OpGen Issues Formal Response to FDA's Requests for Additional Information and Expects Near Term FDA Clearance Decision for Acuitas AMR Gene Panel

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- *OpGen's Acuitas AMR Gene Panel allows testing for a very comprehensive panel of more than 40 diagnostic targets (pathogens and genetic AMR markers) in pure bacterial colonies*
- *Once FDA cleared, OpGen expects to commercially launch the Acuitas AMR Gene Panel in the U.S. via its direct sales and marketing organization*

GAITHERSBURG, Md., Oct. 13, 2020 (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 issued its formal response to the second of the FDA's AI Requests (Additional Information Request) for the Acuitas AMR Gene Panel pre-market submission, addressing what OpGen believes to be all of the FDA's questions and open items.

OpGen had submitted a 510(k) Premarket Notification for the Acuitas AMR Gene Panel for Isolates to FDA in May 2019 and had subsequently received two formal AI Requests from the agency; the first in July 2019 and the second in early 2020. While a 180-day response deadline is normally imposed for these requests, the OpGen response was delayed in June 2020 as consequence of the COVID-19 pandemic when all pre-market submissions on hold as of March 2020 were issued a 90-day extension to the previously established response deadlines. During recent weeks and months, OpGen has been working with the FDA review team on an interactive basis to address any and all outstanding information requests and has received numerous inputs and feedback that have all been built into the formal response.

Johannes Bacher, COO of OpGen commented: "With the successful and timely completion of our formal response we are now eagerly awaiting the Agency's final feedback and hope for a swift FDA clearance decision in the coming weeks. We believe to have a unique panel for a key healthcare threat in antimicrobial resistance with unparalleled comprehensive coverage of genetic AMR markers in the most relevant bacterial pathogens that are of key concern in our hospitals today."

Oliver Schacht, President and CEO of OpGen added: "The Acuitas AMR Gene Panel is already being used for testing isolates as part of a collaborative research project looking at epidemiological surveillance by various major healthcare facilities in New York State as part of a two-year strategic NY State Department of Health collaboration project. Receiving FDA clearance would allow us to make this available much more broadly across the United States for tracking down and tracing outbreaks of hospital superbugs and prevent them from spreading from one hospital to the next."

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with 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 Acuitas AMR Gene Panel for Isolates and its pending submission for regulatory clearance with the U.S. FDA. 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 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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