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Chembio Announces U.S.D.A. Approval of Tests for Detection of Bovine Tuberculosis in Captive Elk and Deer

MEDFORD, N.Y., Jan. 29, 2013 (GLOBE NEWSWIRE) -- **Chembio Diagnostics, Inc.** (Nasdaq:CEMI), a leader in point-of-care diagnostic tests for infectious diseases, announces that its U.S. Department of Agriculture (USDA)-licensed products, CervidTB STAT-PAK[®] and DPP[®] VetTB, have been approved as primary and secondary tests for bovine tuberculosis by the USDA Animal and Plant Health Inspection Service (APHIS) in order to provide the farmed deer industry with more options for meeting the testing requirements for captive cervids (elk and deer) within the regulations.

Based on published results of independent validation studies conducted by the USDA-APHIS, the Company's tests can reliably detect the presence or absence of antibodies to bovine tuberculosis in several species of captive cervids¹). Therefore, the agency has recommended that the captive cervid regulations be amended to recognize these two tests as official tuberculosis tests. This amendment was made effective as of January 9, 2013 without prior notice and opportunity for public comment in order to immediately provide additional testing options to regulated entities that are required to have their captive cervids tested. Public comments may be submitted to APHIS until March 11, 2013.

Commenting on this development, Lawrence A. Siebert, Chembio's Chief Executive Officer, said, "With the increased costs of producing and maintaining healthy livestock, it is vitally important to ensure that herds can be moved and processed, disease-free, in an efficient and timely manner. We welcome the USDA's designation of our CervidTB STAT-PAK[®] and DPP[®] VetTB as official primary and secondary tests. We believe that there is substantial potential for veterinary applications of our technology, both in production livestock as well as in companion animals, and we will continue to pursue opportunities in this important market segment."

Farmed deer constitute a significant alternative livestock industry in the U.S., with their numbers exceeding 500,000, according to a published estimate²). The article further indicates there are an estimated two million farmed deer in New Zealand, one million in China, 400,000 in Russia and 100,000 in Canada.

Testing for tuberculosis in cervids is currently performed using tuberculin skin tests. The single cervical test (SCT) is the primary (screening) test, whereas the comparative cervical test (CCT) is the secondary test. Limited and conflicting information is available regarding the accuracy of the skin testing in captive cervids. However, according to a published USDA study, 25/28 confirmed *M. bovis*-infected elk in Nebraska had false-negative results on the SCT³). In addition, animal handling challenges resulting in high morbidity and mortality are not uncommon, as captive cervids may be required to be captured and restrained for testing up to four different times depending on test results.

Serologic testing offers the advantage over skin testing of limited animal handling, with a reduction in the associated morbidity and mortality. Chembio's tests are rapid (approximately 20 minutes to complete) and simple (one or two steps) animal-side assays that are easy to perform, provide accurate antibody detection results, and do not require laboratory environment, reading equipment, or refrigeration for long-term storage (up to 12 months). An additional advantage is eliminating the subjectivity of interpreting the skin test response at the tuberculin injection site.

¹) **Nelson et al. 2012. Evaluation of serodiagnostic assays for *Mycobacterium bovis* infection in elk, white-tailed deer, and reindeer in the United States.** *Veterinary Medicine International*, volume 2012, Article ID 563293 (<http://www.ncbi.nlm.nih.gov/pubmed/22792512>).

²) **Waters et al. 2008. Blood culture and stimulation conditions for the diagnosis of tuberculosis in cervids by the Cervigam assay.** *Veterinary Record*, Volume 163: 203-208 (<http://www.ncbi.nlm.nih.gov/pubmed/18281626>).

³) **Waters et al. 2011. Bovine tuberculosis in a Nebraska herd of armed elk and fallow deer: a failure of the tuberculin skin test and opportunities for serodiagnosis,** *Veterinary Medicine International*, volume 2011, Article ID 953985 (<http://www.ncbi.nlm.nih.gov/pubmed/21547234>).

About Bovine Tuberculosis

Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium *Mycobacterium bovis*. Although commonly defined as a chronic debilitating disease, bovine tuberculosis can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of *M. bovis*, the disease has been reported in several other species of livestock, including bison and captive cervids. There have also been instances of infection in other domestic and nondomestic animals, as well as in humans. Through the National Cooperative State/Federal Bovine Tuberculosis Eradication Program, the USDA-APHIS work cooperatively with the nation's livestock industry and state animal health agencies to eradicate bovine tuberculosis from domestic livestock and to prevent its recurrence. Regulations restrict the movement of infected cattle, bison, and captive cervids to prevent the spread of bovine tuberculosis.

About Chembio Diagnostics

Chembio Diagnostics, Inc. develops, manufactures, licenses and markets proprietary rapid diagnostic tests in the growing \$10 billion point-of-care testing market. Chembio's two FDA PMA-approved, CLIA-waived, rapid HIV tests are marketed in the U.S. by Alere, Inc. (formerly, Inverness Medical Innovations, Inc.). Chembio markets its HIV STAT-PAK[®] line of rapid HIV tests internationally to government and donor-funded programs directly and through distributors. Chembio has developed a patented point-of-care test platform technology, the Dual Path Platform (DPP[®]) technology, which has significant advantages over lateral-flow technologies. This technology is providing Chembio with a significant pipeline of business opportunities for the development and manufacture of new products based on DPP[®]. Headquartered in Medford, NY, with approximately 170 employees, Chembio is licensed by the U.S. Food and Drug Administration (FDA) as well as the U. S. Department of Agriculture (USDA), and is certified for the global market under the International Standards Organization (ISO) directive 13.485. For further information please visit www.chembio.com.

Forward-Looking Statements

Statements contained herein that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of the Company and its management. Such statements, which are estimates only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to Chembio's ability to obtain additional financing and to obtain regulatory approvals in a timely manner, as well as the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

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