Hologic - Investor Relations

FDA Grants PMA Approval for Hologic's Aptima® HIV-1 Quant Assay

--High-performing HIV viral load test now available alongside broad women's health menu on the fully automated Panther® system--

MARLBOROUGH, Mass., Jan. 3, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) has granted PMA approval for the Company's HIV-1 viral load monitoring assay. The Aptima® HIV-1 Quant assay is a nucleic acid amplification test for the quantitative detection of RNA from HIV in plasma specimens.

The Aptima HIV-1 Quant assay runs on Hologic's Panther® system, a market-leading, integrated platform that fully automates all aspects of testing, from sample to result. The system substantially reduces hands-on time for laboratories by providing random and continuous access with rapid turnaround time.

"Clinical laboratories have an increasing need to consolidate testing onto automated instruments," said Tom West, president, Diagnostic Solutions Division at Hologic. "Adding HIV viral load monitoring to our existing women's health menu allows customers to maximize use of the widely adopted, reliable and user-friendly Panther system."

A number of published studies have compared the performance of the Aptima HIV-1 Quant assay with other HIV viral load monitoring assays currently on the market. The results of these studies demonstrate that the Aptima HIV-1 Quant assay provides repeatable, reliable results for consistent quantitation.[1-4] This consistency is critical for patient management, as it ensures that detected changes in viral load are due to potential clinical changes rather than assay variation.

The Hologic Aptima HIV-1 Quant assay uses a dual target approach against highly conserved regions in the HIV genome and is designed to deliver reliable, consistent quantitation across HIV-1 groups and subtypes. Availability of the assay on the Panther system enables every step, from sample to result, to be completed within a single integrated instrument. This combination of performance and automation will provide labs the ability to become even more efficient while meeting today's demands for HIV treatment monitoring.

"Hologic has an impressive legacy in the virology space, which started two decades ago and spans the development of nucleic acid tests to screen the blood supply for HIV and HCV, to the launch of qualitative assays for HIV and HCV in the early 2000's," said West. "We leveraged this expertise and applied it to the development of the viral load portfolio on the Panther system."

The Aptima HIV-1 Quant assay is not approved for HIV-1 diagnosis in the United States. Outside the U.S., the Aptima HIV-1 Quant Dx assay is CE-IVD marked for both diagnostic and monitoring claims, as is the Aptima HCV (hepatitis C) Quant Dx assay; the Aptima HBV Quant assay is CE-marked for hepatitis B monitoring. The Aptima hepatitis C and B assays are not currently approved for sale in the United States. To learn more about the U.S. Aptima HIV-1 Quant assay, please visit http://usaptimavirology.com.

The Aptima Quant viral load assays are not part of the recently announced pending sale of Hologic's blood donor screening business to Grifols, and the Aptima Quant viral load assays will continue to be owned by Hologic upon closing of the transaction with Grifols.

About Hologic

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products. The company's core business units focus on diagnostics, breast health, GYN surgical, and skeletal health. With a unified suite of technologies and a robust research and development program, Hologic is dedicated to The Science of Sure. For more information on Hologic, visit www.hologic.com.

Hologic Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's diagnostic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

[1]Hopkins, et.al. Comparative performance of the new Aptima HIV-1 Quant Dx assay with three commercial PCR-based HIV-1 RNA quantification assays. Journal of Clinical Virology, 69 (2015) 56-62.

[2]Nair, SV, et al. Aptima HIV-1 Quant Dx – A fully automated assay for both diagnosis and quantification of HIV-1. Journal of Clinical Virology, 77 (2016) 46-54.

[3]Sahoo, et.al. Evaluation of the Aptima HIV-1 Quant Dx assay using plasma and dried blood spots. Journal of Clinical Microbiology, 54 (2016) 2597-2601.

[4]Sam, et.al. Evaluation of performance characteristics of the Aptima HIV-1 Quant Dx assay for detection and quantitation of Human Immunodeficiency Virus Type 1 in plasma and cervicovaginal lavage samples. Journal of Clinical Microbiology, 54 (2016) 1036-1041.

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