



September 8, 2016

Cepheid Targets Development of a Point of Care HIV Viral Load Test From a Few Drops of Blood

Enabling Accurate and Fast Molecular HIV Viral Load Test from Finger Stick Whole Blood

SUNNYVALE, Calif., Sept. 8, 2016 /PRNewswire/ -- Millions of patients, including newborns, in primary health care settings could gain access to a potentially life-changing test for HIV viral load monitoring thanks to a new development effort from Cepheid (Nasdaq: CPHD), which is being partially funded by a grant from the Bill & Melinda Gates Foundation.

The development effort is targeting a new test that is designed to deliver lab-quality results from a few drops of finger stick-collected blood at remote patient sites, in contrast to existing HIV viral load tests that require venipuncture and separation of plasma from venous blood at a limited number of molecular lab locations. Patients today in resource-limited settings can wait weeks to months for important HIV viral load test results that could support better anti-retroviral therapy management. Even worse, it has been estimated that, in some countries, as many as 50% of centralized laboratory results are never delivered to the patient.[1]

The Xpert® Finger Stick HIV-1 Viral Load Assay, now in development, builds on Cepheid's existing plasma-based test for HIV viral load, and is expected to deliver results within one hour, enabling same-visit test and treat algorithms, even in the most remote and challenging environments.

"A Finger Stick whole blood HIV quantitative assay that can reliably differentiate viral load levels at the 1,000 copies/mL level could dramatically impact the course of the HIV epidemic," said Prof Ian Sanne, Founding Director and Chief Executive Officer of Right to Care. "This would enable better clinical management of HIV patients and make the UNAIDS 90-90-90 target a reality. Clinicians challenged the diagnostics industry over ten years ago to come up with a simple, cost effective, bed-side test that has a cut-off relevant for the treatment of HIV. Cepheid may be the first to deliver."

"Coupled with Cepheid's innovative Omni point of care system[2], we believe the Xpert® Finger Stick HIV-1 Viral Load Assay has the potential to revolutionize the management of HIV patients on a worldwide basis," said John Bishop, Cepheid's Chairman and Chief Executive Officer.

The industry-leading simplicity and scalability of this new test, when successfully completed, could support efforts to enable the UNAIDS 90-90-90 target, with the goal to assure, by the year 2020, that 90% of individuals worldwide with HIV know their status, 90% of diagnosed individuals have initiated antiretroviral treatment, and 90% of those on treatment achieve viral suppression.[3] The Finger Stick whole blood test from Cepheid is designed to detect HIV viral load levels, the standard method of monitoring the amount of HIV in the blood and is anticipated to be accurate, precise, and conform to World Health Organization (WHO) guidelines, which defines treatment failure at a HIV viral load of 1,000 copies/mL or above.

The Finger Stick HIV viral load assay is currently in Phase I development by Cepheid, with partial funding from the Gates Foundation. Cepheid's current Xpert test menu includes Xpert® HIV-1 Qual, which has been awarded WHO prequalification, and Xpert® HIV-1 Viral Load, both available outside the United States. For more information on Cepheid's GeneXpert Systems or the complete menu of Xpert tests, visit www.cepheidinternational.com.

About Cepheid

Based in Sunnyvale, Calif., Cepheid (Nasdaq: CPHD) is a leading molecular diagnostics company that is dedicated to improving healthcare by developing, manufacturing, and marketing accurate yet easy-to-use molecular systems and tests. By automating highly complex and time-consuming manual procedures, the company's solutions deliver a better way for institutions of any size to perform sophisticated genetic testing for organisms and genetic-based diseases. Through its strong molecular biology capabilities, the company is focusing on those applications where accurate, rapid, and actionable test results are needed most, such as managing infectious diseases and cancer. For more information, visit www.cepheid.com.

About GeneXpert Systems and Xpert Tests

With more than 11,000 systems in 182 countries, the GeneXpert System is the world's most popular molecular diagnostics'

instrument. The GeneXpert System's modular configuration means that the system is the most scalable available, offering the ability to perform from one to eighty Xpert tests at the same time. As a result, the GeneXpert System meets the throughput requirements of customers of all sizes - from lower volume point-of-care settings to higher volume reference laboratories - enabling accurate, fast and cost effective test results.

GeneXpert Systems run proprietary Xpert test cartridges. The Xpert test menu spans healthcare-associated infections, sexual health, critical infectious disease, and oncology, and today offers 23 tests outside the US, and 20 tests in the US. More information on the GeneXpert System and the Xpert tests is available on our website at www.cepheid.com.

Forward Looking Statements

This press release contains forward-looking statements that are not purely historical regarding Cepheid's or its management's intentions, beliefs, expectations and strategies for the future, including those relating to the funding, successful development, future availability, performance, technical and product specifications, sensitivity, speed, accuracy, diagnostic utility and clinical efficacy of the Xpert® Finger Stick HIV-1 Viral Load Assay (the "Finger Stick Test") , including relative to competing products and technologies, the ability of the Finger Stick Test to impact worldwide HIV diagnosis and treatment levels and treatment efficacy and the ability of the Finger Stick Test to impact the achievement of the UNAIDS 90-90-90 target. Because such statements deal with future events, they are subject to various risks and uncertainties, and actual results could differ materially from Cepheid's current expectations. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to: continued funding of the Finger Stick Test by the Bill & Melinda Gates Foundation; successful completion of development and regulatory approvals of the Finger Stick Test; test performance and speed in the field; utilization of our tests by clinicians and health care professionals in remote environments; future changes in medical practice and protocols; our ability to successfully and timely develop new products; the completion of clinical trials for new products successfully and in a timely manner; uncertainties related to the United States FDA, European and other regulatory processes; the Company's ability to successfully introduce and sell products in global markets; the Company's research and development budget; unforeseen supply, development and manufacturing problems; the potential need for additional intellectual property licenses for tests and other products and the terms of such licenses; the impact of competitive products and pricing; the costs of product components and other factors affecting product pricing; the Company's ability to manage geographically-dispersed operations; and underlying regulatory, political and market conditions worldwide. Readers should also refer to the section entitled "Risk Factors" in Cepheid's Annual Report on Form 10-K, its most recent Quarterly Report on Form 10-Q, and its other reports filed with the Securities and Exchange Commission.

All forward-looking statements and reasons why results might differ included in this release are made as of the date of this press release, based on information currently available to Cepheid, and Cepheid assumes no obligation to update any such forward-looking statement or reasons why results might differ.

[1] [AIDS](#) 2016. Barriers and Opportunities to Scaling up HIV Viral Load Testing. CHAI data from Mozambique, Malawi and South Africa. July 20, 2016.

[2] Projected availability 3Q2017

[3] http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf

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