OpGen Announces Publication of Final Study Results of Unyvero HPN Panel for Diagnosis of Bacterial Co-Infections in ICU Patients with COVID-19 Pneumonia

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Karolinska Institutet Study highlights Unyvero HPN demonstrating a higher diagnostic yield than bacterial culture, enabling rapid diagnosis of pathogens of concern in these patients

- *High negative predictive value of 99.8% may allow for reduction in unnecessary antibiotic use and support antibiotic stewardship efforts*

- *Performance data, comprehensive coverage and turnaround time of less than 5 hours from sample to result of this panel provides clinicians earlier data to inform antimicrobial decisions, especially in critically ill COVID-19 patients during flu season*

GAITHERSBURG, Md., and Holzgerlingen, Germany, March 08, 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, today announced the release of a new peer-reviewed publication that demonstrates that the Unyvero Hospitalized Pneumonia (HPN) panel is a reliable and rapid diagnostic test with high negative predictive value for the detection of bacterial pathogens directly from native lower respiratory tract samples, allowing identification of bacterial co-infections in hospitalized patients with COVID-19 pneumonia in just five hours.

Performance of the Unyvero HPN was evaluated against standard of care (SoC) microbiological testing for detection of bacterial pathogens in lower respiratory tract specimens obtained from hospitalized COVID-19 patients with a clinical suspicion of secondary bacterial infection. These samples were collected during the first wave of the COVID-19 pandemic in Stockholm, Sweden (March 2020 through June 2020). A total of 83 samples were obtained from 68 patients, consisting of 61 (73.5%) tracheal secretions, 11 (13.4%) bronchoalveolar lavage, 8 (9.7%) protected specimen brush (PSB), 2 (2.4%) bronchial secretions, and 1 (1.2%) sputum sample. One sample each was obtained from 57 unique patients, two samples each from 7 patients, and three samples each from 4 patients. The mean age among the study subjects was 58.8 years old, and 74% were male and 26% were female.

Final results of this study have now been published in the *European Journal of Clinical Microbiology & Infectious Diseases* and found that the Unyvero HPN panel provides accurate detection of common agents of bacterial pneumonia with an overall high negative predictive value of 99.8% for pathogen detection. This could potentially allow for reduction in unnecessary antibiotic use and supporting antibiotic stewardship efforts. The overall positive percent agreement (PPA, sensitivity) and negative percent agreement (NPA, specificity) with culture for detection and identification of bacteria that grow in routine cultures were 95.1% and 98.3%, respectively, which is consistent with the performance of the Unyvero Lower Respiratory Panels (LRT and LRT BAL) that have been published recently by Mackenzie E. Collins and colleagues[1] and Matthias Klein et al[2].

The study also demonstrated several advantages of the Unyvero HPN panel, including higher diagnostic yield compared to SoC culture alone, which enabled the identification of additional clinically important pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Serratia marcescens, Haemophilus influenzae, Stenotrophomonas maltophilia*, among several others in 25% of cases that were missed by microbiological methods. Furthermore, data demonstrated that Unyvero HPN could detect bacterial pathogens from patient samples that were negative by culture initially, but when subsequent cultures were ordered on these patients during the later course of their hospital stay they were in fact positive for the same pathogen. This indicates that the HPN panel can detect potential pathogens earlier than culture, which may enable earlier treatment and management of patients.

In their publication titled "The Unyvero Hospital-Acquired pneumonia panel for diagnosis of secondary bacterial pneumonia in COVID-19 patients[3]" the authors highlight the fact that "Current estimates suggest that nearly 80% of the patients admitted in the ICU with COVID-19 receive antibiotics. It is most likely possible that the bacterial super-infections among COVID-19 patients admitted to critical care units are due to the longer durations of stay in the ICU and mechanical ventilation, rather than the viral infection itself, but nonetheless this requires diligent microbiological testing because the signs and symptoms can be similar and confounding."

Antibiotic therapy in the absence of etiological diagnosis of infection has both clinical and public health implications. Inappropriate use of antibiotics is a well-established driver for the emergence of antimicrobial resistance among bacterial pathogens. The authors further comment that "Given this context, the Unyvero HPN panel can be a potential rapid diagnostic test of choice, considering that the panel is able to detect 20 bacterial species, one fungus and 17 antimicrobial resistance genes that includes the most common infectious etiology of both healthcare- and ventilator-associated pneumonia." They conclude that "Unyvero HPN demonstrated a higher diagnostic yield than culture; it is significantly faster, with turnaround time of <5 hours from sample to results compared with average of 2.5 days for culture, providing clinicians earlier data to inform antimicrobial decisions, especially in critically ill COVID-19 patients and the upcoming flu season."

"Rapid and accurate detection is essential to assess bacterial pneumonia co-infections in critically ill COVID-19 patients. We are pleased about this final data being published as it highlights the strong performance and utility of the Unyvero HPN Panel as a culture-independent comprehensive diagnostic tool to help with detection of bacterial pneumonia earlier in the hospital journey of these patients for more prompt and appropriate treatment" said Faranak Atrzadeh, Chief Marketing and Scientific Affairs Officer of OpGen.

The Unyvero Hospitalized Pneumonia (HPN) panel detects 21 clinically relevant pathogens and 17 antibiotic resistance markers in less than five hours directly from native specimens 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 multiplex PCR panels for lower respiratory tract infections that also include *Pneumocystis jirovecii,* a causative agent of *Pneumocystis* pneumonia (PCP) and 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 by OpGen

This press release includes statements regarding the results of a recent study of OpGen's Unyvero HPN panel and its potential clinical benefits. 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.

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[1] https://jcm.asm.org/content/jcm/58/5/e02013-19.full.pdf

[2] https://jcm.asm.org/content/early/2020/12/15/JCM.02497-20

[3] https://link.springer.com/content/pdf/10.1007/s10096-021-04194-6.pdf

Source: OpGen, Inc.