

Contacts

David Van Avermaete, CEO  
VeraLight, Inc.  
925/895-5308  
david.vanavermaete@veralight.com

Charles Versaggi, Ph.D.  
Versaggi Biocommunications®  
415/806-6039  
cv@versaggibio.com

**Editor's Note:** VeraLight will be showing the Scout DS diabetes screening system at Booth #1123 at the ADA Exhibitor Hall D, McCormick Place, Chicago, June 23<sup>rd</sup>-25<sup>th</sup>, 10am-4pm.

## FIRST NON-INVASIVE DIABETES SCREENING DEVICE PREVIEWED AT THE AMERICAN DIABETES ASSOCIATION ANNUAL MEETING

### Early Results Show Scout DS™ One-minute Screen May Outperform Conventional Blood Tests for Diabetes and Pre-Diabetes

CHICAGO, June 22, 2007 — A one-minute experimental diabetes screening system that uses light to detect diabetes-related biomarkers found in skin regardless of color will be previewed tomorrow for the first time at the 67<sup>th</sup> annual meeting of the American Diabetes Association. Previously reported studies of a prototype of the portable desktop system have shown it outperforms both the fasting plasma glucose (FPG) test and the A1C test as a rapid and non-invasive screen for pre-diabetes and type 2 diabetes. The investigational device, not yet approved for use in the United States, is being designed for use at physician-supervised point-of-care locations.

Known as Scout DS™, manufactured by VeraLight Inc. of Albuquerque, New Mexico, the simple-to-use device weighs about 10 pounds and does not require the patient to fast or provide a blood sample. Using light directed onto a small area of an individual's forearm the device is able to detect abnormal concentrations of *advanced glycation endproducts* (AGEs), which correlate well with diabetes and pre-diabetes and are associated with the disease's serious complications. The medical device is slated for U.S. market introduction in the second half of 2008.

The Scout DS prototype is currently undergoing a large-scale pivotal trial in the United States. A calibration trial of 1,700 subjects at risk for type 2 diabetes has completed data collection at eight U.S. sites. This phase of the trial is designed to assure its ability to predict abnormal glucose tolerance in a wide range of individuals. In August 2007, the system will be undergoing further testing at 20 U.S. sites in 5,400 subjects at risk for type 2 diabetes. In all cases, Scout DS is being compared to the gold standard Oral Glucose Tolerance Test (OGTT) as the reference method.

“Considering its excellent speed, convenience and sensitivity, the Scout DS may be ideally suited to detect the more than 70 million individuals worldwide who have undiagnosed type 2 diabetes,” said Timothy J. Lyons, M.D., a clinical investigator for VeraLight who heads the endocrinology section at the Oklahoma University Health Science Center. “VeraLight's diabetes screening technology represents a critical response to the worldwide diabetes epidemic, making screening more accurate and accessible to everyone at risk for this devastating disease.”

More...

## **Diabetes Odometer**

Analogous to a “diabetes odometer,” AGEs are a sensitive metric for the cumulative damage the body endures due to the effects of abnormally high blood sugar and oxidative stress. AGEs harm the proteins that make up the blood vessels, connective tissue, and are thought to be major factors in aging and age-related chronic diseases. According to medical experts, non-invasive skin detection of AGEs could replace the FPG test as the medical workhorse for screening people suspected of having diabetes.

## **Poor Performance of Conventional Screening Tests**

Conventional diabetes screening methods such as the FPG and the OGTT are inconvenient and often perform poorly. Diagnosis of diabetes typically doesn't occur until 7-9 years post onset when 50% of patients have one or more irreversible complications. The FPG requires a fasting blood sample; and the OGTT test requires fasting, ingestion of a glucose load, and multiple blood samples. Due to poor sensitivity the FPG misses up to 60% of the people, and the OGTT suffers from poor reproducibility with a Coefficient of Variation of up to 18%. These deficiencies can lead to false-negative or inconsistent results and add to the undiagnosed problem.

## **Scout DS Outperforms Conventional Tests in Early Clinical Trial**

Published in the May 2007 issue of *Diabetes Care*, a study of the Scout DS prototype involving 351 subjects showed it significantly outperformed both FPG and A1C by detecting 29% more patients with type 2 diabetes and impaired glucose tolerance (IGT) than FPG and 17% more cases than A1C. Further evaluation of a sub-cohort of the clinical data showed the Scout DS prototype was able to identify 78% more individuals with IGT than the FPG test and 47% more than the A1C test. Although this was a limited early clinical trial of a prototype in a small number of patients, VeraLight believes it can match this result in its large-scale trials with the commercially designed device.

After the subject places the palm-side of the forearm onto the cradle of the Scout DS, the device shines multiple wavelengths of light into the skin causing AGEs to emit fluorescent light that is measured by the machine. The instrument compensates for skin pigmentation so that performance is not diminished by skin coloration. The system's software utilizes multivariate statistical techniques that are applied to the spectra to obtain a diabetes risk score. As with all diabetes screening methods, an additional test is required to confirm diagnosis. The recommended confirmation for Scout DS is an OGTT.

## **Need for Early and More Accurate Diabetes Screening**

The World Health Organization estimates there will be 221 million cases of diabetes by 2010. More than 73 million Americans — one third of the adult population — now have diabetes or may be on their way to getting it, according to a NIDDK study published in the June 2006 issue of *Diabetes Care*. The study showed 9.3 percent of adults age 20 and older (19.3 million people) had diabetes in 1999-2002.

## **About VeraLight**

VeraLight, based in Albuquerque, New Mexico, is a privately held medical instrumentation company applying its proprietary SAGE technology to develop the first non-invasive diabetes screening system that provides healthcare professionals with a more accurate and convenient method for detecting type 2 diabetes and pre-diabetes based on the presence of biomarkers found in skin. For more information see <http://www.veralight.com>.

###