

Imalux® Corporation and Preventive Oncology International®, Inc. Differentiate Grades of Pre-Invasive Cervical Dysplasia with Niris Optical Coherence Tomography Imaging System

Studies Yield Statistically Significant Results

CLEVELAND--([BUSINESS WIRE](#))--Imalux Corporation and Preventive Oncology International, Inc. (POI) conducted two studies to determine the diagnostic efficacy of “real time” Optical Coherence Tomography (OCT). The first study was held in December 2007 and the second in April 2008. Both IRB-approved studies took place in China in partnership with the Peking University Shenzhen Hospital and the Renmin Hospital in Buyi-Miao Autonomous District of Guizhou Province. Two thousand (2000) women participated in the studies and approximately two thousand eight hundred (2,800) OCT images were taken and were compared to diagnostic impression and pathologic findings to determine the accuracy of OCT. The studies yielded the statistically significant abilities of OCT to differentiate grades of pre-invasive cervical dysplasia prior to biopsy.

According to Dr. Nancy Tresser, VP and Chief Medical Officer at Imalux, “These studies showed that we could use Imalux’s Niris® Imaging System in both high- and low-resource settings with the intent to improve women’s health care globally.”

Epidemiologist Dr. Suzanne Belinson (POI) will be presenting the statistical results of the study at the 25th International Papillomavirus Conference in Malmo, Sweden this May. Her conclusions are based on the analysis of differences in the brightness of cervical epithelium images. She found that the mean brightness differed significantly between each histological grade (p-values 0.000) for the comparisons of two grades of precancerous dysplasia (CIN II, CIN III) and their comparisons to cancer, as well as squamous metaplasia to cancer.

Cervical cancer is the second greatest cause of cancer deaths in women world-wide and the greatest cause of cancer deaths in women under the age of 50. It is directly linked to the high-risk types of the Human Papillomavirus (HPV). While the current standard for cervical cancer diagnosis in the US is based upon the Pap test, the link between cervical cancer and HPV has made it possible to identify patients at high risk of cervical cancer by testing for the HPV virus.

“POI and Imalux are very encouraged that we have now identified several characteristics associated with pre-invasive and invasive cervical cancer. The Niris System may well be able to provide a rapid, accurate, and efficient method for a single

episode of care ("see and treat") for cervical dysplasia," stated Dr. Jerome Belinson, Founder and President of POI. "We are hoping to conduct similar studies in the near future with a second generation Niris System."

About Imalux

Imalux Corporation, Cleveland, Ohio, is positioned to be a worldwide leader in the development and commercialization of site of care tissue imaging systems utilizing harmless, near-infrared light. The Imalux technology platform, sold under the Niris trademark, is based on our proprietary application of optical coherence tomography using harmless, near-infrared light to provide real-time, high resolution, cross sectional imaging of tissue structures. Niris is a tool to aid in the diagnosis of disease, detection of cancer in its earliest stages, guidance of biopsy and surgery, and post-treatment surveillance in a multitude of clinical applications.

About Preventive Oncology International

Preventive Oncology International (POI) is an international non-profit organization that blends humanitarian work with scientific investigation. Since its founding in 1997, it has been the specific objective of POI to transplant as well as develop techniques of high quality cervical cancer screening, diagnosis and treatment, to the developing countries and other low resource areas. POI has already completed HPV and cervical cancer screening studies in Mexico and Dominican Republic, as well as both urban and rural sites in China. For more information on POI see <http://www.poiinc.org/>

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