OpGen Announces 1,000th Patient Sample Enrolled in Clinical Trial for Unyvero Urinary Tract Infection Panel

June 22, 2022

- *Prospective multicenter trial for the Unyvero UTI panel recruited its 1,000th prospective patient sample*
- *Fourth trial site added to optimize enrollment for different sample types and accelerate trial completion*
- *Clinical performance evaluation aims at a subsequent FDA submission*

ROCKVILLE, Md., June 22, 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 it has enrolled its 1,000th prospective patient sample for its Unyvero Urinary Tract Infection Panel.

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 submission to the U.S. Food and Drug Administration (FDA), includes a prospective multicenter trial at three U.S. sites.

OpGen recently added a fourth study site in the United States to optimize enrollment for different urine sample types to be included in the study. In addition to continued prospective sample testing, results from these samples will be complementing the study data with additional data points for rare pathogens and antibiotic resistance markers.

“We’re pleased to see that the clinical trial has gained significant momentum after initial COVID-related challenges at the different participating trial sites in late 2021 and early 2022, as evidenced by the 1,000th patient sample now enrolled. This is a significant achievement towards the goal of 1,500 prospective samples as required by applicable FDA guidance”, said Johannes Bacher, COO of OpGen, Inc. “Adding another trial site will boost collection rates for the different sample types while working towards accelerating the completion of enrollment during the next few months as planned.”

“The UTI trial completion and final data read out, which we expect in the second half of this year, will be another major milestone for OpGen” commented Oliver Schacht, CEO of OpGen. “Unblinding data from a major clinical trial is always an exciting catalyst, and we believe there is a clear unmet medical need for a rapid, comprehensive, sample to answer test for complicated urinary tract infections”.

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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, 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 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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Source: OpGen, Inc.