Quidel Receives FDA Clearance for Influenza Point-of-Care Diagnostic Test

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QuickVue Influenza Test is First Step in Test and Treat
Program for Flu Sufferers

SAN DIEGO, Sept. 27 /PRNewswire/ -- Quidel Corporation (Nasdaq: QDEL) announced today that it has received clearance from U.S. Food and Drug Administration (FDA) to market its QuickVue(R) Influenza Test, a rapid, point-of-care diagnostic test to detect influenza A and B. The diagnostic test is designed to assist health care providers in identifying patients infected with influenza who would benefit from immediate diagnosis and intervention.

"The flu season is nearing and we are very pleased to have received clearance to market this point-of-care, rapid influenza diagnostic test," said Andre de Bruin, vice chairman, president and chief executive officer of Quidel Corporation. "Our test, coupled with the appropriate therapeutic treatment for the management of influenza, offers physicians a more complete patient care solution directly at the point-of-care. The combination of an easy-to- use, accurate, rapid diagnostic test and an effective therapeutic regimen is an example of the Test and Treat(TM) strategy Quidel has adopted."

The influenza diagnostic was developed through a product development collaboration with Glaxo Wellcome, plc, whose drug Relenza(TM) has recently been clinically proven to reduce the duration of illness caused by influenza virus types A and B. Quidel expects to market the QuickVue(R) Influenza Test worldwide.

Influenza impacts 25 to 50 million people in the U.S. every year and results in 20,000 to 40,000 deaths and 300,000 hospitalizations, with estimated costs of $3 to 5 billion in the U.S. and $12 billion worldwide for related medical conditions and lost work time.

Quidel Corporation discovers, develops, manufactures and markets point-of- care, rapid diagnostic tests for detection of medical conditions and illnesses. These products provide accurate, rapid and cost-effective diagnostic information for acute and chronic conditions that affect women's health throughout the phases of their lives such as reproductive status, pregnancy management and osteoporosis. Quidel also provides point-of-care diagnostics for infectious diseases, including strep throat, H. pylori infection, chlamydia and infectious mononucleosis. Quidel's products are sold to healthcare professionals for use in physician's offices, clinical laboratories and pharmacies, and to consumers through organizations that provide private label, store brand products. These tests provide diagnostic information to enable rapid treatment and improve health outcomes, lower costs, and increase patient satisfaction.

This press release contains forward-looking statements regarding Quidel, its products and its future activities within the meaning of the federal securities laws. These forward-looking statements involve material risks and uncertainties. Many possible factors could affect the future results and performance of Quidel's products, such that actual results and performance may differ materially. If Quidel's products fail to perform as expected, or if there is lower consumer demand for these products than expected, Quidel's financial condition and operating results may be materially and adversely affected. Quidel's financial condition and operating results may also be materially and adversely affected by a number of factors, including, without limitation, seasonality, adverse changes in competitive and economic conditions, actions by the Company's distributors, manufacturing and production delays or difficulties and adverse actions or delays in product reviews by the FDA. Please see the discussion of these and other factors in Quidel's annual reports on Form 10-K and subsequent quarterly reports on Form 10-Q. For more information, please visit Quidel's web site at http://www.quidel.com.

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