OpGen Announces Successful Completion of Unyvero A30 Development Milestone

February 10, 2022

- *Unyvero A30 RQ analyzer successfully completed verification and validation (V&V) testing as well as lifetime testing*
- *Unyvero A30 instruments met all V&V criteria for series-production systems*

ROCKVILLE, Md., Feb. 10, 2022 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, announced today that its subsidiary Curetis has successfully met a key milestone in the development of the new Unyvero A30 *RQ* platform instruments. Over the course of the last several months the A30 *RQ* instruments were put through a rigorous process of final verification and validation (V&V) testing. These tests were designed and conducted per the applicable guidelines and recommendations, including IEC 61010/UL 61010 for instrument safety, IEC 61326 for electromagnetic compatibility and interferences and EN 60086 for transport, storage and operational conditions.

The performed V&V tests included testing of mechanical and electrical safety, radiated and conducted electrical emissions and interference, mechanical robustness when exposed to mechanical shock and vibration, heat, cold, humidity and other environmental factors. The Unyvero A30 *RQ* instruments were put through these tests at a number of external sites and facilities including CSA Group Europe GmbH at their German headquarter test facility, Zollner Elektronik AG, and ELMAC EMC/EMI test labs, and environmental testing lab of TELUS GmbH in Germany. All test reports have now been completed. Complementing the V&V testing efforts, the Curetis team also put the Unyvero A30 *RQ* through a rigorous schedule of lifetime testing of all relevant mechanical instrument components, including all moving parts, cartridge loading/unloading mechanics, Peltier heaters and coolers for reaction chambers, and PCR ultrafast temperature cycling and long-term operation of the integrated hose pump. Some of these tests included tens to hundreds of thousands of repetitions to ensure that the instruments were tested well in excess of their expected lifetime usage. The PCR Peltier element as the most critical part was tested for almost 1 million PCR cycles at the highest possible ramp rates of 10 K/sec creating the most stringent stress conditions for the element. All these tests passed successfully.

Andreas Boos, CTO of OpGen’s subsidiary Curetis commented: “In my over 30 years of engineering and platform development experience in the medical device and diagnostics industry I have never before seen a final instrument V&V program being completed with such flying colors. All findings were minor and we have been able to address all of them and mitigate them for the final series production release of the Unyvero A30 systems.” Andreas Boos added that “this effectively has also allowed us to upgrade to final product specs the ten prototype instruments that we had received in summer of 2021 and use them for further development of the platform including assay development and clinical V&V work going forward.”

Oliver Schacht, CEO of OpGen indicated that “this success in meeting this final key milestone in the Unyvero A30 instrument development now enables us to move into final product design and to get a first set of series-ready instruments built. In parallel, we expect to work on our first A30 cartridge application and look forward to bringing the platform into its first clinical trial later in 2022. Such trial data would then be aimed at future regulatory submission and clearance by the U.S. Food and Drug Administration. Having the A30 ready for clinical trials and subsequent commercialization will also be key to any partnering and licensing conversations going forward.”

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, USA) 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 product portfolio includes Unyvero®, Acuitas® AMR Gene Panel 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 the completion of the Unyvero A30 development milestone and the continued development of the instruments. 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 fact that we may not effectively use proceeds from recent financings, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, 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, 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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