Vigilant Biosciences Completes Feasibility Clinical Study of New “Rinse and Spit” Oral Cancer Test

The Associated Press

MIAMI--(BUSINESS WIRE)--Oct 17, 2012--Vigilant Biosciences, Inc., (VigilantBIO) developer of the “rinse and spit” screening test for the early detection of oral cancer, today announced the completion of a National Cancer Institute (NCI) sponsored clinical study of new technology designed for early detection of oral cancer developed at the University of Miami Miller School of Medicine and exclusively licensed to VigilantBIO.

The study of 300 subjects used a case-control design that ensured cases (oral cancer patients) and controls (volunteers without cancer) were similar with respect to other important factors such as tobacco and alcohol use, age and race. This is the largest oral cancer marker study of its kind in the U.S. The principal investigator of the study is Elizabeth Franzmann, M.D., associate professor of otolaryngology, at the University of Miami Miller School of Medicine.

“The goal of the study was to determine whether the markers could effectively distinguish individuals with oral cancer from those without cancer. Based on preliminary results, we have met our end points and look forward to publishing the results,” said Dr. Franzmann, who is also a member of the Sylvester Comprehensive Cancer Center.

Based on early study results, which will be submitted to a peer-reviewed medical journal for publication, the Company is pursuing product development and seeking investment capital.

“We are very pleased with the progress made by Dr. Franzmann in completing this landmark NCI-sponsored study,” said Vigilant Biosciences founder and Chairman Matthew H.J. Kim, J.D. “Now that the study has established feasibility of the technology, we are moving forward with product commercialization and executing on a plan for U.S. and International regulatory approval.” The product consists of a low-cost, oral cancer-specific oral rinse test strip that provides an immediate and simple color change in the presence of certain levels of proteins clinically proven to be associated with early onset of oral cancer – typically before a lesion is even visually detected with a screening aid. Dental offices and public health screening facilities are seen as primary initial markets for the technology. The test targets smokers, drinkers and people with human papillomavirus (HPV), and initially represents an approximately $600 million U.S. market opportunity and a multibillion dollar opportunity worldwide.

About the technology – The VigilantBIO oral cancer screening technology measures early cancer markers via a saline solution that is swished in the mouth and collected in a tube. Collecting the teaspoon-sized sample takes about ten seconds and results

are designed to be available in minutes. The patented technology was developed at the University of Miami Miller School of Medicine.

About 640,000 people are diagnosed with oral cancer each year worldwide, according to the Oral Cancer Foundation. In the United States, about 35,000 new cases each year result in about 6,800 deaths, according to the American Cancer Society. Oral cancer treatment options include surgery, radiation and chemotherapy.

About Vigilant Biosciences, Inc. – Vigilant Biosciences, Inc. is a medical technology company enabling early intervention to improve outcomes. The company’s initial product development initiatives are aimed at overcoming the oral cancer challenge - identifying more cancers at an earlier stage and thereby improving survival rates and minimizing healthcare costs. For more information, visit www.vigilantbiosciences.com.

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