Sequenom Laboratories Presents New Data Supporting The Accuracy Of The MaterniT21® Plus Laboratory Developed Test In Clinical Setting

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SAN DIEGO, Sept. 22, 2014 /PRNewswire/ -- Sequenom, Inc. (NASDAQ:SQNM), a life sciences company providing innovative genetic analysis solutions, today announced that its wholly owned subsidiary, Sequenom Laboratories, presented patient clinical data substantiating the performance of its MaterniT21® PLUS noninvasive prenatal test (NIPT) in the laboratory. An ad hoc analysis of 185,000 samples from patients at high-risk for fetal chromosome aneuploidy demonstrated stable positivity rates for trisomy 21, 18 and 13, which mirror the positivity rates found in large studies on high-risk populations utilizing invasive diagnostic procedures. Additionally, Sequenom Laboratories reported performance results from clinical testing with the MaterniT21 PLUS test with Enhanced Sequencing Series. These data were presented at the 33rd National Society of Genetic Counselors Annual Educational Conference (NSGC AEC) in New Orleans, Louisiana, which took place September 17-20, 2014.

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In the ad hoc analysis based on voluntary outcomes provided by clinicians, the estimated sensitivity for trisomy 21, 18 and 13 were 99.3%, 98.3% and 97.4% respectively, and the estimated specificity was >99.9% for all three trisomies. These clinical laboratory performance data are equivalent to those published in the clinical validation studies of the MaterniT21 test. Based on these performance metrics, Sequenom Laboratories estimates that the MaterniT21 PLUS test positive predictive value (PPV) for trisomy 21, 18 and 13 were 99.0%, 97.6% and 92.8% respectively, and the negative predictive value (NPV) was >99.9% for all three trisomies.

"PPV and NPV are valuable performance measurements for genetic counselors and clinicians when interpreting the significance of a NIPT result," said Lauren Korty, MS. LCGC, University of California, San Diego Health System. "This information must be interpreted along with the relevant clinical information, especially in the event of a positive result, when counseling the patient and determining the most appropriate next steps in managing the pregnancy."

Sequenom Laboratories also presented the results from more than 120,000 patient samples tested for clinically relevant microdeletions between October 2013 and July 2014, which were reported as additional findings as part of the MaterniT21 PLUS test with Enhanced Sequencing Series. The presentation showed data for the first 100 positive cases that were reported out to clinicians. Included were cases of 22q deletion (DiGeorge syndrome), 5p deletion (Cri-du-chat syndrome), 15q deletion (Prader-Willi/Angelman syndromes), 1p deletion (1p36), as well as two additional trisomies (trisomy 16 and 22). The MaterniT21 PLUS test demonstrated a low false positive rate (FPR) for the reported microdeletions (estimated combined FPR < 0.03%) and high positive predictive values (estimated combined PPV ranged from 62% to 94%). Additionally, positive call rates were consistent with expected outcomes based on the incidence of these conditions.

"We are pleased with the clinical experience and feedback we have received for the first 120,000 samples reported in the MaterniT21 PLUS test with Enhanced Sequencing Series," said Dirk van den Boom, PhD, Chief Scientific and Strategy Officer at Sequenom, Inc. "The high accuracy of the test allows physicians and their patients to obtain important information not only for trisomies but also for these clinically relevant but much rarer conditions."

Sequenom Laboratories Sponsored CEU-Educational Session at NSGC

- Noninvasive prenatal testing for microdeletions: one year later. Nicole Teed, MS,CGC, Sequenom; Heather Marin, MS, LSGC, The Center for Prenatal Diagnosis at St. Vincent Women's Hospital, Indianapolis, IN; Lauren Korty, MS LCGC, UCSD Health System, San Diego, CA

Sequenom Laboratories Presentations at NSGC

- Clinical experience of microdeletion and expanded trisomy detection by noninvasive prenatal testing (NIPT). Jenna Wardrop.
- Performance of noninvasive prenatal testing (NIPT) aneuploidy at different fetal fractions. Ron McCullough, PhD.

Sequenom Laboratories Scientific Posters at NSGC

- Disomic placentas, trisomic babies: Reverse mosiacism and implications for noninvasive prenatal testing (NIPT).
- Clinical experience reporting trisomy 16 and 22 on noninvasive prenatal testing (NIPT): Test performance and implications for genetic counseling.
- Application of risk-score analysis to low-coverage whole genome sequencing data for the noninvasive detection of trisomy-21 and trisomy-18.
- Detection of maternal 22q deletions by noninvasive prenatal testing (NIPT)
- Scientific explanation: When the "false positive" noninvasive prenatal testing (NIPT) result is not false.
- 250,000 cases and counting - the high volume clinical experience with noninvasive prenatal testing (NIPT).

About Sequenom

Sequenom, Inc. (NASDAQ:SQNM) is a life sciences company committed to improving health care through revolutionary genomic and genetic analysis solutions. Sequenom develops innovative technologies, products, and diagnostic tests that target and serve molecular diagnostic markets. Web site: www.sequenom.com

About Sequenom Laboratories

Sequenom Laboratories, a CAP-accredited and CLIA-certified molecular diagnostics laboratory, has developed a broad range of laboratory tests, with a focus on prenatal and ophthalmological diseases and conditions. Branded under the names HerediT™, MaterniT21® PLUS, RetnaGene™, SensiGene® and VisibiliT™, these molecular genetic laboratory-developed tests provide early patient-management information for obstetricians, geneticists, maternal fetal medicine specialists, and ophthalmologists. Sequenom Laboratories is changing the landscape in genetic-disorder diagnostics using proprietary cutting-edge technologies.

Forward-Looking Statement

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the benefits of Sequenom Laboratories' MaterniT21 PLUS test, including the validation of their specificity and sensitivity, Sequenom's ability to offer accurate, comprehensive prenatal information, Sequenom's ability to expand the offering of the MaterniT21 PLUS test, and Sequenom's commitment to improving health care through revolutionary genomic and genetic analysis solutions are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with the performance of the MaterniT21 PLUS test, market demand for and acceptance and use of technology and tests such as the MaterniT21 PLUS test, reliance upon the collaborative efforts of other parties and licensees, healthcare providers and others, Sequenom or third parties obtaining or maintaining regulatory approvals that impact Sequenom's business, government regulation particularly with respect to diagnostic products and laboratory developed tests, publication processes, the performance of designed product enhancements, Sequenom's ability to develop and commercialize technologies and products, particularly new technologies such as noninvasive prenatal diagnostics and laboratory developed tests, Sequenom's financial position, the timing and amount of reimbursement that Sequenom Laboratories receives from payors for its laboratory developed tests, Sequenom's ability to manage its existing cash resources or raise additional cash resources, competition, intellectual property protection and intellectual property rights of others, litigation involving Sequenom, and other risks detailed from time to time in Sequenom's most recently filed reports on Form 8-K, its most recently filed Quarterly Report on Form 10-Q and its Annual Report on Form 10-K for the year ended December 31, 2013, and other documents subsequently filed with or furnished to the Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and Sequenom undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

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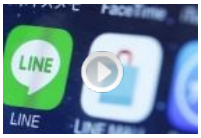

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