



## OpGen Announces New Data Demonstrating Clinical Utility for Antibiotic Resistant Urinary Tract Infection Patient Management and for Rapid Carbapenem-Resistant Bacteria Outbreak Detection

June 13, 2019

### Findings from major health centers to be presented at ASM Microbe 2019

GAITHERSBURG, Md., June 13, 2019 (GLOBE NEWSWIRE) -- [OpGen, Inc.](#) (Nasdaq: OPGN) announced today that data from its Acuitas<sup>®</sup>AMR Gene Panel and Acuitas Lighthouse<sup>®</sup> Software will be presented at [ASM Microbe 2019](#) being held June 20-24 in San Francisco, California at the Moscone Convention Center. The presentation will include a comparative analysis of Acuitas Lighthouse and Whole Genome Sequencing (WGS) for Carbapenemase-producing organisms (CPO) in an outbreak investigation conducted by the New York State Department of Health's Wadsworth Center. The Acuitas Lighthouse data will be shown concordant to WGS but with a faster turnaround time suggesting that Acuitas AMR Gene Panel and Acuitas Lighthouse can be used as front-line tools in clinical settings for transmission and outbreak detection. In addition to general conference acceptance, these data were selected to be featured in a podium presentation.

Also at the meeting, data from a clinical verification study for the Acuitas AMR Gene Panel test for urine will be presented by Geisinger. In this study, over 500 of the remnant urine specimens collected and tested at Beth Israel Deaconess Medical Center (BIDMC), Geisinger, and Intermountain Healthcare were analyzed. The data demonstrate that the Acuitas AMR Gene Panel had greater than 90% agreement with quantitative culture for semi-quantitative pathogen detection and Acuitas Lighthouse phenotype predictions had greater than 90% average total agreement with antibiotic susceptibility testing for *E. coli* and *K. pneumoniae*, the most common pathogens that cause urinary tract infections (UTI).

Other data featured at the conference will be presented by Intermountain Healthcare. These data are from a collaborative study with BIDMC and OpGen demonstrating the potential of Acuitas AMR Gene Panel and Acuitas Lighthouse to be used as a rapid diagnostic to guide early, empiric antibiotic use in patients with UTI from antibiotic resistant bacteria. Lastly, OpGen will present its research into genetic mechanisms that increase the risk of antimicrobial resistance in bacteria.

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 (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.

The ASM Microbe 2019 presentation schedule for OpGen's data is as follows:

- Poster title: **A Comparative Analysis of Highly-Multiplexed Real Time PCR and Whole Genome Sequence Analysis for Outbreak Investigat**
- Presenter: E. Snaveley (Wadsworth Center, New York State Department of Health)
- Date and time: Friday, June 21, 10:30 a.m. – 5:00 p.m. PT  
Sunday, June 23, 3:10 p.m. – 3:20 p.m. PT
- Location: Poster and Exhibit Halls A-E, CPHM Track, Friday Po. 899 (Friday)  
CPHM Lounge and Learn – South – Level 2 (Sunday)
- Poster Title: **Culture Independent, Molecular Detection of Uropathogens and Antibiotic Resistance Genes Direct from Urine Specimens**
- Presenter: B. Lopansri (Intermountain Healthcare)
- Date and time: Friday, June 21, 10:30 a.m. – 5:00 p.m. PT
- Location: Exhibit Halls A-E, CPHM Track, Friday Po. 845
- Poster Title: **Verification of a Real Time PCR for the Detection of Antibiotic-Resistance Markers and Semi-Quantitation of Urinary Tract Path from Urine Samples**
- Presenter: A. Styer (Geisinger)
- Date and time: Saturday, June 22, 10:30 a.m. – 5:00 p.m. PT
- Location: Poster and Exhibit Halls A-E, CPHM Track, Saturday Po. 970

Poster title: **Impaired DNA Mismatch Repair System Increases the Risk of Emerging Antibiotic Resistance in Bacteria**

Presenter: W. Chang (OpGen)

Date and time: Saturday, June 22, 10:30 a.m. – 5:00 p.m. PT

Location: Poster and Exhibit Halls A-E, AAR Track, Saturday Po. 620

Poster presentations will be held daily from 11:00 a.m.-12:00 p.m. and 4:00 p.m.-5:00 p.m. PT. To learn more about these presentations or to schedule a meeting with a member of the OpGen team, please contact [mfarmer@opgen.com](mailto:mfarmer@opgen.com).

#### **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](http://www.opgen.com).

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc.

#### **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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Source: OpGen, Inc.