OpGen Initiates Clinical Trial for Unyvero Urinary Tract Infection Panel

September 30, 2021

- *OpGen's Unyvero Urinary Tract Infection (UTI) Panel tests for a broad range of pathogens as well as antimicrobial resistance markers directly from native urine specimens*
- *Prospective multicenter trial plans to include samples collected from more than 1,500 U.S. patients*
- *Clinical performance evaluation aims at subsequent FDA submission*

ROCKVILLE, Md., Sept. 30, 2021 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that it has initiated the clinical trial for its Unyvero Urinary Tract Infection (UTI) Panel, which allows testing for a broad range of pathogens as well as antimicrobial resistance markers directly from native urine specimens.

The Unyvero System and Unyvero Lower Respiratory Tract panels have already been cleared by the U.S. Food and Drug Administration. The sample-to-answer Unyvero System uses highly multiplexed PCR technology. The Unyvero UTI panel is a new application, and the overall trial design is very similar to previous studies and aims to demonstrate the product's clinical performance. Following FDA guidance, the trial is expected to enroll more than 1,500 prospective patient samples, to be complemented with archived, microbiology positive specimens. Primary endpoint of the study will be assay performance as defined by clinical sensitivity and specificity compared to culture-based standard of care microbiology. The study will be conducted at multiple sites in the U.S. Unyvero instrument setup and site initiation visits are ongoing following the trial sites' Institutional Review Board (IRB) approval of the study protocol, which is designed to meet FDA requirements. Study execution will be supported by all OpGen group companies as well as external third party CRO and laboratory service providers. It is anticipated that the data from this study will be used to support the subsequent submission to the FDA for clearance in the U.S.

"UTIs are among the most common infectious diseases, and they can be devastating. With an estimated 3 million cases each year in the U.S., complicated UTIs are a leading cause of infection-related hospitalization and are associated with higher morbidity and mortality," commented Faranak Atrzadeh, OpGen's Chief Marketing and Scientific Affairs Officer. "Effective treatment of a cUTI depends on the rapid and accurate identification of the pathogen(s) and the correct choice of antibiotic(s). The clinical utility of culture-based laboratory testing is fraught with limitations including subjectivity, specificity, delayed time to results, and missed positive samples, especially in patients hospitalized with urosepsis who often tend to have complex infections with multiple organisms present. We believe that the Unyvero UTI panel would be a valuable diagnostic tool to help treat these patient populations."

Johannes Bacher, OpGen's Chief Operating Officer added, "We are excited to move this major clinical trial towards FDA clearance of our next Unyvero product off the ground. Given the two FDA cleared Unyvero LRT panels addressing patients with suspected pneumonia already, this is a key expansion of the breadth and utility of the Unyvero platform in the U.S. market. It is further complemented by our Acuitas AMR Gene Panel for Isolates. Once again with Unyvero UTI we strive to bring a very broad panel of critical pathogens paired with a very broad panel of genetic AMR markers to patients and their doctors."

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 U.S. FDA has not yet cleared the panel.

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 Acuitas® Lighthouse, 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 a clinical trial for OpGen's Unyvero Urinary Tract Infection (UTI) 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 our financings, the realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the 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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