OpGen Presents Preliminary Acuitas® AMR Gene Panel Data for Detecting Urinary Tract Infections

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As showcased at IDWeek 2019 - Test results show parity with urine culture and whole genome sequencing results

GAITHERSBURG, Md., Oct. 07, 2019 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) today announced the presentation of preliminary data at IDWeek 2019 for the Company's Acuitas ® AMR Gene Panel and Acuitas Lighthouse® Software for the detection of urinary tract infections (UTI). The data demonstrate the concordance of Acuitas AMR Gene Panel results with conventional urine culture and the agreement with whole genome sequencing for the detection of a broad set of resistance genes that span nine antibiotic classes. Data showing antibiotic resistance predictive alignment with antibiotic susceptibility testing were also presented at the meeting.

The data were presented on October 5 by OpGen's Director of Clinical Laboratory, Jamie Lemon, Ph.D., D(ABMM) during the session "Rapid Diagnostics and Resistance: Making Sense of Now and the Future Part 2."

The presented data revealed that, in a study that analyzed over 580 remnant urine specimens, OpGen's rapid, semi-quantitative Acuitas AMR Gene Panel (For Research Use Only 'RUO') was 93% concordant with conventional urine culture results, using a clinically significant threshold. Furthermore, new data presented from a multicenter clinical trial for isolate testing found that, when compared to whole genome sequencing, the Acuitas AMR Gene Panel (For Investigational Use Only 'IUO') had an average positive agreement greater than 96% and a negative agreement of greater than 99% for resistance gene detection. Over 1,000 isolates were tested in this study.

"We are pleased with the results of these recent studies, as we continue the verification and validation work for our Acuitas AMR Gene Panel for UTIs and Acuitas Lighthouse Software. They offer great potential as frontline tools for rapidly detecting UTIs and predicting antibiotic resistance," said Dr. Lemon. "Semi-quantitative detection of pathogens directly from urine in less than three hours, in addition to accurate resistance gene detection and antibiotic resistance predictions, will be important for UTI management and minimizing the growing risk of antibiotic resistance. We are thrilled to share the progress we've made with fellow clinical experts at IDWeek 2019."

The Acuitas AMR Gene Panel is a molecular test, designed to detect five pathogens and up to 47 antibiotic-resistance genes in less than three hours. The test, from OpGen, is currently available for research use only (RUO) 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 study results related 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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