OpGen Submits De Novo request to the U.S. FDA for Unyvero Urinary Tract Infection Panel

April 18, 2023

- *Based on large multi-center study with over 1,800 patient samples*
- *Primary endpoint for Unyvero UTI for urinary tract infection was successfully met and shows overall weighted average sensitivity of 96.8% and overall weighted average specificity of 97.4%*
- *Submission follows FDA's De Novo pathway for novel medical devices*

ROCKVILLE, Md., April 18, 2023 (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 that it has submitted a *De Novo* classification request to the U.S. Food and Drug Administration (FDA) seeking marketing authorization for its Unyvero UTI Urinary Tract Infection (UTI) panel, following successful completion of its 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 against various reference tests, using clean-catch or catheter related urine samples. Across all prospectively enrolled samples, the primary study endpoint was successfully met by demonstrating an overall weighted average sensitivity of 96.8% and overall weighted average specificity of 97.4% when compared against each trial site's standard of care microbiology results. Since completion of enrollment, OpGen has performed testing of contrived samples with well characterized strains to provide additional data for low-prevalence strains and antibiotic resistance markers at its facility in Germany and generated next-generation sequencing (NGS) data at its Rockville, Maryland, lab facility to establish genotypic correlation of antibiotic resistance markers detected during the study.

"Following the in-depth analysis of all of our clinical trial data, we have compiled a comprehensive submission package for our *De Novo* classification request, building on a large data set of Unyvero data and multiple reference methods," explained Johannes Bacher, Chief Operating Officer of OpGen. "This marks a major milestone, and we're looking forward to working closely with the FDA during the interactive review for the Unyvero UTI panel, which we hope to become the first high multiplex molecular diagnostic IVD for urine samples granted by the FDA."

OpGen will present data from the study at the ASM Microbe 2023 conference in Houston, TX, on June 17, 2023, and together with the principal investigators also intends to submit for a peer reviewed publication.

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., 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, ARESasp, 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 submission of a U.S. FDA *De Novo* classification request for its 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, 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 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, our ability to realize any anticipated benefits from the reverse stock split, including maintaining its listing on the Nasdaq Capital Market and attracting new investors, 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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