OpGen Announces Positive Top Line Data from Clinical Trial for Unyvero Urinary Tract Infection Panel

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- *Study has enrolled over 1,800 patient samples at 4 U.S. clinical trial sites*
- *Primary endpoint for Unyvero UTI for urinary tract infection shows overall weighted average sensitivity of 96.4% and overall weighted average specificity of 97.4% in preliminary analysis*
- *Clinical performance results will be used to prepare submission package for FDA De Novo request*

ROCKVILLE, Md., Dec. 13, 2022 (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, today announced top line data from its successfully completed Unyvero UTI clinical trial. 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 trial was designed to compare the performance of the Unyvero UTI Panel for detecting urinary tract infections (UTI), using clean-catch or catheter related urine samples. Preliminary analysis of all prospectively enrolled samples showed that the primary study endpoint was successfully met by demonstrating an overall weighted average sensitivity of 96.4% and overall weighted average specificity of 97.4% when compared against each trial site’s standard of care microbiology results. These findings are also in line with the interim analysis performed during the first part of the trial.

The trial included a total of 1,858 prospective and archived samples and has run over 3,300 Unyvero cartridges, including controls and reproducibility tests performed at the different trial sites. In addition to local microbiology laboratory results and additional standardized central microbiology data from an independent reference laboratory, OpGen is currently generating next-generation sequencing (NGS) data at its Rockville, MD, lab facility to also allow genotypic correlation of antibiotic resistance markers detected during the study. Based on the results of the unblinded data set, testing of additional contrived samples with well-characterized pathogen strains will complement and provide additional data points for low prevalence strains and antibiotic resistance markers. Based on all the data generated and analyzed, OpGen will now start preparing a *De Novo* request package for submission to the U.S. FDA in due course.

“Having completed the study as planned, we have successfully generated a large and very comprehensive study data set with multiple reference methods. We’d like to thank our study sites for their contributions in generating these data.”, said Johannes Bacher, Chief Operating Officer of OpGen. “Now that we have unblinded the results, we are excited to proceed with our in-depth analysis and compile the data submission to the FDA over the next few months.”

"Urinary tract infections represent a major healthcare burden, and diagnosing complicated UTI remains challenging. Microbiological cultures take several days to provide definitive results. Pathogenic microbial species may not be detected due to prolonged exposure to antibiotics, and complex polymicrobial infections may be difficult to elucidate. The Unyvero UTI Panel is a new and promising multiplex molecular test for the rapid detection of a comprehensive range of pathogenic bacteria, fungi, and their associated resistance markers directly from urine in under five hours. Rapid results enable early diagnosis and effective antibiotic therapy to help prevent serious complications in UTI patients," said Dr. Christopher Emery, Associate Director of Clinical Microbiology, Indiana University Health Pathology Laboratory (IUHPL), Indianapolis, IN.

OpGen intends to present data from the study at a future conference as well as to submit for a peer reviewed publication.

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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 U.S. 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, 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 preliminary analysis and top-line data from OpGen’s clinical trial for its Unyvero Urinary Tract Infection 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, 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, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, 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, 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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