World Health Organization Issues Prequalification of BD FACSPresto(TM) Near-Patient CD4 Counter System for HIV/AIDS Monitoring

Point-of-care CD4 analysis system tailored to meet the needs of resource-limited settings

PR Newswire

SAN JOSE, Calif., Sept. 23, 2014 /PRNewswire/ -- BD Biosciences, a segment of BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the World Health Organization (WHO) has issued a report prequalifying the BD FACSPresto(TM) Near-Patient CD4 Counter system for the enumeration of CD4 count to determine eligibility for initiation of Antiretroviral Therapy (ART), staging of the disease and monitoring of HIV-infected patients in middle- and low-volume testing laboratories. Prequalification from the WHO is required in order for a product to be included on the WHO's prequalified list and for international agencies such as the Global Fund and United Nations entities to procure systems.

The WHO report was based on the assessment of product dossier, manufacturing site inspection and laboratory evaluation. According to the report, the BD FACSPresto system has "fulfilled the WHO requirements for prequalification in all three components mentioned above."

CD4 testing allows HIV/AIDS patients to have access to treatment and monitoring, reducing the probability of transmitting the infection to others and providing a plan for improved long-term care. Immediate treatment for infected individuals who meet medical guidelines can dramatically quell the spread of HIV according to the WHO. This is particularly important as many new cases of HIV/AIDS are transmitted from people who are not aware they are infected.([i],[ii])

"We are very pleased that the BD FACSPresto system has received this prequalification and thankful to the WHO for delivering the prequalification so swiftly using the new streamlined process for prequalification of in vitro diagnostics," said Claude Dartiguelongue, Worldwide President, BD Biosciences. "Results from our own clinical studies([iii]) have also demonstrated that the BD FACSPresto system performs comparably with the BD FACSCalibur(TM) cell analysis system in terms of accuracy, precision and linearity across a wide measuring range. Bringing this same level of testing precision to resource-limited settings assures operators and patients a high degree of confidence in results."

Launched in April of this year, the BD FACSPresto Near-Patient CD4 Counter system provides absolute and percentage results of CD4 T lymphocytes and hemoglobin (Hb) concentration in whole blood samples to determine eligibility for initiation of ART, staging and monitoring of HIV/AIDS patients. The system was designed to meet the needs of resource-limited settings with many features that simplify operation without compromising accuracy and precision, including several checks to ensure quality and consistency of testing as well as an intuitive language-independent graphical touchscreen interface. The testing workflow begins with blood collection from a finger-stick or venipuncture that is then transferred to a single-use disposable cartridge. To increase the number of tests that can be conducted per day, the cartridge is incubated outside the instrument for 18 minutes. After incubation, the cartridge is inserted into the BD FACSPresto counter and results are available in less than four minutes.

The BD FACSPresto system is portable, weighs only 6 kg (13.23 lbs.) and can be easily transported. The cartridge uses dried reagents and offers stability across a wide range of storage conditions.

The BD FACSPresto system is CE marked according to the EU IVD Directive 98/79/EC and is available now. The system is priced competitively compared to CD4 systems currently on the market. BD expects pricing for both the counter and reagents to be aligned with expectations of the Clinton Health Access Initiative (CHAI), President's Emergency Plan for AIDS Relief (PEPFAR), The Global Fund, Partnership for Supply Chain Management (PFSCM), and UNICEF. The BD FACSPresto system is not yet available in the U.S.

About BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving drug delivery, enhancing the diagnosis of infectious diseases and cancers, supporting the management of diabetes and advancing cellular research. We are nearly 30,000 associates in 50 countries who strive to fulfill our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of healthcare around the world. For more information, please visit www.bd.com.

([i]) AIDS. 2006 Jun 26;20(10):1447-50. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA.
([ii]) http://www.cdc.gov/hiv/topics/surveillance/resources/reports/.
([iii]) Data on file at BD.

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