OpGen Provides Update on Curetis Group Business Receiving U.S. FDA 510(k) Clearance of its Unyvero LRT for BAL Specimens

December 23, 2019

- Broad Unyvero LRT BAL panel also includes atypical pathogens such as Pneumocystis jirovecii

- Clearance expected to substantially increase total addressable market for Unyvero System in the U.S.

- Commercial launch in the U.S. expected for Q1-2020

GAITHERSBURG, Md., Dec. 23, 2019 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN) reported an update on the business of Curetis GmbH ("Curetis"), the other party to the planned business combination with OpGen. On December 20, 2019 Curetis announced that the Company has received 510(k) clearance by the U.S. Food and Drug Administration (FDA) to market its Unyvero LRT Lower Respiratory Tract Application Cartridge for use with bronchoalveolar lavage (BAL) samples to diagnose lower respiratory tract infections such as pneumonia.

The LRT BAL panel detects a broad spectrum of clinically relevant causative agents, including atypical pathogens, as well as antibiotic resistance markers. It provides clinicians with a valuable diagnostic tool that informs early and supports appropriate antibiotic treatment decisions in this indication.

Infections with atypical pathogens are often associated with community-acquired pneumonia (CAP), but are not considered in the context of hospital-acquired or ventilator-associated pneumonia. Hospitalized patients usually are not tested for these organisms unless there is a suspicion of infection. Further, empiric treatment of these patients does not normally cover atypical pathogens. Unyvero LRT BAL expands the diagnostic capability of clinicians to routinely identify atypical infections that might otherwise escape detection and hence can prevent prolonged inappropriate treatment of patients.

The Unyvero LRT BAL application is the first and only FDA cleared molecular diagnostic pneumonia panel that includes *Pneumocystis jirovecii*. As culture-based diagnosis of *Pneumocystis jirovecii* Pneumonia (PJP) is not possible, identification of this pathogen is often based on morphological detection techniques, which are labor-intensive, time-consuming and lack sensitivity. Rapid diagnosis of PJP, which causes severe and life-threatening symptoms, is crucial in patients with a weak or suppressed immune system. Initiating the appropriate therapy even one day earlier can significantly reduce mortality in this patient group.

By providing a fast and reliable solution for the rapid detection of pathogens and antibiotic resistance markers, Unyvero LRT BAL is an essential, indispensable tool for targeted antimicrobial therapy.

"We congratulate the team at Curetis for the tremendous accomplishment of gaining FDA 510(k) clearance for its expanded Unyvero LRT BAL product," said Evan Jones, Chairman & CEO of OpGen. "We believe there will be substantial opportunity within the U.S. market for utilization of Unyvero LRT BAL for rapid testing of suspected lower respiratory tract infections, which we believe will help improve patient outcomes and advance antibiotic stewardship efforts."

OpGen and Curetis entered into a definitive agreement to combine businesses on September 4, 2019. The closing of the transaction under such definitive agreement has not yet occurred and is subject to a number of significant closing conditions, including receipt of approval from the stockholders of OpGen, Inc. and the shareholders of Curetis, N.V. Until the closing occurs, each of OpGen and Curetis are operating as stand-alone businesses.

To read the full press release from Curetis, please click here.

About OpGen

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas® molecular diagnostics and Acuitas Lighthouse® informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. Currently we offer our Acuitas AMR Gene Panel tests for research use only. For more information, please visit **www.opgen.com**.

Forward-Looking Statements

This press release includes statements relating to FDA clearance of the expanded BAL claim for the Curetis LRT test. 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 success of our commercialization efforts, 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.

OpGen Contact:
Michael Farmer
Vice President, Marketing
(240) 813-1284
mfarmer@opgen.com
InvestorRelations@opgen.com

Press Contact:
Matthew Bretzius
FischTank Marketing and PR
matt@fischtankpr.com

Investor Contacts:
Joe Green
Edison Group
jgreen@edisongroup.com

Source: OpGen, Inc.