OpGen Announces Successful Completion of Clinical Trial Enrollment for Unyvero Urinary Tract Infection Panel

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- *Prospective multicenter trial for the Unyvero UTI Panel has successfully completed enrollment of patient samples*
- *Urine samples have been collected from over 1,800 patients at 4 U.S. clinical trial sites*
- *Clinical performance evaluation aims at a subsequent FDA submission*

ROCKVILLE, Md., Oct. 03, 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 its successful completion of patient enrollment for its clinical trial for the Unyvero Urinary Tract Infection (UTI) Panel.

OpGen’s Unyvero UTI Panel tests for a broad range of bacterial and fungal pathogens as well as antimicrobial resistance markers directly from native urine specimens. OpGen had recently added a fourth study site in the U.S. to optimize enrollment for different urine sample types to be included in the study, which enabled successful collection of over 1,800 urine samples.

“We’re excited to have completed sample enrollment with our four clinical trial site partners as planned. After having reached our goal of at least 1,500 prospective samples as recommended by applicable FDA guidance, our team will now conclude reference testing in preparation of unblinding and final data readout, and we will start working towards a subsequent FDA submission package,” said Johannes Bacher, Chief Operating Officer of OpGen and Managing Director of its German based subsidiary Curetis GmbH.

Given the complexity and comprehensive nature of the data sets, OpGen expects to conclude data analysis in the next couple of months. Unblinded data for each patient sample will comprise Unyvero UTI Panel results, standard of care microbiology from the clinical trial sites, as well as additional standardized central microbiology data from a reference laboratory.

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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 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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