OpGen Presents Unyvero Urinary Tract Infection Panel Trial Results at ASM Microbe 2023 Conference

June 20, 2023

- *'Multi-Center Clinical Trial Using a Novel Semi-Quantitative Multiplex-PCR Based Diagnostic Panel for Urinary Tract Specimens' presented on June 17th, 2023*
- *Presentation focused on primary study endpoint and recommendations for result evaluation*
- *De Novo request for Unyvero Urinary Tract Infection (UTI) currently under Substantive Review by the FDA*
- *Additionally, data presented at the conference on Unyvero Implant and Tissue Infection (ITI) study from the University of Cincinnati*

ROCKVILLE, Md., June 20, 2023 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen" or "the Company"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, reported that its Principal Scientist Dr. Matthias Klein has presented results from the clinical trial for its Unyvero Urinary Tract Infection Panel during ASM Microbe's In Depth Symposium session 'The Year in Clinical Microbiology' on June 17th in Houston, TX. Based on over 1,800 patient samples, the presentation titled "Multi-Center Clinical Trial Using a Novel Semi-Quantitative Multiplex-PCR Based Diagnostic Panel for Urinary Tract Specimens" summarized the objectives of the clinical trial, the Unyvero UTI panel coverage and result evaluation recommendations based on multiple reference testing methods applied during the study.

OpGen's Unyvero UTI panel tests for a broad range of bacterial and fungal pathogens as well as antimicrobial resistance markers directly from urine specimens. The test aims at quantitative detection of microorganisms. The company's *De Novo* classification request to the U.S. Food and Drug Administration (FDA) was submitted in April 2023 and is currently under Substantive Review by the FDA. OpGen is seeking marketing authorization for its Unyvero UTI panel.

"As discussed during my presentation, analysis and evaluation of such a large clinical trial data set was a challenge, given the complexity of result quantitation, multiple reference methods and the frequent presence of flora in urine samples," explained Dr. Klein. "Our data demonstrated that the Unyvero UTI panel covered nearly 94% of all organisms identified in standard of care microbiology culture. It helped identify a significant number of additional organisms in the study that were missed or not reported by standard of care testing alone, with an overall weighted average sensitivity of 96.9% and an overall weighted average specificity of 97.1%."

"We have developed and presented recommendations for the evaluation of UTI results and demonstrated Unyvero UTI's good correlation to local lab culture results. 95.9% of single organisms identified by culture were correctly included in the corresponding Unyvero result, with 74.7% being completely concordant. Given that recurrent UTI infections often are treated with antibiotics, which can compromise microbiology results, we are excited that the Unyvero UTI panel is offering rapid and comprehensive molecular detection. We will continue our in-depth analysis and intend to submit further results for a peer reviewed publication together with the study's principal investigators."

In another poster presentation titled "Multiplex Molecular Panel as a Supplement to Routine Culture for Tissue Infection," the authors Cox et al. at the University of Cincinnati concluded that "multiplex PCR panel may play an important role in supplementing routine laboratory testing and improving the diagnostic yield for tissue infections for culture-negative results." This was based on a study of 47 tissue homogenate samples tested with Unyvero Implant and Tissue Infection (ITI) cartridges in a research use only setting. In that study, Unyvero ITI performed at a sensitivity of 81.5% compared to culture which showed a sensitivity of 72.2%.

Disclaimer
Caution - Investigational Device, Limited by Federal (or United States) law to investigational use. The information contained in this communication does not constitute or imply an offer to sell or transfer any product. Performance characteristics for this device have not yet been established and the FDA has not yet cleared the panel.

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, U.S.A.) 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 current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

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

Forward-Looking Statements

This press release includes statements regarding OpGen's *De Novo* classification request to the FDA for its Unyvero Urinary Tract Infection UTI panel and its recent presentations at ASM Microbe conference. 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, the success of our commercialization efforts, 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, our ability to satisfy debt obligations under our loan with the European Investment Bank, the effect of the military action in Russia and Ukraine on our distributors, collaborators and service providers, our liquidity and working capital requirements, 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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