OpGen Highlights Acuitas® Analytical Validation Data for Rapidly Predicting Antibiotic Resistance Using Drug Resistance Gene Profiles at ECCMID

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DNA Sequencing prediction results and evaluation of Acuitas Resistome Test for infection control presented

GAITHERSBURG, Md., April 24, 2018 (GLOBE NEWSWIRE) -- **OpGen, Inc.**(NASDAQ:OPGN) today announced that it has presented analytical validation results for the Acuitas®AMR Gene Panel u5.47 (RUO) for detection of multi-drug resistant pathogens and antibiotic resistance genes and the use of test results to predict antibiotic resistance using the bioinformatics capabilities of the Acuitas Lighthouse® Software. The results were presented at the 28thEuropean Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Madrid, Spain.

The poster, titled “Analytical Validation of a Rapid Molecular Test for Semi-Quantitative Detection of Bacterial Pathogens and Antibiotic Resistance Genes in Urine,” demonstrated the semi-quantitative detection of five pathogens and 47 antibiotic resistance genes from primary urine specimens and bacterial isolates. Results from the Acuitas AMR Gene Panel u5.47 (RUO) were used with the Acuitas Lighthouse Software to predict phenotypic resistance for 35 isolates from the CDC & FDA Antibiotic Resistance (AR) Isolate Bank. For the ten *E. coli* isolates tested, the Acuitas Lighthouse Software predicted antibiotic resistance to thirteen antibiotics with 94% sensitivity, 93% specificity, and 94% agreement with traditional testing methods. Results for the ten *K. pneumoniae* isolates were 85% sensitivity, 100% specificity, and 88% agreement. For the ten *P. aeruginosa* isolates, the predictions were at 100% sensitivity and agreement. The AR Isolate Bank is provided by the U.S. Centers for Disease Control and the U.S. Food and Drug Administration to help industry with development of new diagnostic devices, tests, assays and therapeutics. The study demonstrated a lower limit of detection for each pathogen of approximately 1,000 organisms per milliliter of urine, accurate detection of pathogens with semi-quantitation over 10^3 to 10^6 organisms per milliliter of urine, and no species cross-reactivity with 39 pathogens commonly associated with urinary tract infections.

Terry Walker, PhD, OpGen’s Senior Vice President R&D, commented, “In the validation study, the Research-Use-Only Acuitas AMR Gene Panel u5.47 accurately semi-quantitated the organisms and resistance genes in our test. The Acuitas Lighthouse Software demonstrated accurate prediction of phenotypic resistance to thirteen antibiotics commonly prescribed for these pathogens.” Dr. Walker concluded, “Development of our Acuitas products continues to progress. We recently reduced time to result to two hours and the preliminary performance continues to meet our expectations.”

A second poster, titled “Comprehensive analysis of fluoroquinolone resistance in *Pseudomonas aeruginosa*,” demonstrated an example of OpGen’s whole genome sequencing analysis and prediction pipelines. In the study of 616 isolates, sensitivity and specificity for prediction of resistance to two fluoroquinolone antibiotics ranged between 91% and 95%.

The Imperial College Healthcare NHS Trust, London, United Kingdom, presented “Evaluation of a gene-resistance profile testing platform (OpGen) with traditional typing methods as a potential for more accurate and quicker identification of carbapenem-resistant Enterobacteriaceae (CRE) outbreaks.” The study demonstrated 100% agreement with the Cepheid Carba-R FDA cleared test for carbapenem resistance genes and capabilities of the Acuitas Resistome Test for detection of 46 antibiotic resistance genes for infection control of drug-resistant pathogens in a National Health Service Hospital.

About OpGen

OpGen, Inc. is harnessing the power of informatics and genomic analysis to provide complete solutions for patient, hospital and network-wide infection prevention and treatment. For more information, please visit www.opgen.com.

The Acuitas AMR Gene Panel u5.47 (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

Forward-Looking Statements

This press release includes statements relating to OpGen’s analytical validation results for its Acuitas AMR Gene Panel u5.47 and Acuitas Lighthouse Software products in development. These statements and other statements regarding OpGen’s future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and services offerings, the rate of adoption of our products and services by hospitals and other healthcare providers, the success of our commercialization efforts, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with OpGen's business, please review our filings with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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