OpGen Releases Preliminary Data Demonstrating its Unyvero HPN Panel for Pneumonia Identifies Life-Threatening Bacterial Co-Infections in COVID-19 Patients in Just Five Hours

June 9, 2020

- *Performance of the Unyvero HPN Panel for pneumonia proves to be strongly concordant (98.2%) compared to bacterial lower respiratory tract culture*
- *Collaboration with Karolinska Institutet highlights critical need for rapid diagnostic tests, as one in four COVID-19 patients in the ICU had a bacterial co-infection*
- *Providing results in hours instead of days provides clinicians with early organism differential, including resistance marker information, allowing earlier treatment decisions and support for improving antimicrobial stewardship*

GAITHERSBURG, Md. and HOLZGERLINGEN, Germany, June 09, 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 preliminary data from an investigator initiated collaboration with Karolinska Institutet, Stockholm, Sweden, to identify bacterial co-infections in hospitalized patients with COVID-19 pneumonia. The patients in this cohort had been admitted to the ICU after respiratory deterioration during hospital stay, and their lower respiratory tract samples were analyzed with the Unyvero HPN panel.

Preliminary data demonstrates that the performance of the Unyvero HPN Panel for pneumonia as compared to bacterial culture is strongly concordant (98.2%) for organism targets. In 31 out of 35 patient samples that were evaluated, Unyvero results confirmed all pathogens reported by culture. Unyvero detected additional pathogens in 7 patients, one of which was subsequently tested again by microbiological culture 7 days later and confirmed positive. These results indicate that the Unyvero system, while not always completely concordant with culture results, can detect possible pathogens which are missed by culture. Results obtained by the Unyvero Panel in five hours instead of up to several days by culture methods provides clinicians with an early organism differential, including information on antibiotic resistance markers, allowing earlier treatment decisions and support for antimicrobial stewardship efforts. Among the 35 lower respiratory specimens tested to-date, 63% were tracheal aspirate, 34% BAL/mini-BAL, and 3% sputum.

"We are pleased to share preliminary data that highlights what we already know – when it comes to managing bacterial co-infections, time is critical! Our Unyvero HPN panel provides comprehensive diagnostic information to clinicians in just a few hours, with only minutes of actual hands-on time, ensuring faster treatment decisions," said Oliver Schacht, PhD, CEO of OpGen. "This rapid testing technology is even more important in the face of a global pandemic when time is of the essence in preventing global spread. We are encouraged by the preliminary results of our Unyvero HPN panel in Sweden and look forward to contributing testing capabilities to additional healthcare facilities around the world in the future."

The samples were derived from patients admitted to ICUs in four acute care hospitals in Sweden – Karolinska University Hospital, Solna; Karolinska University Hospital, Huddinge; South General Hospital; Danderyd Hospital, and were taken from a patient population of SARS CoV-2-positive patients being admitted to the ICU. Patients were sampled during their hospital stay for suspected hospital-acquired pneumonia, as they were already in crowded hospitals and had experienced deterioration and inevitably requiring ventilators. Of the above-described patient population, one in four (25%) tested positive for a bacterial co-infection by microbiology.

"Although secondary bacterial infections are uncommon upon admission to hospital, these patients are at risk for hospital-acquired bacterial pneumonia, and the positivity rate is fairly high," said Professor and Senior Consultant Physician Christian Giske, at the Department of Laboratory Medicine, Karolinska Institutet, Stockholm, Sweden. "That makes receiving test results in a matter of hours instead of days critically important. The Unyvero HPN panel empowers clinicians to make earlier treatment decisions, while supporting antimicrobial stewardship efforts, to give the best opportunity to quickly treat and manage bacterial co-infections."

High-risk COVID-19 patients, especially in intensive care units and on ventilation, many of whom may be elderly or have preexisting conditions that compromise their immune system, are at a higher risk of acquiring bacterial co-infections that pose severe life-threatening complications. These co-infections are not always easily determined based on clinical symptoms alone, and, if they go unnoticed or diagnosis is delayed, it can lead to dire outcomes including mortality. Within this preliminary study, the median patient age was 58 years old.

The Unyvero Hospitalized Pneumonia (HPN) panel detects 21 clinically relevant pathogens and 19 antibiotic resistance markers in less than five hours directly from native specimen with only around two minutes of hands-on time, compared to routine bacterial cultures that can take up to several days for confirmatory pathogen identification and antimicrobial susceptibility testing results. In the U.S., the Unyvero LRT and LRT BAL panels for rapid detection of lower respiratory tract infections such as pneumonia are FDA-cleared for tracheal aspirate samples and bronchoalveolar lavage fluids, respectively. Unyvero HPN and LRT BAL are the only syndromic pneumonia panels that also include *Pneumocystis jirovecii,* a key fungal pathogen often found in immunocompromised patients that can be difficult to diagnose.

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 the clinical evaluation of diagnostic tests by subsidiaries of OpGen. 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 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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Source: OpGen, Inc.