Freedom Meditech Receives FDA 510(k) Clearance for ClearPath DS-120™

The Associated Press

SAN DIEGO--(BUSINESS WIRE)--Feb 12, 2013--Freedom Meditech, Inc., developer of non-invasive ophthalmic products for the detection of disease and management of patient health, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market and sell its first product, the ClearPath DS-120™ Lens Fluorescence Biomicroscope.

The ClearPath is cleared by FDA as a tool for the measurement of autofluorescence by scanning the crystalline lens of the eye with a blue light. In independent scientific studies published in peer-reviewed journals, elevated autofluorescence measurements have been linked to high levels of advanced glycosylated end products which accumulate as a result of the aging process and the presence of systemic disease.

The ClearPath scan is pain free, takes just six seconds and produces an immediate, quantitative result available to the patent and healthcare provider. Unlike some eye exams, the scan does not require dilation or other special preparation by the patient. The ClearPath is also different from diagnostic tests in that it is completely non-invasive and does not require a blood draw to produce a result.

“Receiving FDA clearance for the ClearPath is the most significant milestone to date for the company and removes the last significant risk in product development prior to marketing,” said Craig Misrach, Chairman and CEO of Freedom Meditech. “We are in the process of conducting additional validation studies which we anticipate will support enhanced claims in the labeling for the ClearPath including its ability to further improve patient outcomes and maximize overall public health.” The company plans to launch the ClearPath in the U.S. by the end of the second quarter 2013. Also, the company is in the process of acquiring the CE Mark for the product. The CE Mark is required to sell in the 27 countries that comprise the European Union and is a gateway to other non-regulated markets.

In clinical trial results submitted to the FDA the ClearPath proved to be more precise than standard of care ophthalmic devices marketed and widely utilized by health care providers in the U.S. today. The ClearPath demonstrated a Repeatability Coefficient of Variation (variability among measurements taken on the same eye using the same operator and device) and Reproducibility Coefficient of Variation (variability among measurements taken on the same eye using different operators and devices) of 5.8 % and 6.4% respectively.

The ClearPath is the first product from Freedom Meditech. Also in development is the I-SugarX non-invasive monitor that measures glucose levels in the aqueous of the eye. The I-SugarX is designed to be operated by holding the small handheld

device, similar to a miniature telescope, in front of the eye to provide people with diabetes a convenient and pain-free alternative to the “finger stick” method of glucose monitoring.

About Freedom Meditech Freedom Meditech, Inc. is a medical device company focused on the commercialization of novel ophthalmic technologies for the detection of disease and management of patient health. The company maintains corporate and engineering operations in San Diego, CA with supporting research and development activities throughout the state of Ohio. For more information, visit www.freedom-meditech.com.

The I-SugarX is an investigational device and is limited by federal law to investigational use. ClearPath DS-120™ Lens Fluorescence Biomicroscope is a trademark owned by Freedom Meditech, Inc.

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