OpGen's Acuitas® AMR Gene Panel Shows Potential for Reducing Total Time to Targeted Therapy

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Collaborator data demonstrating OpGen's rapid prediction of antibiotic resistance and detection of uropathogens presented at ASM Microbe 2019

GAITHERSBURG, Md., June 27, 2019 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) today announced the presentation of data obtained from the first multisite assessment evaluating the potential clinical utility of its Acuitas® AMR Gene Panel using clinical samples. The study tested 531 remnant urine specimens from Beth Israel Deaconess Medical Center, Geisinger, and Intermountain Healthcare with the Acuitas AMR Gene Panel (For Research Use Only 'RUO'), to detect five pathogens and 47 antibiotic resistance genes common to urinary tract infections (UTI). Results for the Acuitas AMR Gene Panel (RUO) were produced in less than three hours.

These data were presented on June 22 by Geisinger researchers at ASM Microbe 2019 in a poster titled "Verification of Real Time PCR for the Detection of Antibiotic-Resistance Markers and Semi-Quantitation of Urinary Tract Pathogens from Urine Samples."

For the two most prevalent microbial species, *E. coli* and *K. pneumoniae*, the Acuitas Gene Panel had a total agreement of 96% and 97%, respectively, for pathogen detection, compared to MALDI-ToF mass spectrometry. Acuitas Lighthouse predictions for phenotypic Antimicrobial Susceptibility Testing (AST) showed 93% total agreement for *E. coli* and 92% total agreement for *K. pneumoniae,* when compared to each site's method for phenotypic AST.

"Reducing the total time to targeted therapy, especially in complicated UTIs that have an increased risk to harbor antimicrobial resistance, has the potential to reduce hospital length of stay and mortality rates among patients," said Dr. Donna Wolk, Division Director, Molecular and Microbial Diagnostics, Geisinger.

The total agreement by antibiotic class for both the *E. coli and K. pneumoniae* pathogens averaged 97% for aminoglycosides, 92% for fluoroquinolones, and 93% for cephalosporins. These data demonstrate that the Acuitas AMR Gene Panel and Acuitas Lighthouse informatics may have the potential to serve as a front-line diagnostic to reduce time to targeted therapy for urinary tract infections (UTI), reducing length of stay and mortality.

"We are pleased with the results of the presented data, which further demonstrate the capabilities of our Acuitas diagnostic test in development and Acuitas Lighthouse Software as front-line tools in clinical settings to detect and predict antibiotic resistance in urine specimens. We believe these data further demonstrate the utility of our offering as a diagnostic tool to help identify and manage complicated urinary tract infections," said Evan Jones, Chairman and CEO of OpGen.

UTIs are a significant cause of hospital admissions and can be associated with mortality linked to urosepsis. It is reported that 50-60% of all women will experience a UTI in their lifetime, while 25% experience a second UTI within six weeks of the first. Rapid and accurate detection has the potential to reduce the time to targeted therapy for certain UTI-causing pathogens, leading to a decrease in length of stay and mortality.

The Acuitas AMR Gene Panel is a new molecular test being developed by OpGen, designed to detect five pathogens and 47 antibiotic-resistance genes in less than three hours. The test is currently available for research use only and is not for use in diagnostic procedures. Earlier this year, clinical trials were conducted for establishing the performance of the Acuitas AMR Gene Panel for use with bacterial isolates. Data obtained from the clinical trials were submitted in a 510(k) submission to the U.S. Food and Drug Administration (FDA). OpGen is conducting clinical trials in 2019 to support a submission for its direct-from-urine Acuitas AMR Gene Panel test and the Acuitas Lighthouse Software for antibiotic resistance prediction direct from clinical samples and the management of antimicrobial resistance data in healthcare institutions.

About OpGen

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (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. For more information, please visit **www.opgen.com.**

Forward-Looking Statements

This press release includes statements relating to OpGen's Acuitas AMR Gene Panel 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. 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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