OpGen Wins Chinese NMPA Approval for the Curetis Unyvero System

March 1, 2021

- *Chinese regulatory authority NMPA completes registration of Unyvero instrument system as IVD for Chinese market*
- *Application of Unyvero cartridge for pneumonia is under review and pending NMPA approval*
- *OpGen's subsidiary Curetis and its Chinese partner Beijing Clear Biotech continue working with the NMPA towards approval of pneumonia test in China*

GAITHERSBURG, Md., March 01, 2021 (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 recently received regulatory approval of the Curetis Unyvero System as an in vitro diagnostics (IVD) instrument system in China from the Chinese authorities (National Medical Products Administration, NMPA). The Medical Device Registration Certificate has been issued under the Registration number 20213220019.

Since filing the submission dossier for the complete Unyvero System, consisting of the Unyvero A50 Analyzer, the Unyvero L4 Lysator and the Unyvero C8 Cockpit in February 2019, NMPA has been actively engaged in an interactive review process with OpGen's subsidiary Curetis and its Chinese partner Beijing Clear Biotech (BCB) prior to this approval decision. The parties continue to interact closely with the NMPA during the interactive review of the submission and filing for the Unyvero A50 pneumonia cartridge as their first Unyvero-based diagnostic application for the Chinese market. A dossier for the review and potential future approval of the pneumonia cartridge was submitted in February 2019, which includes comprehensive data from various clinical trials and regulatory submissions of the Unyvero LRT and LRT BAL products (which are FDA cleared in the USA) and the Unyvero HPN cartridge for hospitalized pneumonia patients (which is CE-IVD marked in Europe). Timelines for NMPA response submissions and review had been extended by several months in 2020 due to the COVID-19 pandemic. The start of commercialization of the Unyvero platform in China remains subject to also getting approval of the pneumonia cartridge.

Oliver Schacht, CEO of OpGen commented, "We are truly excited to see the Chinese regulators approve our Unyvero System based on the A50 Analyzer as a diagnostic instrument for the Chinese market. We have been working very closely with the NMPA and our partner BCB for several years towards this key milestone. Once we also receive NMPA approval for the Unyvero pneumonia cartridge for the Chinese market we expect a swift commercial launch in China by our partners BCB with tremendous growth potential for many years to come."

Zeeman Zhang, CEO of Beijing Clear Biotech (BCB) added, "Pneumonia remains one of the leading causes of death in hospitalized patients with severe infections and is the number two cause of death in children in China. We believe there is a large unmet medical need for faster and better diagnostics of the pathogens as well as their antimicrobial resistance marker profile. With Unyvero, we have a first-in-class platform that has been developed and is made in Germany and it has been sold in Europe and the U.S. for many years. We are delighted to bring this exciting new platform to China, to the benefit of doctors and patients alike in our hospitals, improving clinical outcomes and antibiotic stewardship."

OpGen's subsidiary Curetis and BCB are parties to an exclusive multi-year distribution agreement for the Unyvero platform and cartridges in China. Once NMPA approves the products, BCB has agreed to contractual minimum purchases of 360 Unyvero systems and more than 1.5 million cartridges cumulative over an 8-year exclusivity period which at current transfer prices between the parties is expected to amount to approximately $180 million in revenue to OpGen at current exchange rates.

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 Chinese regulatory approval of OpGen's subsidiary Curetis' Unyvero System and pending review and potential future approval of its Unyvero pneumonia cartridge and the potential future commercial launch of the Unyvero platform in China. These statements and other statements regarding OpGen's Unyvero products, 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 fact that we may not effectively use proceeds from recent financings, including our February 2021 and November 2020 financings, 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.

OpGen:
Oliver Schacht
President and CEO
InvestorRelations@opgen.com

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

OpGen Investor Contact:
Megan Paul
Edison Group
mpaul@edisongroup.com

Source: OpGen, Inc.