

## FOR IMMEDIATE RELEASE

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## VisionGate Presents Blinded Trial Data at WCLC 2016 Demonstrating LuCED<sup>®</sup> Test for Lung Cancer Could Help Alleviate Worry Over Incidental Lung Nodule Findings

PHOENIX, Ariz. (December 15, 2016) – More than 1.5 million people in the United States will have suspicious nodules detected incidentally in their lungs this year. Additionally, roughly one-fourth of smokers over the age of 50 will have suspicious nodules detected on a low dose CT scan done in the setting of lung screening programs. However, less than 5 percent of those nodules will be diagnosed as cancerous<sup>1</sup>. Knowing that nodules are more often not malignant, physicians are frequently faced with the quandary to "watch and wait" – see if the nodule grows over time – or perform additional, often invasive procedures.

However, as demonstrated at the 17<sup>th</sup> World Conference on Lung Cancer (WCLC) last week in Vienna, Austria, VisionGate's proprietary non-invasive LuCED test on sputum for the early detection of lung cancer may offer an alternative, non-invasive next step for patients.

VisionGate's blinded clinical study of the LuCED test included 139 patient specimens and demonstrated 90% sensitivity to lung cancer with a 97% specificity finding patients without the disease.

"With each clinical milestone, we are encouraged by LuCED's unparalleled performance," VisionGate Founder and Chief Executive Officer Alan Nelson, PhD said. "If LuCED were able to help confirm or rule out cancer earlier in these patients – utilizing a non-invasive method – it would transform the way these incidental nodules are managed."

LuCED is a physician-ordered test performed at home. Three spontaneous sputum samples (phlegm) are collected and mailed to VisionGate's laboratory in Phoenix. They are processed on VisionGate's Cell-CT<sup>®</sup>, a platform that generates high-resolution 3D images of each cell in a sputum sample. It then automatically analyzes cells to identify 700 key features, or structural biomarkers, associated with malignancy.

LuCED has the potential to be used to help triage incidental lung nodule findings, as an adjunct to low-dose CT in lung cancer screening to reduce false positives, and as a primary screener for lung cancer following FDA clearance.

In a second presentation at the WCLC, LuCED also demonstrated promise in detecting bronchial dysplasia, a precursor to cancer. When dysplasia is detected, patients become candidates for chemoprevention drug therapies such as Iloprost. VisionGate and the University of Colorado are poised to embark on a Phase III clinical trial involving Iloprost to reduce dysplasia with LuCED as the tool to detect dysplasia.

"We were very proud to present this compelling data at the WCLC last week. We are encouraged – now more than ever – that VisionGate is successfully developing cost-effective solutions to aid both physicians and patients in managing lung cancer, and eventually could be the missing link to eradicating the world's deadliest cancer once and for all," Nelson said.

VisionGate is headquartered in Phoenix, AZ, with a Research & Development office in Seattle, WA. For more information about VisionGate, visit <u>www.visiongate3d.com</u>.

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## About VisionGate®

VisionGate, Inc. is led by Dr. Alan Nelson, physicist, bioengineer and 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. VisionGate's proprietary LuCED test is a non-invasive diagnostic test for early-stage lung cancer, demonstrating exquisite sensitivity and specificity in blinded clinical studies. This physician-ordered, take-home sputum test is processed on the world's first automated 3D cell imaging platform, the Cell-CT, named aptly because it is similar in principle to taking a CT scan of individual cells, but using visible light without harmful radiation. Moreover, with the exclusive patent license from the University of Colorado for the drug called Iloprost, VisionGate will drive the therapeutic market for chemoprevention of lung cancer and, ultimately, the eradication of this killer. With 146 issued patents in 13 countries, VisionGate expects to play a leading role in the battle against the world's number one cancer killer.

<sup>1</sup>Gould et al. Recent Trends in the Identification of Incidental Pulmonary Nodules. Am J Respir Crit Care Med Vol 192, Iss 10, pp 1208–1214, Nov 15, 2015