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VisionGate’s Cell-CT™ 3D Cellular Imaging Platform Detects the Presence of Cancer-Associated Cells (CACs) that have undergone Malignancy Associated Change (MAC)

Important New Research Presented at the 2018 AACR Annual Meeting

SEATTLE, WA (April 16, 2018) – VisionGate, a clinical stage oncology pharmaceutical and diagnostics company, today presented a breakthrough research study demonstrated its Cell-CT™ platform can detect subtle changes in cellular and nuclear morphology of cancer-associated cells (CACs) as a result of the cancer field effect. These non-cancerous cells have been affected by the presence of the cancer cells and have undergone structural changes which include alterations in nuclear chromatin compaction – a phenomenon also known as Malignancy Associated Change (MAC). This is the first study report of VisionGate’s use of its Cell-CT 3D optical computed tomography platform to detect these changes in non-cancerous cells that presumably reside in tumor microenvironment. The study was presented at the 2018 American Association of Cancer Research (AACR) annual meeting in Chicago, Illinois.

A spectrum of change in the cellular composition is typical in patients with cancer so that malignant, pre-malignant and atypical cells are observed in biopsy specimens. Cell diagnosis is based on microscopic evaluation of cells on slides. This process is compromised by obscuration 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 to be within normal limits. The Cell-CT platform renders cells through optical computed tomography and presents cells in true 3D with sub-micron resolution. The system characterizes the cells analytically and repeatably allowing measure of cell biosignatures that cannot be reliably perceived through human review.

The research presented was performed using cells that were within normal limits from patients with biopsy confirmed lung cancer and from donors who were cancer free. Cells from sputum were imaged by the Cell-CT platform which produced a set of morphometric biosignatures from each cell. The feature data was analyzed to select those features that best allowed detection of the cells from the cancer patients. The result was the creation of artificial intelligence (AI) networks to process cells from the risk population at large.

With this study, VisionGate has demonstrated these conclusions:

- 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 MAC phenomenon but more importantly, shows that through Cell-CT platform imaging, it can be reliably detected.

“The study findings have important implications for how cancer detection is managed with the Cell-CT platform. 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”, said Alan C. Nelson, PhD, Chairman and CEO.
Importantly, this capability could further boost LuCED lung test’s sensitivity, reduce the potential for false positive tests and improve the efficiency of our laboratory operations by reducing specimen processing time and workload“, Dr. Nelson added.

This study was done using patient sputum from normal and lung cancer patients. Further work will develop the MAC detection feature set and emphasize results at the case rather than cellular level. Moreover, we may be able to detect minor, but significant changes in cancer progression and therapy response that are not perceivable by human visual review. VisionGate envisions further potential applications based on additional liquid biopsy specimens for detection of other cancers.

The abstract details are:

**Title:** The Malignancy Associated Change Hypothesis Tested Through 3D Cellular Imaging  
**Presentation Number:** Abstract #LB-175  
**Session:** Late-Breaking Research: Epidemiology and Prevention  
**Date and Time:** Monday, April 16, 2018, 1:00 p.m. – 5:00 p.m. CDT, Chicago  
**Location:** Poster Section 44, Poster Board 18

Full session details and data presentation listings for AACR 2018 can be found at: [http://www.abstractsonline.com/pp8/#!/4562](http://www.abstractsonline.com/pp8/#!/4562)

For more information on VisionGate, please visit [http://www.visiongate3d.com](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, currently in clinical development for the treatment of pre-cancerous bronchial dysplasia and the prevention of lung cancer following a successful Phase 2 clinical trial. The LuCED® lung test will be the 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™ 3D Imaging Platform**

The automated Cell-CT™ 3-Dimensional Single Cell Imaging and Analysis Platform 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 in the US.

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.