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## **ChemBio Diagnostics Announces Positive Data From Independent Study of Rapid, Point-of-Care Hepatitis C Test Published in the Journal of Clinical Virology**

MEDFORD, NY, Jun 19, 2012 (MARKETWIRE via COMTEX) --ChemBio Diagnostics, Inc. (NASDAQ: CEMI), a leader in point-of-care diagnostic tests for infectious diseases, reported today that data from a study evaluating performance characteristics (sensitivity and specificity) of three pre-market rapid point-of-care tests (one oral fluid and two finger-stick assays) in settings providing services to young adults who inject drugs was recently published online in the Journal of Clinical Virology and is expected to be published in the July 2012 print edition. The study authors concluded that the ChemBio blood rapid assay, which is currently in development, demonstrated acceptable sensitivity and specificity, and was comparable to conventional assays currently in use. The complete article, "Field-based performance of three pre-market rapid hepatitis C virus (HCV) antibody assays in STAHR (Study to Assess Hepatitis C Risk) among young adults who inject drugs in San Diego, CA," can be accessed online at <http://www.sciencedirect.com/science/article/pii/S1386653212001333>.

The study was designed to assess the performance of three recently developed rapid anti-HCV assays that had undergone both a laboratory-based validation and a field evaluation. The ChemBio DPP<sup>®</sup> HCV finger-stick blood and oral fluid tests were evaluated. The rapid assays evaluated were single use, disposable, in vitro, qualitative, immuno-chromatographic assays to detect anti-HCV with visual results in less than 40 minutes. Behavioral risk assessment surveys and testing for HCV were conducted among persons who reported injection drug use (IDU) within the past 6 months as part of the Study to Assess Hepatitis C Risk (STAHR) among people who inject drugs (PWID) aged 18-40 years in 2009-2010. Sensitivity and specificity of the rapid anti-HCV assays were evaluated among STAHR participants, using two commonly used testing algorithms.

The study results showed that ChemBio DPP<sup>®</sup> HCV finger-stick blood test had a sensitivity of 92.8% against a laboratory-based enzyme immunoassay (EIA) screening assay reference while it demonstrated 97.1% sensitivity against The Centers for Disease Control and Prevention (CDC) reference method algorithm which utilizes a third generation recombinant immunoblot assay (RIBA). The DPP<sup>®</sup> finger-stick blood test achieved 99.0% specificity on both reference methods. The study concluded, "We found further evidence that sensitive rapid anti-HCV assays can be useful for the detection of anti-HCV among persons at risk for HCV, such as PWID who can be reached through specific social service settings, such as syringe exchange programs. Of the three assays evaluated, the ChemBio blood rapid assay demonstrated acceptable sensitivity and specificity, and was comparable to conventional assays currently in use."

Commenting on the study, Lawrence Siebert, ChemBio's Chief Executive Officer, noted, "We are pleased that these data independently confirm that our DPP<sup>®</sup> HCV rapid assay, which is currently in development, demonstrated acceptable sensitivity and specificity in this HCV population and is comparable to conventional assays currently in use that may take weeks to provide results. These findings give us confidence that with additional time and resources we can develop a superior product for this important market."

"With approximately 4.1 million Americans estimated to have been infected with HCV, and with 45-85% unaware of their infection, the development of a rapid, point-of-care HCV test is an important public health initiative particularly for high-prevalence, high-risk populations such as young PWID. Using a sensitive anti-HCV rapid assay like our DPP<sup>®</sup> HCV, PWID would receive their results at the point-of-care on the same day, increasing the likelihood that they could be provided with prevention counseling messages and referrals for follow up. We look forward to advancing the clinical development of our DPP<sup>®</sup> HCV diagnostic and to bringing this rapid, POC HCV diagnostic to market as a solution for this growing public health problem," added Mr. Siebert.

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<sup>®</sup> 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<sup>®</sup>) 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<sup>®</sup>. 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.

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 are estimates only. Such statements 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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