

OncoE6™ Cervical Test Predicts Development of Cervical Cancer: Arbor Vita Corporation Reports at AOGIN 2013

FREMONT, Calif. —Dec. 3, 2013—Cervical cancer is the number two cause of cancer deaths in women worldwide. More than 80% of deaths occur in the developing world, where no screening is available. Screening can save these lives because cervical cancer is curable when detected early. Current technologies are neither portable nor accurate enough for a "screen and treat" point of care strategy that many experts feel is needed in developing countries. Typically, extensive and resource costly work up must be performed before treatment can be administered because there are too many false positives. Investigators of the START-UP clinical trial reported that the Arbor Vita Corporation (AVC) OncoE6™ Cervical Test is significantly better than current technologies at predicting which women will develop cervical cancer/pre-cancers and may be suitable for a "screen and treat" strategy.

At the international 4th AOGIN Congress on "Emerging Solutions for Eradication of Cancer of the Cervix" on November 15 - 17, 2013 in Jabalpur, India, investigators reported on this breakthrough. The OncoE6™ Cervical Test was able to predict which patients without lesions on biopsy would one year later develop disease (CIN3+) and which patients with abnormal biopsy would regress without treatment. These results suggest that AVC may have a technology that is more predictive than Pap, VIA and HPV.

In an earlier report at EUROGIN 2013, results from the START-UP studies reported that the OncoE6™ Cervical Test was more accurate (specific) at detecting women that needed treatment compared to conventional screening technologies. For CIN3+ pathology, investigators found that one out of two women testing positive by the OncoE6™ Cervical Test needed treatment (PPV of 41%), while only one out of ten women with positive HPV DNA or VIA test results (PPV of 9%) required treatment.^{1,2} In the one year follow up, one out of five women developed cervical disease that required treatment (CIN3+) if they were positive by the OncoE6™ Test and women with disease by biopsy and regressed were 85% OncoE6™ Cervical Test negative. In contrast, HPV was not predictive because all women that regressed and progressed had the same degree of HPV positivity (90% for progressors and regressors).

In the follow up study, 2,797 women were rescreened one year later. They consisted of 1,978 women who were positive by OncoE6™ Cervical Cancer Test, and/or HPV DNA tests ,and/or VIA, and 932 (17.7%) women who were selected at random that tested negative.

Compared to baseline, the results from the 1 year follow up study showed:

- **For women with low grade pathology (\leq CIN1) who progressed to CIN2+, a positive OncoE6™ Cervical Test was 26 fold more predictive of progression than HPV (HC2).**
- **For women with low grade abnormal pathology (\leq CIN1) who regressed to no visible lesion after 1 year, a negative OncoE6™ Cervical Test was 7-fold better than HPV (HC2).**

The OncoE6™ Cervical Test is robust, simple to use, accurate and rapid, permitting a same day "screen and treat" strategy. A positive OncoE6™ Cervical Test result not only identifies high grade cervical disease, but is also predictive of future high risk of cervical cancer while a negative OncoE6™ Test result is highly predictive of future regression. The high specificity and predictive value of the OncoE6™ Cervical Test is key to cost effectiveness, allowing for the best utilization of scarce resources for follow up of women for treatment and those who are at risk for cervical disease (CIN2+).

About OncoE6™ Cervical Test

Cervical cancer is caused by HPV (Human Papillomavirus). Most HPV infections do not progress to cancer and clear without treatment (greater than 99%). When HPV-infected cells become pre-cancer or cancer, the virus infected cells make the E6 protein in larger amounts. As the oncogenic driver, the E6

protein is the most informative biomarker to distinguish infection from cancer. The OncoE6™ patented technology will identify the 1% of women who truly need follow up / treatment. Thus resources can be focused on the woman with disease and give peace of mind to the hundred plus other women who do not.

The OncoE6™ Cervical Test is simple, easy to use, "dipstick" format, requires no refrigeration, minimal training and can be run anywhere in the world. It is highly accurate (99% specificity) and is now available in many parts of the world.

About PATH and START-UP

Initiated in 2008, the START-UP project is focused on the development of simple, rapid, portable, and robust biochemical tests that are inexpensive, acceptable to women and healthcare providers, safe, accurate, and appropriate for use in low-resource settings. The START-UP clinical study organized by PATH and CICAMs enrolled a total of 7,543 women, aged 25-65, in three rural sites in China. The study was designed to compare specificity and sensitivity across multiple screening regimens, including VIA, Arbor Vita Corporation's OncoE6™ Cervical Cancer Test and the Qiagen HC2 HPV DNA Test. In addition, all individuals with a positive test received a one-year follow-up.

PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act in order to improve global health and well-being.

About Arbor Vita Corporation

Arbor Vita Corporation is a privately held company located in Fremont, California that was founded in 1998 to focus on the discovery, development and commercialization of a novel class of proteomic-based diagnostics and therapeutics. The Company's proprietary PDZ protein technology platform continues to produce groundbreaking solutions to complex health challenges, including infectious disease, cancer and neurological and cardiovascular disorders such as stroke.

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