OpGen Completes Clinical Trials for its Initial FDA 510(k) Submission

February 5, 2019

GAITHERSBURG, Md., Feb. 05, 2019 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) announced today that it has completed the clinical trials needed to support its 510(k) submission for the detection of antimicrobial resistance genes in bacterial isolates to the U.S. Food & Drug Administration ("FDA") for clearance of its Acuitas® AMR Gene Panel u5.47 product.

The clinical trials tested more than 1,000 clinical isolates at four participating clinical sites: The Johns Hopkins University School of Medicine; Wadsworth Center, New York State Department of Health; University Hospitals Cleveland Medical Center; and IHMA, Inc. The company has completed the majority of analytical testing activities including reproducibility studies and DNA sequencing of over 1,000 isolates to support the planned 510(k) submission.

"We are pleased to have completed the isolate clinical trials as an important milestone toward submission for FDA clearance of our Acuitas AMR Gene Panel u5.47 product. We are encouraged by the preliminary results, and look forward to continuing the process toward submission, as we seek clearance for use of our technology throughout the U.S." said Evan Jones, CEO, OpGen, Inc.

The Acuitas AMR Gene Panel u5.47 is a new molecular test developed by OpGen designed to detect five key pathogens and 47 antibiotic-resistance genes semi-quantitatively in less than three hours. It is currently available for research use only (RUO). In addition to the isolate 510(k) submission, OpGen is conducting clinical trials in 2019 to support a submission for direct-from-urine testing and the Acuitas Lighthouse® Software for antibiotic resistance prediction direct from clinical samples and management of antimicrobial resistance data in healthcare institutions. These trials will test samples collected from patients with urinary tract infections (UTI).

There are more than one million patients each year in the U.S. with complicated UTI, and many of these patients are at risk for multidrug-resistant infections. Complicated UTI cases are a major cause of hospital admission, morbidity, mortality, and excess health care costs as a growing number of infections are healthcare-associated in origin.

About OpGen

OpGen, Inc. is harnessing the power of informatics and genomic analysis to provide complete solutions for patient, hospital, and network-wide infection treatment and prevention. The Acuitas Lighthouse Software (RUO) is the first cloud-based software to predict antibiotic resistance, track antimicrobial resistance, and determine bacterial strain relatedness in healthcare settings using bacterial genetic data. The Acuitas AMR Gene Panel (RUO) is the most comprehensive, rapid PCR test for detecting five pathogens and 47 resistance genes which cover nine antibiotic classes. OpGen's solutions will provide the power to prescribe empiric therapy with precision. 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 regulatory submission timeline for 2019. 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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