Quidel and Life Technologies Receive FDA Clearance for Clostridium difficile Assay and QuantStudio™ Dx and 7500 Fast Dx Real-Time PCR Instruments

March 18, 2013

FDA issues 510(k) Clearance for Quidel Molecular Direct Clostridium difficile Assay and Life Technologies Real-Time PCR Instruments for Monitoring Hospital-Acquired Infections

SAN DIEGO and CARLSBAD, Calif., March 18, 2013 /PRNewswire/ -- Quidel Corporation **(NASDAQ: QDEL)** and Life Technologies Corporation (NASDAQ: LIFE) announced today that they received 510(k) clearances from the United States Food and Drug Administration (FDA) to market the Quidel Molecular Direct C. difficile Assay with Life Technologies' QuantStudio ™Dx and 7500 Fast Dx Applied Biosystems® Real-Time PCR Instruments.

(Photo: http://photos.prnewswire.com/prnh/20130318/LA78485)

Clostridium difficile bacterial infections are life-threatening, especially for the elderly, immunocompromised populations, and for patients on a prolonged antibiotic regimen. *C. difficile* infection (CDI) is frequently associated with antibiotic therapy and extended hospital stays.

"According to The Centers for Disease Control and Prevention (CDC), 14,000 deaths are attributed to CDI in the U.S. each year, which costs the national healthcare system about $1 billion in excess treatment. For this reason, a fast and accurate diagnosis is vital to the patient's proper treatment and speedy recovery,"[1] said Douglas Bryant, president and chief executive officer for Quidel Corporation, who added, "With the clearance of our C. difficile assay, we extend our Quidel Molecular product line beyond respiratory infections with products that address the needs of hospital laboratories in higher-volume settings."

"Molecular diagnostic assays have become the gold standard for infectious disease testing in the clinical lab," said Ronnie Andrews, president of medical sciences at Life Technologies. "Molecular testing is the fastest-growing segment of the diagnostics market, and Life Technologies' deep expertise in real-time PCR instrumentation, together with our demonstrated effectiveness in pursuing regulatory pathways for our instruments, uniquely positions Life to become a leader in the diagnostics market."

This Quidel Molecular Direct C. difficile Assay is part of Quidel's expanding line of molecular diagnostics products. The Quidel Molecular product line offers PCR reagent kits for use by molecular diagnostic laboratories, including Life Technologies' QuantStudio™ Dx and 7500 Fast Dx. These reagents provide attractive features that include refrigerated storage instead of freezing, convenient ready-to-use reagents, a short time to result, and other benefits that favorably enhance the molecular workflow.

The Quidel Molecular Direct C. difficile Assay kit includes an extraction-free, three-step sample preparation process that requires no heat step, no timed step, and no centrifugation as an added benefit. This fast and easy direct-to-amplification procedure allows the assay to generate a result in less than 70 minutes by an efficient and economical method.

"Combining multiple system capabilities in a single footprint, the QuantStudio™ Dx is our flagship instrument in the diagnostic lab market," said Andrews. "Life Technologies is committed to providing physicians and clinical laboratories with instrumentation designed for flexibility and ease of use, as well as best-in-class diagnostic tests where we see unmet clinical need."

The QuantStudio™ Dx Real-Time PCR instrument's touch screen, reagent and sample tracking, and LIMS (Laboratory Information Management Systems) interface are specifically designed for ease of use, and the six-color feature allows for a multiplex of six targets in one reaction.

The 7500 Fast Dx Real-time PCR Instrument system is a five-color real-time PCR instrument that delivers the performance required for high-quality results in a 96-well format. The 7500 Fast Dx is also FDA cleared for diagnostic use with the Center for Disease Control's H1N1 assay and with the Quidel Molecular assays for Influenza A+B and human metapneumovirus (hMPV).

With the QuantStudio™ Dx, flexibility is enabled through an optional Test Development mode allowing the use of easily interchangeable thermal cycling blocks that accommodate 96- or 384-well plates and a proprietary qPCR microfluidics card, which can perform 48 tests on eight samples simultaneously without the need for liquid-handling robots. The card can also be used to design and implement custom tests. Life Technologies is currently developing diagnostic tests utilizing this format. In this Test Development mode, the QuantStudio™ Dx can perform numerous functions, including pathogen detection, gene expression analysis, SNP genotyping, copy number analysis, mutation detection, micro-RNA and other non-coding RNA analysis, and high-resolution melt analysis.

The current 510(k) clearance represents another milestone in the extension of Life Technologies' move into the diagnostics arena. In September 2012, Life Technologies launched Pervenio™ Lung RS, a lab-developed test distinguishing high-risk from low-risk early stage lung cancer patients. In February 2013, the company received 510(k) clearance for its 3500 Dx Genetic Analyzers and SeCore® HLA typing kits.

The Quidel Molecular Direct C. difficile Assay is Quidel's first assay with a streamlined stool processing procedure. Quidel also sells FDA approved molecular tests in the Real-Time PCR format for Influenza A+B, hMPV and RSV + hMPV.

1. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm?s_cid=mm6109a3_w

About Life Technologies

Life Technologies Corporation (NASDAQ: LIFE) is a global biotechnology company that is committed to providing the most innovative products and services to leading customers in the fields of scientific research, genetic analysis and applied sciences. With a presence in more than 180 countries, the company's portfolio of 50,000 end-to-end solutions is secured by more than 5,000 patents and licenses that span the entire biological spectrum -- scientific exploration, molecular diagnostics, 21st century forensics, regenerative medicine and agricultural research. Life Technologies has approximately 10,000 employees and had sales of $3.8 billion in 2012.

About Quidel Corporation

Quidel Corporation serves to enhance the health and well being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Sofia® and AmpliVue® brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's comprehensive product portfolio, visit www.quidel.com and Diagnostic Hybrids at www.dhiusa.com.

Life Technologies' Safe Harbor Statement

This press release includes forward-looking statements about Life Technologies' anticipated results that involve risks and uncertainties. Some of the information contained in this press release, including, but not limited to, statements as to industry trends and Life Technologies' plans, objectives, expectations and strategy for its business, contains forward-looking statements that are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by such forward-looking statements. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. Important factors which could cause actual results to differ materially from those in the forward-looking statements are detailed in filings made by Life Technologies with the Securities and Exchange Commission. Life Technologies undertakes no obligation to update or revise any such forward-looking statements to reflect subsequent events or circumstances.

Quidel Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, our ability to develop new products and technology, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and actions of our major distributors, technological changes and uncertainty with research and technology development, including any future molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse regulatory actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), compliance with FDA and environmental regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our growth strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, intellectual property, product liability, environmental or other litigation, potential required patent license fee payments not currently reflected in our costs, adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill, and lower-than-anticipated acceptance, sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the Securities and Exchange Commission (SEC) from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. We undertake no obligation to publicly release the results of any revision or update of the forward-looking statements, except as required by law.

Life Technologies Contact
Suzanne Clancy
760-602-4545
858-205-4235 (mobile)
suzanne.clancy@lifetech.com

Quidel Contact:
Ruben Argueta
858-646-8023
rargueta@quidel.com

SOURCE Life Technologies Corporation; Quidel Corporation