Quidel Receives FDA Clearance for Its Quidel Molecular Human Metapneumovirus (hMPV) Assay

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SAN DIEGO, CA, Dec 23, 2011 (MARKETWIRE via COMTEX) --**Quidel Corporation (NASDAQ: QDEL)**, a leading provider of rapid diagnostic testing solutions and cellular-based virology assays, announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for the sale of its first molecular diagnostic test -- the Quidel(R) Molecular hMPV Assay for the detection of human metapneumovirus.

This is one of several forthcoming assays from Quidel's expanding molecular diagnostics programs. The Quidel Molecular product line offers PCR reagent kits for use by molecular diagnostic laboratories with their existing Applied Biosystems(R) 7500 Fast DX thermocycler. These reagents include attractive features that provide for simple transport and storage of the kit, convenient workflow, a short time to result, and other benefits that favorably affect diagnostic test outcome.

"We are very excited about the clearance of our first molecular offering in the United States," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We are pleased with our continued execution of the R&D pipeline."

The 510(k) clearance grants Quidel authorization to market its Quidel Molecular hMPV Assay in the United States just in time for the upcoming respiratory disease season. The product was launched in Europe shortly after receiving the CE Mark in September 2011.

Human metapneumovirus, recently discovered in 2001, infects most children by the time they reach five years of age.(1) It can cause serious respiratory infections, especially in infants, young children, the elderly, and in patients of all ages that are immunocompromised.(1) This disease accounts for about 7% of children admitted to the hospital with respiratory infection.(1) Symptoms of hMPV are very similar to and sometimes indistinguishable from those caused by human respiratory syncytial virus (RSV).(2)

(1) Sugrue R, Tan B-H, Loo L-H (2008). "The Emergence of Human Metapneumovirus." Future Virology 3 (4): 363-371. (2) Sloots T, Mackay I (August 2006). "Human Metapneumovirus, Australia, 2001-2004." Emerging Infectious Diseases 12 (8): 1263-1266.

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(R), D3(R) Direct Detection and Thyretain(R) leading brand names, as well as under the new Sofia(TM) and Quidel Molecular brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including 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.

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 molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), our ability to comply with FDA, environmental and other regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our 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 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.

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