT scan of individual cells, but using visible light without harmful radiation. With 176 issued patents in 13 countries, VisionGate expects to play a leading role in the battle against lung cancer - the world's number one cancer killer. VisionGate, Inc. is led by Dr. Alan Nelson, physicist, bioengineer, and serial entrepreneur who previously developed the world's first and only automated screening test to detect cervical cancer, marketed globally today as FocalPoint by Becton Dickinson. The LuCED lung test is a product in development and is not currently available commercially.

About the Cell-CT™ Platform

The automated Cell-CT™ platform, with 3-dimensional single cell Imaging and analysis capability, is the enabling technology which produces high-resolution 3D images of individual cells using a technique called *optical computed tomography.* This 3D optical CT platform breaks new ground in the field of quantitative cell analysis by its unique ability to compute the true 3D internal structure of cells based on molecular optical absorption densities. The Cell-CT platform produces high-resolution 3D images of individual cells and measures hundreds of critical disease indicators in each cell. Together with advanced artificial intelligence (AI) algorithms, these produce accurate cell classifications that aid in the early detection of disease. Additionally, the Cell-CT platform has the potential to deliver molecular and genetic biosignatures of disease longitudinally to compliment drug development in the biopharma services arena. Cells are not placed on slides, but rather, they are suspended in fluid (liquid biopsy) and injected through a micro-capillary tube that permits multiple viewing perspectives around 360°. The Cell-CT platform is a device under development and not currently cleared by the FDA.

Cautionary Note Regarding Forward-Looking Statements for VisionGate

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and made in reliance on the "safe harbor" provisions of said act. These forward-looking statements are based on estimates, projections, beliefs and assumptions of the Company at the time of such statements and are not guarantees of future

performance. Forward-looking statements involve risks and uncertainties in predicting future results and conditions that may cause actual results to differ materially, including unanticipated developments and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug and diagnostics development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances. Actual results could differ materially from those projected in these forward-looking statements due to a variety of factors, including, without limitation, the acceptance by customers of our products, our ability to develop new products cost-effectively, our ability to raise capital in the future, the development by competitors of products using improved or alternative technology, the retention of key employees and general economic conditions. Forward-looking statements are subject to change without notice. VisionGate disclaims any intent or obligation to update these forward-looking statements. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this press release.

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[i] The Malignancy Associated Change Hypothesis Tested Through 3D Cellular Imaging, Poster #LB-175, Meyer, et. al., 2018 American Association for Cancer Research (AACR)