OpGen Announces Interim Analysis Results from Clinical Trial for Unyvero Urinary Tract Infection Panel

April 5, 2022

- *Interim analysis performed with initial 150 U.S. patient samples enrolled in its prospective multicenter trial for the Unyvero UTI panel - Clinical Trial to be continued without any changes*
- *Reproducibility Study successfully completed prior to start of enrollment*
- *Clinical performance evaluation aims at a subsequent FDA submission*

ROCKVILLE, Md., April 05, 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, reported today that, following the successful completion of a reproducibility study earlier this year, it has now unblinded and analyzed a limited data set comprising of the first 150 prospectively enrolled U.S. patient samples. Clinical trial enrollment continues at all sites.

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. The clinical performance evaluation, which aims at a subsequent FDA submission, includes a prospective multicenter trial at three U.S. sites.

The objective of the interim analysis was to confirm the absence of significant performance variations in results between the testing sites, and to furthermore confirm that blinded data collection across all data sources and study participants is executed as planned.

“We’re pleased to see that the clinical trial protocol has been implemented as planned across the different participating trial sites,” said Johannes Bacher, COO of OpGen, Inc. and Managing Director of German based Curetis GmbH. “Based on our preliminary analysis of the different data sources generated for this limited sample set, we have decided to continue enrollment towards our study goal of 1,500 prospective samples without any changes. We will furthermore include archived urine samples in order to complement the study data with additional data points for rare pathogens and antibiotic resistance markers.”

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 the interim analysis results of OpGen’s clinical trial for its Unyvero Urinary Tract Infection. 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, 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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