OpGen Announces CE-IVD Marking and Commercial Launch in Europe of its Own Developed Molecular Diagnostic SARS-CoV-2 Kit with PULB for Detection of the Virus Causing COVID-19

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- Own developed SARS-CoV-2 Kit with PULB for COVID-19 uses real-time PCR (RT-PCR) technology on open PCR platforms, designed to provide results in approximately one hour

- 100% Sensitivity and 97.3% Specificity demonstrated in isolated RNA

- Inclusion of PCR-Compatible Universal Lysis Buffer (PULB) in the kit as a workflow option allows labs to circumvent the need for extraction equipment and reagents

GAITHERSBURG, Md., and HOLZGERLINGEN, Germany, Aug. 20, 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 its subsidiary Curetis GmbH has obtained the CE mark certification in the European Union for its own SARS-CoV-2 Kit with PULB for the detection of SARS-CoV-2, the virus that causes COVID-19.

Developed and manufactured by Curetis’ team in Germany, the SARS-CoV-2 Kit with PULB uses real-time reverse transcription polymerase chain reaction (RT-PCR) technology for qualitative detection of the SARS-CoV-2 virus isolated from oropharyngeal and nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider or for screening of asymptomatic individuals. This kit can be used with RNA isolated by performing standard RNA isolation processes, as well as with oropharyngeal or nasopharyngeal swabs collected in PCR compatible viral transport medium treated with PCR-Compatible Universal Lysis Buffer (PULB) provided in the kit. Including PULB in the kit as a workflow option allows labs to circumvent the need for extraction equipment and extraction kits/reagents, thereby providing operational and workflow efficiencies, time and cost savings. The kit is designed to provide time to results in approximately one hour, and it runs on open real-time PCR instruments such as the QuantStudio™ 5 Real-Time PCR System and the Bio-Rad CFX96™ Real-Time PCR Detection System.

“The CE-IVD Marking is an important step in advancing our efforts to support critical COVID-19 testing; the Curetis SARS-CoV-2 Kit with PULB provides additional testing capacity in countries that recognize the CE Mark to test patients,” said Johannes Bacher, COO of OpGen.

“By launching this new product in Europe, we are committed to helping our distributors and customers to expand the availability of SARS-CoV-2 diagnostic testing, and our own-developed CE-IVD marked SARS-CoV-2 Kit with PULB is expected to help increase availability of these much-needed tests," said Oliver Schacht, PhD, CEO of OpGen. “Our customers will benefit from an optimized workflow and a test that delivers great performance and significantly shorter time-to-result at favorable economics compared to many of the commercially available open PCR platform COVID-19 tests including the BGI SARS-CoV-2 kit. Having access to our own SARS-CoV-2 kit allows us to have that product distributed rather than the BGI test kit which we will cease distributing effective immediately.”

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 by OpGen
This press release includes statements regarding the commercial launch of a SARS-CoV-2 Kit by OpGen’s subsidiary, Curetis GmbH. These statements and other statements regarding OpGen’s SARS-CoV-2 test kits, their commercialization and launch, 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 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 realization of expected benefits of our business combination transaction with Curetis GmbH, 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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