



Daktari Awarded \$1.3 Million NIH SBIR Grant for HIV Point-of-Care Diagnostic

Direct-to-Phase II grant supports development of rapid, sensitive, whole-blood HIV viral load assay

CAMBRIDGE, Mass. – December 1, 2016 – Daktari Diagnostics, a company focused on making “Anywhere. Care.™” a reality with its portable and ultrasensitive immunoassay-based CarePlatform™, today announced it was awarded a \$1.3 million, two-year Small Business Innovation Research (SBIR) grant from the National Institutes of Health’s National Institute of Allergy and Infectious Diseases (NIAID) to support the development of a point-of-care (POC) HIV viral load (VL) test for use in addressing unmet needs in global health settings.

HIV treatment guidelines from the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) recommend VL testing as the preferred monitoring tool for HIV patient management¹. VL testing is also an integral part of UNAIDS’ “90-90-90” treatment target goal of 90 percent of people on treatment having suppressed viral loads by 2020². Currently, only about half of the 35 million HIV-infected individuals know their status and there are still 1.5 million AIDS-related deaths a year³.

“The ability to provide high-quality care to people living with HIV/AIDS is still limited in many countries due to poor access to care, including diagnostic testing,” said Marta Fernández Suárez, PhD, Vice President of Assay Research & Development at Daktari and co-principal investigator. “Daktari is developing a highly portable, easy-to-use, whole-blood HIV viral load assay that aims to solve this access problem, including reaching the 77 percent of people living in developing countries who are unreachable today by currently available lab-based systems.” Daktari is collaborating on this project with Partners for Health and Development in Africa (PHDA) and Dr. Julius Oyugi (University of Nairobi), co-principal investigator.

Daktari’s viral load test is based on the quantification of virion-associated p24 protein, unlike traditional diagnostic p24 assays that only measure free protein p24 circulating in plasma. In a preliminary study, Daktari’s test demonstrated a strong correlation between its p24-based measurements and standard RT-PCR-based viral load values, with the potential to achieve a limit of detection equivalent to 1,000 copies/mL, a clinically relevant measurement as defined by the WHO.

“Attaining the 90-90-90 goal will require a viral load test that can be performed at the point of care. Daktari’s HIV viral load test has the potential to overcome the limitations of currently available tests, as well as those in development, due to its ability to deliver a viral load count directly from whole blood, in under 30 minutes, anywhere,” said Donald B. Hawthorne, President and Chief Executive Officer at Daktari. “We are grateful to the NIH and NIAID for this support, which validates the potential of our CarePlatform™ technology to revolutionize point-of-care HIV viral load testing and address a significant unmet need for clinically relevant, highly portable diagnostic solutions.”

About Daktari Diagnostics

Daktari Diagnostics, a privately held company based in Cambridge, Mass., is focused on developing ultrasensitive, point-of-care diagnostics that enable timely testing and access to healthcare so that

patients around the world can be linked to appropriate care. Daktari's immunoassay CarePlatform™ encompasses a proprietary diagnostic detection technology, a highly portable device, automated sample preparation with whole blood in a single-use disposable cartridge, and a wireless, cloud-based connectivity platform to allow seamless data management for enhanced clinical care. Daktari is initially developing three diagnostic products based on the CarePlatform: a High-Sensitivity Cardiac Troponin (hs-cTnI) cardiac distress screening test, a Hepatitis C Virus Core Antigen (HCV-cAg) confirmatory test being developed in collaboration with Merck, and an HIV viral load monitoring test. For more information, visit www.daktaridx.com.

1. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Geneva: World Health Organization; 2013 (<http://www.who.int/hiv/pub/guidelines/arv2013/en/>).
2. How AIDS changed everything. Geneva: Joint United Nations Programme on HIV/AIDS; 2015 (http://www.unaids.org/en/resources/documents/2015/MDG6_15years-15lessonsfromtheAIDSresponse).
3. Putting HIV and HCV to the Test (http://www.msfacecess.org/sites/default/files/HIV_HCV_Report_Diagnostic_Guide_2015.pdf).

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