OpGen Announces Publication of Results from the Acuitas AMR Gene Panel Multicenter Clinical Trial in the Journal of Clinical Microbiology

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- *Publication demonstrates FDA cleared Acuitas AMR Gene Panel detects and differentiates a broad range of 28 AMR markers that can be associated with up to 9 antimicrobial classes*
- *Provides results at least a day earlier than traditional methods to guide patient management and support antibiotic stewardship and infection control programs*
- *Associating the Acuitas AMR Gene Panel markers with "not susceptible" results from culture is a key differentiator*

ROCKVILLE, Md., Feb. 10, 2022 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, announced today the release of a new peer-reviewed journal publication that demonstrates that the Acuitas® AMR Gene Panel accurately detects and differentiates 28 genetic antimicrobial resistance (AMR) markers performed on isolated colonies from 26 different pathogens including *Pseudomonas aeruginosa*, select members of *Enterobacterales*, and *Enterococcus faecalis*, and it associates AMR genes with not susceptible (i.e. intermediate, resistant) antimicrobial susceptibility (AST) results for up to 9 antimicrobial classes or subclasses.

OpGen's clinical trial used for the FDA submission of the Acuitas AMR Gene Panel was conducted at four U.S. study sites and included testing of 1,224 de-identified stocks created from 584 retrospectively collected isolates and 83 prospectively collected clinical isolates. The Acuitas AMR Gene Panel results were compared with a combined reference standard including whole genome sequencing (WGS), organism identification and phenotypic antimicrobial susceptibility testing using standard of care microbiology culture. The results of this study have now been published in the *Journal of Clinical Microbiology* and the authors found that the Acuitas AMR Gene Panel is capable of detecting and differentiating a broad range of 28 AMR markers that can be associated with up to 9 antimicrobial classes from cultured isolates of *Pseudomonas aeruginosa*, select members of *Enterobacterales*, and *Enterococcus faecalis* with ≥ 94.4% Positive Percent Agreement (PPA) and ≥ 96.5% Negative Percent Agreement (NPA) as compared with a composite reference standard, including WGS, in just 2.5 hours.

In this publication titled "Multicenter Evaluation of the Acuitas® AMR Gene Panel for Detection of an Extended Panel of Antimicrobial Resistance Genes among Bacterial Isolates[1]," the authors note that "associating the AMR markers with not susceptible phenotypic results is a key differentiator of the FDA-cleared Acuitas AMR Gene Panel compared to other molecular panels that simply detect the presence or absence of a gene." The associated agents include many of the most commonly prescribed antimicrobial agents including beta-lactams, fluoroquinolones, trimethoprim-sulfamethoxazole and aminoglycosides. The authors conclude that "this is the first FDA-cleared commercially available diagnostic tool that is capable of detecting a broad array of AMR markers among select *Enterobacterales*, *P. aeruginosa* and *E. faecalis* from cultured isolates, with the ability to associate non-susceptible results for 9 antimicrobial classes or subclasses more rapidly than traditional phenotypic methods by at least a day to guide patient management and support antibiotic stewardship and infection control programs."

Several clinical cases illustrating the potential utility of the Acuitas AMR Gene Panel were presented during a recent webinar titled "Discovering the FDA-cleared Acuitas AMR Gene Panel: Building a Case for Clinical Utility." The advantages of the Acuitas AMR Gene Panel over other currently available molecular test methods were summarized by the speakers, as follows: 1) AMR detection and linkage to a particular organism; 2) turnaround time of 2.5 hours; and 3) offering the most comprehensive AMR panel, including non-beta-lactam AMR genes, and those for what might be considered "salvage-therapy antibiotics" such as colistin. Recording of the webinar can be accessed here.

A recent publication[2] in *The Lancet* confirms the rapid spread of AMR infections and highlights that, an estimated 4.95 million deaths were associated with AMR in 2019, and between 2014 and 2019, the burden of fatalities directly attributable to bacterial AMR rose from 700K to 1.27M. The growing threat of AMR to public health is exacerbated by existing and newly developed antibiotics facing a wide range of drug resistance mechanisms in pathogens of concern. Recent Infectious Diseases Society of America (IDSA) treatment guidance for multidrug-resistant Gram-negative bacterial infections[3] highlights how detection of AMR genes or a specific mechanism of resistance can help guide reporting practices for novel antimicrobial agents and tailor therapy for these difficult to treat infections. Furthermore, it can help with infection prevention and control initiatives such as patient isolation procedures when multiple isolates with the same AMR profile are detected as an early indication of transmission within a facility or for surveillance of serious or emerging AMR threats. "The Acuitas AMR Gene Panel is a unique and powerful diagnostic tool useful in clinical patient care as well as in support of hospital infection control and epidemiology programs to identify and track AMR pathogens," said Faranak Atrzadeh, Chief Marketing and Chief Scientific Affairs Office of OpGen.

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with our subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen's product portfolio includes Unyvero®, Acuitas® AMR Gene Panel and the ARES Technology Platform including ARESdb®, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements regarding the publication of results of a recent study of the Acuitas AMR Gene Panel. 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 fact that we may not effectively use proceeds from recent financings, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the continued impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, 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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[1] https://journals.asm.org/doi/10.1128/JCM.02098-21

[2] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext

[3] https://pubmed.ncbi.nlm.nih.gov/33106864/

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