# OpGen Presents Data at ASM Microbe 2018 Demonstrating High Accuracy of Acuitas® for Predicting Antibiotic Resistance in Urine Specimens

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90% accuracy data presented for rapid antibiotic resistance prediction using Acuitas AMR Gene Panel and Acuitas Lighthouse on urine clinical specimens

Prospective clinical trial in Colombia demonstrates 57% improvement in survival and reductions in antibiotic usage when OpGen rapid diagnostic test used

GAITHERSBERG, Md., June 12, 2018 (GLOBE NEWSWIRE) -- **OpGen, Inc.**(NASDAQ:OPGN) today announced the presentation of data from the first phase of its Acuitas® urine clinical verification study demonstrating high accuracy in predicting antibiotic resistance in urine specimens. In the study, remnant urine specimens were provided by Intermountain Healthcare and Beth Israel Deaconess Medical Center and were tested with the Acuitas AMR Gene Panel u5.47 (Research Use Only 'RUO') to detect 5 pathogens and 47 resistance genes common to urinary tract infections. From the resulting genetic data, the Acuitas Lighthouse® Software (RUO) then predicted antibiotic resistance with greater than 90% accuracy.

OpGen's Senior Vice President of R&D, Terry Walker, Ph.D., presented the data this past weekend at ASM Microbe 2018 in a poster titled "Semi-Quantitative Molecular Detection for 5 Bacterial Pathogens and 47 Antibiotic Resistance Genes in Urine Specimens" and also at OpGen's Symposium held on June 8.

In total, 229 remnant urine specimens were tested using the Acuitas AMR Gene Panel u5.47 (RUO). The test data were analyzed by Acuitas Lighthouse (RUO) to predict antibiotic resistance and these predictions were then compared with conventional antibiotic susceptibility testing. For the 4 Gram-negative pathogens featured in the presentation, the accuracy for predicting antibiotic resistance across 12 antibiotics was as follows: *E. coli* (92%), *K. pneumoniae* (91%), *P. mirabilis* (92%) and *P. aeruginosa* (100%).

"The first set of data from testing urine specimens is very promising and is another demonstration of the capabilities of the new Acuitas test and Acuitas Lighthouse Software," said Dr. Walker. "The ability of the test and software to rapidly detect and accurately predict antibiotic resistance in urine specimens has the potential to become a useful diagnostic tool for helping manage patients with complicated urinary tract infections. Results of our larger prospective clinical verification study will be provided after completion of the patient accrual and testing later this year. We are also continuing to refine our products in advance of our upcoming clinical trials in support of our 510(k) filings to the U.S. Food and Drug Administration for our Acuitas AMR Gene Panel u5.47 and the Acuitas Lighthouse Software."

Separately, at ASM Microbe 2018 researchers from El Bosque University and CIDEIM in Colombia presented results of a 153 patient prospective clinical trial evaluating the impact of using rapid diagnostic testing for identification and treatment of bacteremia and fungemia in hospital intensive care units in Colombia. The study demonstrated a 57% improvement in survival rate and reductions in antibiotic usage for patients tested with the OpGen rapid diagnostic test. Use of the OpGen QuickFISH® test to identify pathogens in positive blood cultures resulted in improved clinical outcomes compared with conventional methods. In the poster "Impact of Using A Rapid Diagnostic Test for the Identification and Treatment of Bacteremia and Fungemia in Four Colombian Hospitals' Intensive Care Units," the researchers concluded that use of the QuickFISH test resulted in a 47% decrease in time-to-result reporting, a more than 60% increase to the rate of empiric therapy adjustment and a 19% reduction in the duration of therapy. The survival rate for patients tested with the OpGen rapid test was 74% vs. 47% for patients receiving current standard of care protocols.

The authors concluded, "Our findings suggest that new molecular technologies such as QuickFISH lead to a better clinical outcome compared to the conventional methods by reducing the time to final reports and duration of therapy in intensive care unit patients with bloodstream infections. Survival may be associated with a better chance of appropriate therapy. These results are consistent with the findings in other international settings."

"We are encouraged by the positive impact to clinical outcomes by the QuickFISH test in the Colombian hospitals and expect this will help drive commercialization there and across South America and other developing world markets," Dr. Walker added.

The QuickFISH rapid test identifies pathogens in positive blood cultures in under thirty minutes. Antibiotic resistance results for the new AMR Gene Panel (RUO) and Acuitas Lighthouse Software (RUO) are available in under three hours directly from urine and bacterial isolates.

**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) and the Acuitas Lighthouse Software (RUO) are intended for Research Use Only and are 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 Acuitas AMR Gene Panel u5.47 and Acuitas Lighthouse Software products in development and expansion of the use of OpGen's QuickFISH products into new markets. 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. 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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